HERBERT SMITH FREEHILLS

LC Paper No. CB(2)584/16-17(24)

The Chairman & Clerk to Panel on Health Services
Panel on Health Services
Legislative Council
Legislative Council Complex 1
Legislative Council Road Central
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
D +852 2101 4629
DX 009028
E dominic.geiser@hsf.com
www.herbertsmithfreehills.com

Our ref
6461/17503/30993177
Your ref
FH CR 3/3231/15
Date
10 January 2017

By email and by hand

Dear Sirs,

Government's proposal to change the graphic health warnings ("GHWs") on tobacco products packets and retail containers ("Proposal") as set out in the Legislative Council Paper No. CB (2)386/16-17(05) ("2016 Legislative Council Paper")

We act for British American Tobacco Company (Hong Kong) Limited ("**BAT HK**"), and write in connection with the Proposal, which is agenda item number III of the meeting of the Legislative Council's Panel on Health Services ("**Panel**") on 17 January 2017 (the "**Meeting**"). We would be grateful if you could kindly table a copy of this letter for consideration by the Panel in advance of the Meeting.

We note that the Proposal has been discussed in the Panel meetings on 18 May 2015 ("**2015 May Meeting**"), 6 July 2015 ("**2015 Special Meeting**"), 19 December 2016 ("**19 December Meeting**") and will be further discussed at the Meeting. We have also previously made the following submissions to the Government and/or the Panel on behalf of BAT HK, which we enclose again for your ease of reference:

1. Our letter to the Panel dated 23 June 2015 ("**BAT HK's 2015 Submissions**") (enclosed as Appendix 1 to BAT HK's December 2016 Letter mentioned below);

2. Our letter to the Panel dated 20 July 2015 ("**BAT HK's July 2015 Letter**") (enclosed as Appendix 1 to BAT HK's December 2016 Letter mentioned below);

3. Our letters to the Secretary for Food and Health dated 29 and 30 July 2016 ("**BAT HK's 2016 Submissions**") (enclosed as Appendix 1 to BAT HK's December 2016 Letter mentioned below); and

4. Our letter to the Panel dated 13 December 2016 ("**BAT HK's December 2016 Letter**") as **Appendix A**.

(together, "**BAT HK's Previous Submissions**").

However, to date, the Government has failed to provide any written response to BAT HK or at all regarding the concerns raised in BAT HK's Previous Submissions. This is contrary to the Government's previous practice. In particular, in 2006, the Government provided a detailed formal response to Japan Tobacco Inc's submission in respect of Clause 11 of the Smoking (Public Health) (Amendment) Bill 2005 ("**2005 Bill**"), which proposed to prohibit various words (e.g. "light", "mild", "low tar" etc) which would imply or suggest that those cigarettes were less harmful than others. Please see section 3 below for more information[1].

BAT HK is extremely concerned with the Government's insistence in putting forward the Proposal during the 19 December Meeting, despite the industry's concerns on the legality, the merits and the technical difficulties with the Proposal. Notwithstanding the Panel chairman's suggestion to the Government in the 2015 Special Meeting to communicate with the tobacco industry and the relevant stakeholders having regard to their concerns over the Proposal, the Government has since only held one briefing session ("**2016 Technical Briefing**") on 23 November 2016 (more than 16 months after the 2015 Special Meeting) which was merely a presentation to unilaterally inform certain stakeholders about the technical aspects of the Proposal. The Government also ignored the Panel chairman's suggestion to engage with the industry regarding its various concerns over the Proposal before reverting to the Panel in the 19 December Meeting.

In view of the Government's continued failure to adequately consult and consider the industry's concerns, we set out below BAT HK's concerns that (1) it wishes to specifically bring to the Panel's attention or (2) were mentioned in the 19 December Meeting for the Panel's further consideration ahead of the Meeting:

1. The Proposal is unconstitutional;

2. The Proposal amounts to deprivation of property under the Basic Law which could expose the Government to civil claims for judicial review and/or compensation;

3. The Government has no legal authority to implement the Proposal by negative vetting;

4. The Government would be in breach of its duty to conduct formal public consultation and/or a regulatory impact assessment ("**RIA**");

[1] See Government's response dated January 2006 at http://sc.legco.gov.hk/sc/www.legco.gov.hk/yr04-05/english/bc/bc61/papers/bc610120cb2-901-3e.pdf

5. On the basis that the Government decides to implement the Proposal, the Government has refused to give the industry a reasonable length of adaptation period necessary to comply with the Proposal;

6. There is no reliable evidence to support the effectiveness of the Proposal;

7. The Proposal lacks justification;

8. The Proposal would violate Hong Kong's international obligations; and,

9. It is illogical to disregard World Health Organisation's ("**WHO**") recommendation against the display of tar and nicotine content figures while at the same time purporting to rely on WHO's opinion in making the Proposal.

The Panel will note the above list does not cover all of the concerns mentioned by BAT HK, which are set out in BAT HK's Previous Submissions, such as the technical difficulties raised in paragraph 2.7 of BAT HK's December 2016 Letter. Please refer to BAT HK's Previous Submissions for all of BAT HK's concerns with the Proposal.

We explain the above concerns in more detail as follows.

1. THE PROPOSAL IS UNCONSTITUTIONAL

1.1 The Court of Final Appeal in the recent case of *Hysan Development Company Limited and Others v Town Planning Board and Another*[2] acknowledged that Articles 6 and 105 of the Basic Law expressly protect private property rights.

1.2 The Proposal interferes with BAT HK's property rights, including but not limited to BAT HK's right to use its trademarks in the following ways:

1.2.1 The Proposal would make it impossible to use a number of trademarks consisting of logos and other devices placed at certain positions on the pack (including, but not limited to, position marks and entire pack marks). For example, BAT HK has various 3D or pack shot trademarks that cannot be displayed at all in the remaining 15% of the pack should the Proposal be implemented. Please refer to paragraph 4.5 of BAT HK's 2016 Submissions for a detailed explanation.

1.2.2 As for trademarks that can still be displayed in the very limited remaining space of less than 15%, this is insufficient to effectively designate the product and will leave the trademark without its function as an identification of the commercial origin and the quality of the underlying product.

1.3 The Government must demonstrate that the restriction is proportionate, which includes showing that it is rationally connected to the aim of reducing smoking prevalence, that it is no more than necessary to accomplish that aim and that the

[2] FACV 21/2015, 26 September 2016

social benefit gained is not outweighed by its detrimental impact. However, it has failed to do so and BAT HK's position is the Proposal is clearly disproportionate and therefore unconstitutional. Please refer to paragraphs 1.9 to 1.17 of BAT HK's December 2016 Letter and section 5 of BAT HK's 2015 Submissions for a detailed explanation on this issue.

1.4 In addition, the following factors further evidence the disproportionate nature of the Proposal:

1.4.1 Smoking prevalence in Hong Kong is among the lowest in the world. According to the statistics provided by the Government in the 2016 Legislative Council Paper, the latest smoking prevalence in Hong Kong is 10.5%, which is the second lowest among the 11 jurisdictions cited by the Government.[3] It is also lower, by several percentage points, than the smoking prevalence in Australia, Canada, the UK and the US[4]. It is clear that the public in Hong Kong is well aware of the risks of smoking and as Hon. Helena Wong Pik-Wun noted at the 19 December Meeting, existing tobacco measures are effective. Indeed, according to an independent tobacco survey, 95.4% of the youth in Hong Kong are well aware of the risks of smoking.[5]

1.4.2 The Government indicated in the 2015 May Meeting that they were targeting to reduce smoking prevalence in Hong Kong to a single digit, representing a reduction of only 0.6%. As Hon. Chan Chi-chuen explained in the 19 December Meeting, any attempt to further reduce the already low level of smoking prevalence in Hong Kong by enlarging the size of GHWs would be of marginal effectiveness. Hon. Helena Wong Pik-Wun, also noted it would be difficult to further reduce the already low smoking prevalence in Hong Kong, given smoking was a conscious choice for some smokers, who are well aware of the risks of smoking. She noted that there would always be 9 to 10% of Hong Kong citizens who would smoke regardless, unless the Government adopted drastic measures such as completely banning smoking in Hong Kong.

1.4.3 The Government has not provided any evidence that further increasing the size of the GHWs is in any way rationally connected to reducing smoking prevalence. On the contrary, there is a demonstrated lack of effectiveness of larger warnings in other jurisdictions such as Australia, Canada and

---

3 2016 Legislative Council Paper, page 3 of Annex A and Annex E. Furthermore, of the countries referred to, only one (Thailand) has 85% GHWs but the Government has provided no explanation as to why it is necessary to adopt such an extreme size in Hong Kong.

4 As shown in the expert report of Professor Viscusi, Appendix 3 of BAT HK's 2015 Submissions, at figure 1.

5 As demonstrated by the independent 2009 Global Youth Tobacco Survey (GYTS) data for Hong Kong which found that 95.4% of respondents answered 'Definitely Yes' (89.8%) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?'

Thailand,[6] and expert evidence submitted by BAT HK has clearly indicated that increasing the size of warnings in Hong Kong has not had any beneficial effect above smaller warnings.[7] It was also accepted by the US Court of Appeal for DC Circuit that it "*lacks any evidence showing that the graphic warnings are likely to reduce smoking rates...the dearth of data...strongly implies that such warnings are not very effective at promoting cessation and discouraging initiation.*"[8]

1.4.4 The examples of jurisdictions which introduced larger GHWs or plain packaging regulations cited by the Government in Annex E of the 2016 Legislative Council Paper, are misleading and in any event do not show that increasing the size of GHWs will reduce smoking prevalence. In particular:

(A) The general descriptions of smoking trends in various countries are not at all informative about the impact of GHWs or plain packaging. It is clear that smoking prevalence has generally been falling in these countries for a long time, and that factors other than GHWs or plain packaging – in particular substantial price increases – have reduced smoking. It is therefore necessary to strip out the effects of other factors like prices in order to determine what effect, if any, GHWs or plain packaging is having on smoking. Thus, the Government provides no evidence whatsoever that GHWs or plain packaging has had any impact on smoking behaviours in these countries. We note that, in contrast to the Government's failure to undertake any proper analysis, the analyses undertaken by the U.S. Food and Drug Administration, which are to our knowledge the most comprehensive analyses of GHWs undertaken by any country to date, found no evidence of a beneficial effect of graphic warnings on smoking behaviour.[9]

(B) Whilst the Government mentioned the smoking prevalence in Australia had decreased from 2010 to 2013, it failed to mention that the proportion of daily smokers has been declining steadily in Australia over time and the proportion in 2013 is almost exactly on the trendline (despite a 25% tax increase on tobacco in 2010). This suggests that there was no significant effect on daily smoking from the introduction of plain packaging in Australia. Furthermore, the percentage of 12-17 year olds who smoked on a daily basis also increased from 2.5% to 3.4% between 2010 and 2013 and the

6 As explained in BAT HK's July 2015 Letter.
7 As explained in the expert report of Professor Viscusi, Appendix 3 of BAT HK's 2015 Submissions, at para 30. See also the study carried out by Professor Kevin Tsui in the John E Walker Department of Economics at Clemson University.
8 *R.J. Reynolds Tobacco Co. v. Food and Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).
9 We refer to section 5 of BAT HK's 2015 Submissions.

percentage of occasional smokers aged 12-17 also increased from 1.3% to 1.6% over this period. In addition the number of respondents strongly agreeing or somewhat agreeing that graphic warnings encouraged smokers to quit reduced from 40% in 2012 to 36% in 2013 (after the introduction of plain packaging in Australia in December 2012), suggesting that health warnings were less effective at encouraging smokers and recent quitters to stop smoking after the introduction of plain packaging.[10]

(C) The Government also refers to an expert report of Dr. Chipty that was provided as part of the Australian post-implementation review. Dr. Chipty's suggestion that smoking prevalence in Australia decreased by 0.55% after the introduction of, inter alia, plain packaging in 2012 is clearly flawed even on the face of the report. For example, the report only considers three tax increases out of the 14 that occurred in Australia between 2010 and 2015, so the tax increases might have had a larger impact on the slight decrease in smoking prevalence than the plain packaging regulations. Further, Dr. Chipty had produced reports for Australia supporting the effectiveness of plain packaging in the context of a World Trade Organisation dispute and was only subsequently tasked with evaluating its effectiveness for the purpose of the post implementation review, which casts doubt on her objectivity and/or impartiality[11]. The report has also been the subject of criticism by other experts[12], such that it cannot be considered reliable.

(D) The Government considered pre-2016 smoking prevalence data in the United Kingdom, which was before the introduction of the plain packaging regulations there. Indeed evidence demonstrates that the introduction of more prominent graphic warnings in the UK did not have an impact on smoking behaviours. This was confirmed by the Public Health Research Consortium (2010) report which concluded that there was no fundamental change in risk beliefs or behaviour after the advent of graphic warnings in England. More specifically, the report stated: *"[t]he range and depth of knowledge about the health risks of smoking did not change after the pictures were introduced."* Awareness of some conditions featured in the

---

10 National Drug Strategy Household Survey detailed report: 2013, Drug statistics series no. 28, Australian Institute of Health and Welfare, Nov 2014 http://www.aihw.gov.au/publication-detail/?id=60129549469.

11 See paragraph 2 of Dr. Chipty's report dated 24 Janaury 2016 at http://www.health.gov.au/internet/main/publishing.nsf/content/491CE0444F7B0A76CA257FBE00195BF3/$File/PIR%20of%20Tobacco%20Plain%20Packaging%20-%20with%20Addendum.pdf

12 See Dr A. Lilico, Europe Economics, (August 2016), "Analysis of the Chipty Report's conclusions regarding packaging changes and smoking prevalence in Australia", available at http://www.jti.com/how-we-do-business/key-regulatory-submissions/ ; and Davidson, S. (2016), "Submission to the Slovenian Restriction of the Use of Tobacco (Products) and Related Products Act Inquiry," available at http://catallaxyfiles.com/2016/04/01/plain-packaging-resources/

warnings, such as gum/mouth disease, rose, but there was no net effect on behaviour. These results suggest that targeted warnings can address specifically defined information gaps. But the overall impact of the graphic warnings was limited: *"[t]here were very few smoking-related behavior changes observed after the pictures were introduced."* Additionally, the warnings had a "negligible" impact on young people.[13]

(E) The Government also refers to the introduction of plain packaging in New Zealand, but this has not been implemented.

(F) As mentioned by the Under Secretary for Food and Health, Dr. Sophia Chan at the 19 December Meeting, two studies were commissioned by the Thai government after the introduction of 85% GHWs in Thailand, one of which showed a slight decrease in the prevailing smoking rate and the other one showed a slight increase. Although the Government alleges that there was a further subsequent slight decrease in the prevalence of smoking, it is clear that the measure in Thailand is inconclusive or ineffective given the rate of increase and decrease was negligible.

1.4.5 As stated by Hon Helena Wong Pik-wun at the 19 December Meeting, despite the Democratic Party's stance in supporting anti-smoking policies, she casted doubt as to the effectiveness of the Proposal and was not persuaded that the smoking prevalence in Hong Kong would be reduced to a single digit figure with the 85% GHW increase for the following reasons, inter alia:

(A) Given the low smoking prevalence it was not imminently necessary to take any new measures in Hong Kong.

(B) The circumstances in Thailand, which provided for 85% GHW, were very different to Hong Kong given smoking prevalence in Thailand (nearly 20%) was much higher. Even so, the experience in Thailand suggested that 85% GHWs was not effective in reducing smoking prevalence.

(C) The Government should instead deploy resources to other tobacco control measures, such as promoting quit smoking classes.

1.4.6 Most of the Members of the Panel who expressed their views in the 19 December Meeting were not persuaded that the Proposal was a necessary measure or that the Proposal could be effective in reducing smoking prevalence in Hong Kong.

[13] Public Health Research Consortium. "Evaluating the Impact of Picture Health Warnings on Cigarette Packets, Short Report 12", National Centre for Social Research (2010).

1.5 Further, as the Hon. Junius Ho Kwan Yiu mentioned at the 19 December Meeting, the Government has failed to explain any basis for setting the GHWs size requirement at 85%. We should be grateful for the Government's response on the same as well as an explanation of how and why the Proposal would be proportionate under Hong Kong law.

1.6 In view of the above, BAT HK believes that the Government has failed to demonstrate that the Proposal is proportionate. In any event, the principle of good administration requires the Government to refrain from implementing a policy that would infringe constitutionally protected fundamental rights.

2. DEPRIVATION OF PROPERTY UNDER THE BASIC LAW

2.1 Apart from the protection mentioned above, Article 105 of the Basic Law also requires the Government to protect the "*right to compensation for lawful deprivation of their property*" (emphasis added). This means that, even if the Proposal is proportionate, if it amounts to a deprivation of property then the Government will be liable to pay compensation.

2.2 The Proposal would result in deprivation of at least the following property of BAT HK and other tobacco industry members:

2.2.1 trademarks that could no longer be displayed within the space of less than 15% of the two largest surface areas on tobacco packets due to their inherent size and design requirements;

2.2.2 trademarks that would be rendered effectively redundant and valueless as the space of less than 15% of the surface area on tobacco packets would be patently insufficient to effectively designate and differentiate products of BAT HK in the market; and

2.2.3 the property rights in the physical chattels that constitute the retail packaging of tobacco packets. The right of a manufacturer to control the form, appearance, and content of material printed on cigarette packs that they own, is an aspect of the bundle of proprietary rights comprising ownership of the packet. The Proposal would therefore deprive manufacturers of a substantial property interest in their cigarette packets.

2.3 Please refer to paragraphs 1.2 to 1.7 of BAT HK's December 2016 Letter, section 3 of BAT HK's 2016 Submissions and section 4 of BAT HK's 2015 Submissions for a detailed explanation of why the Proposal would result in deprivation of trademarks referred to in paragraphs 2.2.1 and 2.2.2 above.

2.4 As such, the Proposal would engage Article 105 of the Basic Law in Hong Kong, deprive the owners of their property rights and the Government would accordingly be required to compensate all aggrieved persons. This would involve countless numbers of trademarks currently owned or licensed to tobacco companies and

tobacco packets and/or containers that were produced or to be produced for sale in Hong Kong, exposing the Government to significant claims and substantial liabilities.

2.5 BAT HK therefore urges the Panel to require the Government to reconsider the Proposal to avoid an unnecessary and disproportionate exposure to substantial claims and liabilities.

3. THE GOVERNMENT HAS NO LEGAL AUTHORITY TO IMPLEMENT THE PROPOSAL BY NEGATIVE VETTING

3.1 In its 2016 Legislative Council Paper, the Government stated its intention to implement the Proposal by tabling the proposed amendment order at the Legislative Council in the first quarter of 2017, which would be scrutinized via the negative vetting procedure.

3.2 The Government's power in relation to this matter is regulated by the Smoking (Public Health) Ordinance (Cap. 371) ("**SPHO**"). Section 18 provides as follows:

> *(1) The Chief Executive in Council may make regulations for all or any of the following matters- (Amended 60 of 2000 s. 3)*
>
> *(a) prescribing anything required or permitted to be prescribed under this Ordinance;*
>
> *(b) prescribing the manner in which the tar and nicotine yields of a cigarette are to be determined; (Replaced 93 of 1997 s. 23)*
>
> *(c) requiring notification of anything done by any person which may be relevant to the tar and nicotine yields of cigarettes and imposing penalties not exceeding a fine at level 3 for a failure to comply with such requirement; (Amended 9 of 1992 s. 15)*
>
> *(d) excepting any tobacco advertisement from the provisions of Part 4 either absolutely or subject to such exceptions as may be prescribed; and*
>
> *(e) for the better carrying into effect of this Ordinance.*
>
> *(2) Subject to the regulations, the Secretary may by order in the Gazette prescribe all or any of the following matters—*
>
> *(a) the form (including specifications) of—*
>
> *(i) (Repealed 21 of 2006 s. 20(b))*
>
> *(ii) any health warning; and*

(iii) any indication of tar and nicotine yields;

(b) the manner in which any of the matters referred to in paragraph (a) is to be displayed. (Replaced 21 of 2006 s. 20(a))

3.3 Whilst section 18 gives the Government a general power to make regulations or orders to prescribe the form of GHWs and the manner in which they are to be displayed, upon a proper construction of the section, the Government is not authorised to prescribe GHWs that would abrogate or curtail a fundamental right protected by the Basic Law and common law, namely property rights in this case.

3.4 The Court of Final Appeal in *A v Commissioner of Independent Commission Against Corruption* (2012) 15 HKCFAR 362 has recognised and applied the principle of legality as a canon of statutory construction. By virtue of this principle, "*human rights and fundamental principles of law, even where derogable, cannot be overridden except by express words or necessary implication*" in the relevant statute. This principle was meant to "*guard against the risk that the full implications of general or ambiguous statutory language said to have abrogated or curtailed fundamental rights or freedoms went unnoticed by the legislature*".

3.5 Hence, trademark rights, which are fundamental rights of property protected by both the Basic Law and the common law, cannot be abrogated or curtailed except by ***express words*** or ***necessary implications*** in the SPHO. First, nothing in the SPHO expressed the Legislative Council's intention to authorise the Government to abrogate or curtail trademark rights by making regulations or orders that prescribe GHWs. During the Second Reading of the 2005 Bill (which introduced the current GHWs requirement) on 18 October 2006 (the "**2006 Reform**"), there was also no mention of the Legislative Council's intention to use general language to intrude on any trademark rights by the introduction of GHWs. Secondly, there is no necessary implication in the SPHO to abrogate or curtail trademark rights as it is possible to prescribe GHWs of a size that allows sufficient space on packaging for the display of trademarks. In this regard, we refer to the decision of the Court of Appeal of Sri Lanka (discussed in section 3 of BAT HK's 2015 Submissions) in which the court held that 80% graphic health warnings on cigarette packages would not allow sufficient space to display trademarks and directed that the size of the graphic health warnings should only occupy a space of 50% to 60% of the packs. Further, in its opinion dated 25 June 2013 ("**Opinion**"), the European Parliament Committee on Legal Affairs stated that the introduction of 75% GHWs would not be in accordance with national constitutional law as well as international treaties such as the TRIPS Agreement and recommended 50% GHWs. Owing to various considerations, the European Union ultimately adopted 65% GHWs. [14] In view of the above, the principle of legality would apply to guard against any abrogation or curtailment of property rights.

[14] The Opinion can be found at http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2F%2FEP%2F%2FNONSGML%2BCOMPARL%2BPE-510.591%2B02%2BDOC%2BPDF%2BV0%2F%2FEN

3.6 Further, the Government was aware that its original proposed bill, which sought to prohibit the display of certain words (e.g. "light", "mild") on the cigarette packet or retail container, may amount to a prohibition of the trademarks of tobacco companies, thereby constituting a de facto deprivation of property under Article 105 of the Basic Law.[15] After consulting the Department of Justice and the Intellectual Property Department, the Government decided to withdraw such prohibition in view of "*the risk that litigation might follow*". This suggests that the Government, when drafting the 2005 Bill, did not intend to restrict trademarks through SPHO and in fact deliberately avoided such effect. The fact that the Government (1) considered the risk of infringing trademarks in this respect; and (2) had not added any express clear words to authorise infringement of trademarks when prescribing GHWs clearly suggests that there was no intention to deprive any trademarks through GHWs. Indeed, no such intention was brought to the attention of the Legislative Council.

3.7 We note, for example, that in contrast to the SPHO, section 94(7)(a) of the Children and Families Act 2014 in the United Kingdom provided that the Secretary of State may by regulations "*impose prohibitions, requirements or limitations relating to – the markings on the retail packaging of tobacco products (including the use of branding, trademarks or logos)*". In Australia, the Federal Parliament has also expressly curtailed or abrogated trade mark rights by primary legislation. Section 20 of the Tobacco Plain Packaging Act 2011 (Cth) provides that "*No trade mark may appear anywhere on the retail packaging of tobacco products*", save for limited exceptions specified in the legislation. The lack of such express language in the SPHO clearly indicates that the Legislative Council had not authorised the Government to abrogate or curtail trademark rights through subsidiary legislation.

3.8 In light of the above, any attempt by the Government to implement the Proposal by negative vetting would be *ultra vires*, regardless of whether the Proposal is constitutional or not.

4. THE GOVERNMENT WOULD BE IN BREACH OF ITS DUTY TO CONDUCT FORMAL PUBLIC CONSULTATION AND/OR AN RIA

4.1 As previously explained in BAT HK's Previous Submissions, BAT HK has a legitimate expectation that the Government would follow fair and proper regulatory processes, such as conducting a formal public consultation and RIA before any tobacco control reform (at least on GHWs). Please refer to paragraph 1.18 of BAT HK's December 2016 Letter, section 2 of BAT HK's 2016 Submissions and section 8 of BAT HK's 2015 Submissions for a detailed explanation on this legitimate expectation. BAT HK notes in particular that the Government has repeatedly cited overseas examples to purportedly justify the Proposal, which is problematic, since this does not take into sufficient account of local circumstances and features. However, even assuming it was lawful for the Government to proceed with the

[15] Minutes of the Legislative Council Meeting on 18 October 2006, page 183.

Proposal, the Government should follow the same consultation process adopted in overseas jurisdictions which it has cited, including conducting an RIA, public consultation and commissioning studies. For example, we note that the UK Government carried out an RIA, conducted several rounds of consultation and commissioned various studies prior to submitting its plain packaging proposal to Parliament.

4.2 However, to date the Government has not conducted any proper public consultation. The Government has neither produced any consultation document for the public to consider the Proposal nor invited the public to submit their views on the same, which deviates from the established standards and consultation practices adopted by the Food and Health Bureau in recent years. Please refer to the table in paragraph 2.15 of BAT HK's 2016 Submissions for more information. The 2015 Special Meeting was held only on the Panel's initiative, rather than the Government's.

4.3 Hon Peter Shiu Ka-fai also shared the same concern and stated, *inter alia*, in the 19 December Meeting that the Government did not have any communication with industry players regarding their concerns until the 2016 Technical Briefing (more than 16 months after the 2015 Special Meeting). Even that instance was merely an attempt by the Government to inform the industry unilaterally of the details of the Proposal while a lot of stakeholders were not present in the 2016 Technical Briefing.

4.4 The Government has also failed to undertake an RIA to date in order to properly consider the impacts, costs and benefits of the Proposal.

4.5 The Government would therefore be in breach of its duties to (1) consult in respect of the Proposal and (2) conduct an RIA, thereby denying BAT HK's legitimate expectation.

5. ON THE BASIS THAT THE GOVERNMENT DECIDES TO IMPLEMENT THE PROPOSAL, THE GOVERNMENT HAS REFUSED TO PROVIDE A REASONABLE ADAPTATION PERIOD TO THE INDUSTRY

5.1 As mentioned in BAT HK's December 2016 Letter, the Government has persistently refused to provide a reasonable adaptation period, which BAT HK submits ought to be at least 12 months, to the industry, although this was granted in the 2006 Reform and is consistent with the Guidelines to the FCTC which the Government relies on in support of the Proposal, which also contemplate a period of 12 months from the enactment of the legal measures for adaptation.[16] Further, it should be noted that Article 11 of FCTC mandates only 30% text warnings and that the 12 months recommendation was made in that context. The difficulties in adapting to 85% GHWs are clearly more significant and hence it is even more

[16] Paragraph 59 of the Guidelines for implementation of Article 11 of the FCTC.

glaring that the 6-month adaptation period proposed by the Government is unreasonable and unrealistic.

5.2 At the 19 December Meeting, the Government attempted to justify this discrepancy on the ground that the 2006 Reform required the industry to include 50% GHWs from scratch, but the Proposal only involves enlarging GHWs to 85%. However, as both BAT and the industry have repeatedly explained to the Government, this is misconceived as the amount of work involved is the actually same– BAT HK would still need to go through the redesigning, reprinting and logistics procedures with new GHWs requirements. Please refer to section 2 of BAT HK's December 2016 Letter for a detailed explanation of why the adaptation period is unreasonable and insufficient.

5.3 We are instructed that a longer adaptation period of at least 12 months would be necessary. This is the minimum time necessary to ensure that BAT HK can implement the relevant changes, minimise market disruption and reduce the amount of economic loss that BAT HK will inevitably suffer as a result of the Proposal. The below table illustrates the procedure and the estimated timeline required to implement the Proposal:

Procedure	**Estimated time required (minimum)**
Packaging re-design on all of the 37 Stock Keeping Units ("SKUs") to accommodate the proposed changes on the GHWs requirements BAT HK manufactures a total of 37 different SKUs whose packs would need to be redesigned. This is a laborious and complicated process, which would involve liaising with various internal and external parties and carrying out quality control checks on all of the SKUs.	At least 3 months
Printing and manufacturing from various sourcing countries BAT HK would need to coordinate with overseas printing houses on issues such as designing new printing moulds, carrying out printing trials and making adjustments as necessary. Further, finished goods would need to be shipped into Hong Kong from a number of different manufacturers and countries, including Singapore, Malaysia, South Korea, Indonesia and Brazil.	At least 6 months

Delivery of finished goods from overseas factories to Hong Kong and clearance from overseas' customs For example, the shipping time from Indonesia is around 40 days port to port.	At least 1 month
Depletion of current stock with health warnings based on existing requirements Time to exhaust current stock of SKUs bearing the existing 50% GHW, and launch the new cigarette packs with the larger GHW. For example, BAT HK's safety stock level is 8 weeks taking into account the time required for international manufacturing and shipping. Otherwise, massive product recall would be necessary, leading to wasted costs, lost sales and loss from tobacco duty paid could ensue without adequate time for stock transition.	At least 2 months (a longer period may be required if there will be excise increase in the interim period as stock clearance will be much slower)
Total Period (Please note a longer period may be required if other events occur such as bad weather, industrial strikes and duty increase. Further, package redesign can only commence upon receipt of the trial high resolution adobe illustrator artwork file (otherwise known as ".ai" file) from the Government, not the publication date of the gazette.)	**At least 12 months**

6. NO RELIABLE EVIDENCE TO SUPPORT THE EFFECTIVENESS OF THE PROPOSAL

6.1 As explained in section 1 above, the Government has failed to provide any reliable evidence to support the effectiveness of the Proposal. A large number of Members in the Panel also expressed their concern in this regard in the 19 December Meeting. Even Members who support stronger tobacco regulation expressed their view that they had doubts as to the justification of the Proposal. For example, Dr Hon Pierre Chan, member of the Medical functional constituency, agreed with the industry on the view that:

6.1.1 the Government was trying to introduce a policy without supporting statistics and data;

6.1.2 even with statistics, the Government disclosed and adopted statistics selectively; and

6.1.3 it was a bit absurd why the Government decided to adopt the example in Thailand but not other countries.

6.2 For a detailed explanation in this regard, please refer to section 1 above.

7. THE PROPOSAL LACKS JUSTIFICATION

7.1 There is no justification for increasing the size of GHWs to 85%. Members of the Panel also shared the same view in the 19 December Meeting. For example, Hon Peter Shiu Ka-fai criticised why the Government increased the size of the GHWs by such an extreme amount to 85% and yet failed to mention that there were many jurisdictions with smaller GHW requirements. For example, 65% in the European Union, 50% in Korea, 35% in Taiwan, 50% in Singapore, 30% in Japan (text only) and even no GHWs were required in the USA.

7.2 Further, the Government's justification for introducing the Proposal is illogical. For example, in the 19 December Meeting:

7.2.1 the Government noted the WHO recommended GHWs be changed every 12 to 36 months, but the GHWs had not been changed since their introduction in 2007. However, this point does not assist the Government. The Government could have changed the pictures in GHWs, as WHO recommended, without changing their size. There are also alternative means, such as introducing a targeted youth education program and implementing a regular and moderate tax increase policy according to inflation rate to achieve the Government's aims before it introduced the Proposal which would intrude BAT HK's property rights. Please refer to paragraphs 5.29 to 5.31 of BAT HK's 2015 Submissions for more information.

7.2.2 the Government noted that some advanced countries had already adopted plain packaging. However, this provides no evidence of the need for increased GHWs in Hong Kong or the effectiveness of such measures. It appears that the Government is intending on introducing the Proposal simply to seek international favour rather than considering whether the proposal is actually necessary in Hong Kong. The plain packaging measures introduced by other countries are also the subject of ongoing legal challenges including in the World Trade Organization.

7.2.3 in response to the question raised by Dr Hon Junius Ho Kwan-yiu, the Government said the 85% GHWs was introduced in response to WHO's recommendation. However, Article 11 of the WHO FCTC requires that a Party shall "*adopt and implement, in accordance with its national law, effective measures to ensure that*" tobacco product packaging carries health warnings in the form of text warnings covering "*no less than 30% of the principal display areas*" of packages. The FCTC only suggests that such warnings "should" (not "shall") cover 50% or more of the principal

display areas and "may" (not "shall") be in the form of or include pictures or pictograms. In this regard, please refer to Professor Wouter's paper on the status and legal effect of the FCTC in International Law at **Appendix B** for more information. Hong Kong's existing GHWs of not less than 50% are already over and above the FCTC requirements. Accordingly, there is nothing in the FCTC that requires increasing the size of graphic health warnings to 85%.

8. THE PROPOSAL WOULD VIOLATE HONG KONG'S INTERNATIONAL OBLIGATIONS

8.1 The Proposal would violate Hong Kong's international obligations under the World Trade Organisation Agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Agreement on Technical Barriers to Trade. For a detailed explanation in this regard, please refer to section 6 of BAT HK's 2015 Submissions. Furthermore, Article 8(1) of the TRIPs Agreement establishes a rule to the effect that Members may only adopt measures for the attainment of the identified objectives which are *"necessary"* for the specified purpose and at the same time *"consistent with the provisions of this Agreement."* This double constraint in Article 8(1) establishes a framework in which (since it is entirely lawful for tobacco products to be sold and supplied over the counter to persons aged 18 or above) it is necessary to adopt a position in which the protection of public health co-exists with the protection of intellectual property by providing for the protection of each in a way which is commensurate with real and substantial protection for the other (a result that would not be achieved by further increasing the size of GHWs above the current provisions which leave 50% of pack surface available for elements of branding and design).

9. IT IS ILLOGICAL TO DISREGARD WHO'S RECOMMENDATION AGAINST THE DISPLAY OF TAR AND NICOTINE CONTENT WHILE AT THE SAME TIME PURPORTING TO RELY ON WHO'S OPINION IN MAKING THE PROPOSAL.

9.1 During the 19 December Meeting, Hon Alice Mak Mei-kuen noted that the WHO recommended ***against*** the display of tar or nicotine content as it would mislead consumers into thinking that the levels of nicotine or tar content are indicative of how healthy the cigarettes are. In response, Dr Jeff Lee Pui-man, head of the Tobacco Control Office, admitted that the Government was aware of the WHO's recommendation against displaying tar or nicotine content in tobacco packaging but nevertheless decided to maintain such requirement.

9.2 It is very difficult, if not impossible, to understand the Government's logic in acting against WHO's recommendation to not display of tar and nicotine content, but at the same time, purporting to rely on WHO's recommendation to enlarge the GHWs to 85% (despite the FCTC only requiring 30% text warnings). As Hon Alice Mak Mei-kuen notes, such inconsistency confuses the public, making them very difficult

to be persuaded by the Government regarding the basis of introducing the Proposal.

9.3 In view of the above, BAT HK respectfully urges the Panel to ask the Government to (1) refrain from implementing the Proposal and (2) properly address all the concerns raised in BAT HK's Previous Submissions. In any event, the Government has no power to implement the Proposal by negative vetting because the SPHO does not authorise the Government to prescribe GHWs in such a manner that would abrogate or curtail a fundamental right protected by the Basic Law and common law, namely property rights in this case.

Please do not hesitate to contact us should you have any queries.

Yours faithfully,

Herbert Smith Freehills

Encl.

cc: Dr. KO Wing-Man, BBS, JP
Secretary for Food and Health
Food and Health Bureau,
18/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong
(By hand)

cc: Mr. Rimsky Yuen, SC
Secretary for Justice
Department of Justice
G/F, Main Wing, Justice Place,
18 Lower Albert Road, Central,
Hong Kong
(By hand)

HERBERT SMITH FREEHILLS

The Chairman
Panel on Health Services
Legislative Council
Legislative Council Complex 1
Legislative Council Road Central
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
D +852 2101 4629
DX 009028
E dominic.geiser@hsf.com
www.herbertsmithfreehills.com

Our ref
6461/17503/30975151
Your ref
FH CR 3/3231/15
Date
13 December 2016

By email & by hand

Dear Sir,

Re: Government's proposal to change the Graphic Health Warnings ("GHWs") on Tobacco Products Packets and Retail Containers and briefing meeting on 23 November 2016 with the tobacco industry

We act for British American Tobacco Company (Hong Kong) Limited ("**BAT HK**"), and write in connection with the Government's briefing on technical issues related to the proposal ("**Proposal**") to amend, inter alia, health warnings on tobacco products packets and retail containers on 23 November 2016 at which we petitioned for a public consultation ("**23 November Meeting**"). In this regard, we enclose the following for your reference:

1. Our letters to the Secretary for Food and Health dated 29 and 30 July 2016 ("**BAT HK's 2016 Submission**") as **Appendix 1**; and

2. The Government's press release on 23 November 2016 ("**Government Press Release**") as **Appendix 2**.

BAT HK is extremely concerned by the Government Press Release[1], which clearly demonstrates the Government's continuing failure to address the substantive and technical concerns raised by the tobacco industry. The Government Press Release is misleading in that it disregards the large number of differences between the Government and the industry raised at the 23 November Meeting. They include that:-

1. The Government's Proposal is unconstitutional and unlawful;

[1] http://www.fhb.gov.hk/en/press_and_publications/press/2016/press161123.htm

2. the Government's failure to conduct any formal public consultation, which is unfair and procedurally improper;

3. the lack of any reliable evidence (including any local evidence) which shows that increasing the size of GHWs would be effective in reducing smoking prevalence and the Government's failure to conduct a regulatory impact assessment ("**RIA**");

4. the industry's concern that a grace period of 6 months would be wholly insufficient and the failure of the Government to provide any reasonable basis for the 6 month adaptation period, either by reference to overseas or by local practice; and

5. the proposed changes to the tar and nicotine content label are not consistent with the Government's warning labelling and past practice.

We address these differences as follows.

1. THE PROPOSAL IS UNLAWFUL

(A) A VIOLATION OF FUNDAMENTAL RIGHTS PROTECTED UNDER HONG KONG LAW

1.1 The Proposal is unlawful as it would deprive trademark owners of the "use" of lawfully registered trademark rights, in breach of constitutionally protected private property rights guaranteed under Articles 6 and 105 of the Basic Law in Hong Kong.

1.2 The law of trademarks is not merely concerned with features of trademarks, but more importantly, trademarks are essential for product differentiation and thus, competition in an advanced consumer market. However, the Proposal would prevent manufacturers from using or exploiting, or using in any meaningful or substantive fashion, their trademarks, copyright and get-up in connection with the sale of cigarettes, and to exercise any meaningful or substantive control over the appearance of cigarette packs owned by them.

1.3 The Proposal would make it impossible to use a number of trademarks consisting of logos and other devices placed at certain positions on the pack (including, but not limited to, position marks and entire pack marks). The right to use these trademarks would be eliminated. For example, if the GHWs are increased to 85%, BAT HK has various 3D or pack shot trademarks that cannot be displayed at all in the remaining 15% of the pack. Please refer to paragraph 4.5 of BAT HK's 2016 Submission. Although there is still some very limited space left of less than 15%, this is insufficient to effectively designate the product. This leaves the trademark without its function as an identification of the commercial origin and the quality of the underlying product.

1.4 As Professor Zerrillo explains "*trademarks and their related brands are practically destroyed [by 85% GHWs] and the goodwill inherent in the trademarks and their related brands will be lost, along with the decades of significant investment it took to generate such goodwill.*"[2]

---

[2] The expert report of Professor Philip Zerrillo, Ph.D., a Professor in the Marketing department at Singapore Management University, Appendix 4 of BAT HK's 2015 Submission ("**Zerillo Report**"), at para 48.

1.5 Given manufacturers are deprived of "all meaningful use", or "all economically viable use"[3], of their trademarks and as trademarks and goodwill constitute property, the deprivation of the same caused by the Proposal would amount to a breach of Articles 6 and 105 of the Basic Law in Hong Kong. This would invalidate any basis upon which the Government can make these regulations.

1.6 Existing regulation, that is specific to tobacco products, such as the ban on advertising tobacco products, further exacerbates the manufacturers' vulnerability to deprivation of their property rights as a result of the Proposal. Please refer to paragraph 4.5 of BAT HK's 2015 Submission (attached as Annex 1 to BAT HK's 2016 Submissions) for more details of the other specific regulation of tobacco products.

1.7 Over 550 trademarks have already been registered in Hong Kong by the BAT Group of affiliated companies and many of these, which have inherent size and design requirements, would be rendered effectively useless by the Proposal, and their economic value would be destroyed. Given the commercial value of BAT HK's trademarks and the associated goodwill built over the years in the brand portfolios, the loss caused by the Proposal would be very substantial.

(B) THE PROPOSAL EXCEEDS THE SCOPE OF THE POWER AND AUTHORITY UNDER SECTION 18(2) OF THE SMOKING (PUBLIC HEALTH) ORDINANCE (CAP 371)

1.8 The power conferred upon the Secretary under section 18(2) of the Smoking (Public Health) Ordinance (Cap 371) is restricted to the "*form (including specifications)*" of the health warning and the manner in which it is to be displayed. Accordingly, the Government is precluded from implementing this proposed change which would violate rights protected under the Basic Law, which is higher law. Please refer to paragraphs 3.11 and 3.12 of BATH HK's 2016 Submission.

(C) THE PROPOSAL IS MANIFESTLY DISPROPORTIONATE

1.9 As the interference resulting from the Proposal goes to the very essence of the fundamental rights of property, the requisite thresholds for justification and proportionality are at their highest. This is particularly so, in view of the proportionality test set down by the recent Court of Final Appeal decision in *Hysan Development Company Limited v Town Planning Board* (the "**Hysan Case**")[4] to weigh the detrimental impact of the restriction of use on private property against the social benefit gained.

The Government has failed to adduce any evidence as to what social benefit would be gained as a result of the Proposal, and more specifically what percentage of smoking prevalence rate can be effectively reduced by the Proposal. Accordingly, the Government would not be able to establish that the restriction is proportionate.

1.10 Given the Government's failure to show that the Proposal is a necessary, adequate and proportionate measure, the burden imposed by the 85% GHWs requirement, particularly in

---

[3] Fine Tower Associates Limited v Town Planning Board, CACV 356/2006
[4] FACV 21 & 22/ 2015

relation to BAT HK's ability to make use of its trademarks, would manifestly outweigh the illusory benefit that has been conveyed by the Government.

1.11 The Government wrongly relies on the World Health Organisation ("**WHO**") Framework Convention on Tobacco Control ("**FCTC**") as the basis for the Proposal. As explained in section 7 of BAT HK's 2015 Submission, the FCTC neither requires nor authorises the increase in the size of GHWs to 85%. Hong Kong's existing GHWs of not less than 50% are already over and above the FCTC requirements.

1.12 The Proposal completely disregards the already high levels of awareness of the risks of smoking in Hong Kong which currently stands at 95.4% (for the youth), and thus renders it totally unjustified.[5] Instead, the Proposal appears to be proceeding without any analysis or evidence whatsoever in support of the claimed inadequacy of the current mandatory size of the GHWs, in terms of the extent by which the Hong Kong public is informed of the health risks, such that an increase to 85% would somehow be more effective in achieving that purpose given there is already universal awareness. Moreover, the Government has not provided any evidence that further increasing the size of the GHWs would reduce smoking prevalence in Hong Kong. On the contrary, there is a demonstrated lack of effectiveness of larger warnings in other jurisdictions such as Australia, Canada and Thailand[6]. In view of the additional requirement in the proportionality test set down by the Court of Final Appeal in the Hysan Case to weigh the detrimental impact of the restriction against the social benefit gained, this lack of evidence would make the restrictions in the Proposal even more difficult to justify.

1.13 In addition, there is expert evidence that *increasing* the size of warnings in Hong Kong has *not had any beneficial effect* above smaller warnings, and may have led to an increase in consumption in a long run. In other words, there is neither any local study nor other reliable basis upon which it can be properly substantiated that a further increase in the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviour:

> "*In the absence of any effect of additional warnings on risk beliefs, one would not expect that warnings that reiterate what consumers already know would alter smoking behavior. It is well documented that reminder warnings do not alter consumer or worker behavior. Independent studies have also demonstrated that further attempts to modify consumer behavior are misguided if they are premised on the notion that people lack adequate information about smoking.*"[7]

---

5 As explained in the expert report of Professor Viscusi, Appendix 3 of BAT HK's 2015 Submission ("**Viscusi Report**"), the public, including youth in Hong Kong are well informed about the risks of smoking, This include youth, as demonstrated by the independent 2009 Global Youth Tobacco Survey (GYTS) data for Hong Kong which found that 95.4% of respondents answered 'Definitely Yes' (89.8%) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?'.

6 LC Paper No. CB(2)1951/14-15(01), available at http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1951-1-e.pdf.

7 Viscusi Report, at para 30. See also the study carried out by Professor Kevin Tsui in the John E Walker Department of Economics at Clemson University, who studied the effectiveness of the Government's mandatory GHWs and found that the inclusion and expansion of GHWs had no practical effect on reducing the overall smoking rate in Hong Kong.

1.14 If the Government had undertaken a proper evidence-based analysis, it would have reached a similar outcome to the U.S. Food and Drug Administration, which undertook the most comprehensive analyses of GHWs by any country to date and found no evidence of a beneficial effect of graphic warnings on smoking behaviour. It was accepted by the US Court of Appeal for DC Circuit that the "*FDA has not provided a shred of evidence... showing that the graphic warnings will directly advance its interest in reducing the number of Americans who smoke...*"[8]

1.15 Further, the Proposal could result in severe consequences that actually undermine the Government's public health objective, such as (1) stimulating price competition leading to down trading, which may turn lead to an increase of consumption, (2) exacerbating a serious illicit trade problem in Hong Kong; (3) distorting competition and raising barriers to entry; and (4) stifling innovation. Please refer to paragraph 1.16 of BAT HK's 2016 Submissions for more details on these points.

1.16 It is clear that a measure, which cannot be shown to be effective, and that would virtually extinguish the last means of communication between the manufacturer of a legal product and a consumer, is manifestly unjustified and disproportionate. Further, the detrimental impact of the Proposal would greatly outweigh the illusory social benefit gained.

1.17 Moreover, it is submitted that given (1) the requirement to display tar and nicotine yields has always been included as part of the current 50% GHWs; (2) the Government's failure to provide evidence showing that the separate display of the tar and nicotine yields from the GHWs would reduce smoking prevalence; (3) the recommendation under the FCTC that the display of tar and nicotine should not be required; and (4) the separate display of the tar and nicotine yields from the GHWs would further reduce the already limited space available to BAT HK to display its trademarks, bar code and authenticating features to even less overall packaging space, the Proposal would also be manifestly disproportionate as the detriment suffered would manifestly outweigh any illusory social benefit gained. Please refer to section 4(B) of BAT HK's 2016 Submissions for more details. BAT HK strongly urges the Legislative Council Panel on Health Services (the "**Panel**") to ask the Government to reconsider its Proposal and, if the display of tar and nicotine yields is to continue to be required that it be included as part of the GHW as is the current requirement.

(D) THE PROPOSAL IS PROCEDURALLY IMPROPER

1.18 Further, the Government has failed to follow a fair and proper regulatory process and failed to act with procedural propriety and fairness in proceeding with the Proposal, in breach of BAT HK's legitimate expectations, established international principles of Better Regulation to which Hong Kong has subscribed, and Government's own previous consultation standards. Please refer to section 2 of BAT HK's 2016 Submission.

2. THE ADAPTATION PERIOD OF 6 MONTHS IS WHOLLY INSUFFICIENT, UNLAWFUL AND/OR IRRATIONAL

---

[8] R.J.Reynolds Tobacco Company, et al., Appellees v FDA, et al., Appellants, No. 11-5332, Appeals from the United States District Court for the District of Columbia (No. 1:11-cv-01482)

(A) INSUFFICIENT ADAPTATION PERIOD FOR IMPLEMENTATION

2.2 The Proposal is unlawful and/or irrational as it fails to consider or address the numerous technical problems and impracticalities scattered throughout the Proposal. In particular, the proposed adaptation period of 6 months is wholly inadequate and unreasonable.

2.3 As mentioned in BAT HK's 2015 and 2016 Submissions, taking into account the estimated time required for packaging redesign, printing, manufacturing, shipping, delivery and depletion of current stock, BAT HK considers that an adaptation period of at least 12 months would be required. BAT HK will incur costs of well over HK$100 million if the Government were to insist on a 6 month adaptation period, which will impose a significant economic cost on BAT HK as opposed to a lower compliance cost for a 12 month adaptation period, in addition to the cost of damage to the goodwill attached to the registered trademarks as a result of the irreparable harm to the branding. Much of this extra cost would be attributable to the lost duty paid on the cigarettes and costs associated with loss of sales due to the inadequate adaptation period and write-off of stock and raw materials. Therefore, whilst BAT HK would still incur compliance costs, these would be reduced with the introduction of a longer adaptation period.

2.4 In response to the current suggested adaptation period of 6 months, it is observed that:

2.4.1 An adaptation period of 12 months was provided for the implementation of the 50% GHWs requirement under the Smoking (Public Health) (Amendment) Ordinance 2006. In particular, at the second reading of the Smoking (Public Health) Amendment Bill 2005 on 18 October 2006 before the Legislative Council, the then Secretary for Health stated at the time[9] that the Government would "*provide **a transitional period of 12 months** for the tobacco industry to bear, in accordance with the new requirement, on the packaging of tobacco products the new graphic health warnings and the indication of the tar and nicotine yields; and to comply with the amended section 10(3) of the Ordinance regarding the restriction of prohibiting the use of misleading words and descriptors on the packaging of tobacco products*" (emphasis added). Given the similarity in the nature of proposed amendments in 2005 and present, it would be irrational and unreasonable for the Government to insist on a much shorter adaptation period. This would also be in breach of BAT HK's legitimate procedural expectation.

2.4.2 A period of at least 12 months was provided for similar implementation in other countries, yet the Government claims that it took into account overseas experience in its letter of 31 May 2016. Please refer to the table set out in paragraph 4.4.3 of BAT HK's 2016 Submissions. Further, when BAT HK's representative asked the Government at the 23 November Meeting which overseas jurisdiction the proposed 6 months' grace period was based on, the Government replied it had not relied on any overseas examples and was unable to refer to any similar local examples where only a 6 month adaptation period was given. These contradictory statements further suggest that there are no solid grounds for the Proposal.

---

9. Page 396 of the Legislative Council meeting on 18 October 2006, which can be found at http://www.legco.gov.hk/yr06-07/english/counmtg/hansard/cm1018-translate-e.pdf

2.4.3 The Guidelines to the FCTC, which are relied on by the Government to support the Proposal, also contemplates an adaptation period of 12 months from the enactment of the legal measures[10].

2.4.4 The Government had indicated at the 23 November Meeting that a shorter adaptation period had been considered given improvements in the printing technology. However, as explained in paragraphs 2.2, 2.3 and 2.4.1 to 2.4.3 above, printing is only one of many steps involved in the manufacturing process of cigarettes. The Government's statement at the 23 November Meeting illustrates a fundamental lack of understanding of and a failure by the Government to consider the difficulties previously explained in BAT HK's 2016 Submissions. The Proposal would involve, inter alia, (1) redesigning the packaging of all of the 37 Stock Keeping Units ("**SKUs**") affected by the Proposal, which is a laborious and intensive process; (2) coordinating with a number of overseas suppliers and printing houses in a number of different countries; and (3) exhausting the current stock of SKUs, otherwise massive recall of products bearing the existing 50% GHWs would be necessary, which is a lengthy and costly process. Please refer to section 4 (A) of BAT HK's 2016 Submissions for more information.

2.4.5 The Government has also failed to address whether the Government would refund to BAT HK excise duties which BAT HK has already paid for products bearing the existing 50% GHWs, if BAT HK is unable to deplete its stock (which will be the case given the short adaptation period).

2.5 The failure to take into account the necessary time that would be required to implement the changes to the packaging of BAT HK's products is also demonstrative of the lack of industry consultation that the Government was directed to undertake by you at the special meeting on 6 July 2015.

2.6 We are instructed that a longer adaptation period of at least 12 months would be necessary to ensure the industry has sufficient time to conduct the laborious process, minimise market disruption and reduce the amount of economic loss that BAT HK (and other participants in the tobacco industry affected by the Proposal) will inevitably suffer as a result of the Proposal. Please refer to section 4 (B) of BAT HK's 2016 Submissions for more details.

(B) OTHER TECHNICAL DIFFICULTIES

2.7 In addition, the Government did not provide any examples of the 12 versions of the proposed new GHWs during the 23 November Meeting. Further, the Government has failed to provide clear guidance in relation to the tar and nicotine yields. For example, at the 23 November Meeting, the Government stated that "*Chinese characters and numbers on the same line are printed in "中黑體" typeface. English letters and numbers on the same line are printed in Univeres Bold typeface*". However, we are instructed that this does not provide sufficient guidance as (1) there are many types of "中黑體" and "Univers Bold" font styles available and (2) the "Univers Bold" font style is not commonly available in word processing systems.

---

10 Paragraph 59 of the Guidelines for implementation of Article 11 of the FCTC.

In order to address the typeface issue, our client suggests that the Government be required to provide a high resolution adobe illustrator artwork file (otherwise known as ".ai" file) of the tar and nicotine box required so that our client can ensure the output meets the Government's requirements. Alternatively, the Government should be required to provide a fonts file (字體使用檔) for BAT HK to develop. However, this is less preferable as there is a chance that the final output may not be what the Government has in mind and thus, be in breach of the legal requirements. Further, when releasing the nicotine/tar information box with the required white background, the Government has failed to consider the overall artistic design of the packet and/ or whether the nicotine/ tar information box will stand out vis-a-vis the pack colour. For example, a white nicotine/tar yield box on a white coloured packet may not stand out as much and thus, fail to have the effect of alerting customers to the various nicotine/ tar yields.

The Government still failed to address other specific concerns raised in BAT HK's 2016 Submissions, such as the layout of the health warning messages, in particular (1) the colour of the health warning; (2) what the requirement of "different orientation" means; (3) whether the characters, letters and numbers should be surrounded by a white line, as required under the specifications for the health warning. Please refer to section 4(B) of BAT HK's 2016 Submissions for more information.

2.3 In view of the above and that the Government has not addressed to BAT HK's satisfaction (whether by written response or at the 23 November meeting) any of the issues raised in BAT HK's 2015 and 2016 Submissions, our client strongly urges the Panel to ask the Government to reconsider the Proposal and to conduct further and more comprehensive consultation with the relevant stakeholders so as to facilitate and best ensure that proportionate policy-making that properly takes into account the wider range of interests. The Proposal, in its current form, should not be put forward for negative vetting by the Legislative Council.

Please do not hesitate to contact us should you have any queries.

Yours faithfully,

Herbert Smith Freehills

Encl.

cc: Dr. KO Wing-Man, BBS, JP
Secretary for Food and Health
Food and Health Bureau,
18/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong
(By hand)

Appendix 1

HERBERT
SMITH
FREEHILLS

Dr. KO Wing-Man, BBS, JP
Secretary for Food and Health
Food and Health Bureau,
18/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
D +852 2101 4629
DX 009028
E dominic.geiser@hsf.com
www.herbertsmithfreehills.com

Our ref
6461/17503/30975151
Your ref
FH CR 3/3231/15
Date
29 July 2016

By hand

Dear Sirs,

Re: Government's proposal to change the Health Warnings on Tobacco Products Packets and Retail Containers

We refer to the Food and Health Bureau's letter to British American Tobacco Company (Hong Kong) Limited ("**BATHK**"), for whom we act, dated 31 May 2016.

We enclose a Written Submission together with appendices in respect of the Government's captioned proposal, on behalf of BATHK.

Please do not hesitate to contact us should you have any queries.

Yours faithfully,

Herbert Smith Freehills

Encl.

RESPONSE OF BRITISH AMERICAN TOBACCO COMPANY (HONG KONG) LIMITED
TO THE GOVERNMENT'S REQUEST FOR COMMENT'S ON THE PROPOSAL
TO INCREASE THE SIZE OF HEALTH WARNINGS FOR PACKETS AND RETAIL CONTAINERS OF CIGARETTES TO 85%

JULY 2016

TABLE OF CONTENTS

As set forth in British American Tobacco Company (Hong Kong) Limited's ("BAT HK") 2015 Submission[1] ("BAT HK's 2015 Submission") and as explained and updated below, BAT HK is strongly opposed to the Government's proposal to change the prescribed form of health warnings and the indication of tar and nicotine yields on packets and retail containers of cigarettes and relevant tobacco products (the "Proposal"). The Proposal is unlawful. The Proposal would substantially and impermissibly expand the size of graphic health warnings ("GHWs") on packets and retail containers of cigarettes to at least 85% which is beyond what is necessary. Furthermore, the Government has followed a flawed process and failed to act with procedural propriety and fairness in proceeding with the Proposal. There are also a number of technical difficulties with the Proposal that the Government has failed to consider.

1. EXECUTIVE SUMMARY

This submission is a response to the Government's letter dated 31 May 2016 to BAT HK setting out the Proposal in detail and inviting views on the same. The grounds upon which BAT HK opposes the Proposal are as follows:

1.1 **The Government has failed to follow a fair and proper regulatory process and thus denied BAT HK's procedural legitimate expectations.** The Government has ignored the express directions made by the Chairman of the Legislative Council Panel on Health Services (the "**Panel**") to the Government to revert to the Panel on how it would take forward the Proposal *after* communicating with the tobacco industry and the relevant stakeholders with regard to their concerns; its own recommendation to conduct a regulatory impact assessment ("**RIA**"); established international principles of Better Regulation to which Hong Kong has subscribed; and its own previous consultation standards.

---

[1] On 23 June 2015, BAT HK submitted evidence-based opposition to the Government's proposal to introduce 85% GHWs, which was supplemented by further evidence set out in a letter from its legal counsel dated 20 July 2015.

1.2 First, the invitation to respond only to the technical aspects of the Proposal, which was also only sent to tobacco manufacturers, precluded the possibility of a genuine dialogue and genuine potential to affect policy development. This is contrary to the Chairman's express direction to the Government during the Special Meeting of the Panel held on 6 July 2015 (the "**2015 Special Meeting**") to address industry concerns and thereby undertake a meaningful consultation on the subject matter of the Proposal.

1.3 Secondly, a proper RIA, as previously recommended by the Government in the regulatory impact analysis undertaken in 2001, that: "*take[s] into account the likely financial and economic costs of implementation and weigh[s these]* against *the likely health and economic benefits likely to arise*",[2] ought to have also been undertaken in order to properly consider the impacts, costs and benefits of the Proposal.

1.4 Thirdly, consultation and an RIA are the cornerstone of internationally accepted principles of Better Regulation[3] as endorsed by the World Bank and the Asia-Pacific Economic Cooperation ("the **APEC**").

1.5 Fourthly, the Government's failure to hold a proper and meaningful public consultation, particularly a trade consultation, deviates from the established standards and practices adopted by the Food and Health Bureau in recent years.

1.6 If the Government had undertaken a proper evidence-based analysis it would have reached a similar outcome to the U.S. Food and Drug Administration (the "U.S. FDA"), namely that increasing the size of the existing warnings would not be effective in reducing smoking prevalence[4].

1.7 As a result of these failings, the Proposal cannot be properly justified and neither can its impact be properly understood; indeed, reliance on the flawed

---

2 As stated in the Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, at p 107. http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf.

3 See 2012 Recommendation of the Council of the OECD on Regulatory Policy and Governance, available at <http://www.oecd.org/gov/regulatory-policy/49990817.pdf>

4 See paragraphs 2.19 to 2.24 below.

process to date as a basis for implementing the Proposal would be "*manifestly inappropriate*"[5] and constitute procedural impropriety.

1.8 **The Proposal is unlawful.** Trademarks are essential for product differentiation and thus for competition in an advanced consumer market. Accordingly, they facilitate local and international trade. However, trademarks can only perform these functions if they can be effectively used as registered but the significant size restriction under the Proposal would eviscerate the essential role of trademarks in distinguishing between different manufacturers' products as: "*trademarks and their related brands are practically destroyed [by 85% GHWs] and the goodwill inherent in the trademarks and their related brands will be lost, along with the decades of significant investment it took to generate such goodwill.*" [6] Therefore, as trademarks and goodwill constitute property, the deprivation of the same caused by the Proposal would amount to a breach of Articles 6 and 105 of the Basic Law in Hong Kong. Furthermore, it would invalidate any basis upon which the Government can make these regulations.

1.9 Over 550 trademarks have already been applied for or registered in Hong Kong by the BAT Group of affiliated companies and many of these have inherent size and design requirements that would be foreclosed by the Proposal. Given the commercial value of BAT HK's trademarks and the associated goodwill built over the years in the brand portfolios, the loss caused by the Proposal would be very substantial.

1.10 Hong Kong has been ranked no.1 in the world for economic freedom over the last 12 years by a leading think-tank, the Heritage Foundation.[7] Rule of law and the degree by which the law protects private property is one of the criteria. The strong rule of law that exists in the territory is a principal reason why Hong

---

5 Refer to the expert report of Mr Stephen Gibson, an economist, consultant and founder of SLG Economics Ltd, Appendix 2 of BAT HK's 2015 Submission ("**Gibson Report**").

6 The expert report of Professor Philip Zerrillo, Ph.D., a Professor in the Marketing department at Singapore Management University, Appendix 4 of BAT HK's 2015 Submission ("**Zerillo Report**"), at para 48.

7 Miller, Kim, 2016 Index of Economic Freedom, The Heritage Foundation, at p 229. Available at http://www.heritage.org/index/pdf/2016/book/index_2016.pdf

Kong is attractive to investors and thus all efforts should be made to uphold and fortify that reputation.

1.11 Moreover, if Hong Kong's status as an international centre for investment is diminished as a result of the Government's actions in damaging the right to property or it does not protect property to the greatest possible extent envisaged by the law, as would be the case if the Proposal is adopted, then the Government will have breached its obligation under Article 109 of the Basic Law to: "*provide an appropriate economic and legal environment for the maintenance of the status of Hong Kong as an international financial centre.*"

1.12 The power conferred upon the Secretary under section 18(2) of the Smoking (Public Health) Ordinance (Cap 371) is restricted to the "form (including specifications)" of the health warning. Accordingly, the Government is precluded from implementing this proposed change which would violate rights protected under the Basic Law which is higher law.

1.13 **The Proposal is also manifestly disproportionate**. As the interference resulting from the Proposal goes to the very essence of the fundamental rights of property, the requisite thresholds for justification and proportionality are at their highest. Given the Government's failure to show that the Proposal is a necessary, adequate and proportionate measure, it is submitted that the burden imposed by the 85% GHW requirement would manifestly outweigh the illusory benefit that has been conveyed by the Government.

1.14 The Proposal completely disregards the high levels of awareness of the risks of smoking in Hong Kong which currently stands at 95.4% (for the youth), and thus renders it totally unjustified[8]. Instead, the Proposal is proceeding without any analysis or evidence in support of the claimed inadequateness of the current mandatory size of the GHWs in terms of the extent by which the Hong Kong

---

[8] As explained in the expert report of Professor Viscusi, Appendix 3 of BAT HK's 2015 Submission ("**Viscusi Report**"), the public, including youth in Hong Kong are well informed about the risks of smoking, This include youth, as demonstrated by the independent 2009 Global Youth Tobacco Survey (GYTS) data for Hong Kong which found that 95.4% of respondents answered 'Definitely Yes' (89.8%) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?'.

public is informed of the health risks, such that an increase to 85% would somehow be more effective in achieving that purpose given there is already universal awareness. Moreover, the Government has not provided any evidence that further increasing the size of the GHWs would reduce smoking in Hong Kong. Contrarily, there is a demonstrated lack of effectiveness of larger warnings in other jurisdictions such as Australia, Canada and Thailand[9].

1.15 Further, there *is* expert evidence that *increasing* the size of warnings in Hong Kong has *not had any beneficial effect* above smaller warnings, and may have led to an increase in consumption by some smokers. In other words, there is neither any local study nor other reliable basis upon which it can be properly substantiated that a further increase in the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviour:

> "*In the absence of any effect of additional warnings on risk beliefs, one would not expect that warnings that reiterate what consumers already know would alter smoking behavior. It is well documented that reminder warnings do not alter consumer or worker behavior. Independent studies have also demonstrated that further attempts to modify consumer behavior are misguided if they are premised on the notion that people lack adequate information about smoking.*"[10]

1.16 Further, the Proposal could result in unintended consequences that actually undermine the public health objective:

- hindering a manufacturer's ability to differentiate its products from its competitors through branding features, of which trademarks are key, will lead to packages looking largely the same across the market; trademarks create quality and value attributes. Accordingly, manufacturers would

---

9 LC Paper No. CB(2)1951/14-15(01), available at http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1951-1-e.pdf

10 Viscusi Report, at para 30.

only be able to compete on price[11] and cheaper products are much more likely to lead to an increase in consumption[12]; and

- since trademarks help to distinguish genuine products from their illicit counterparts, trademarks also facilitate law enforcement's ability to fight the serious problem of illicit trade in Hong Kong[13] and any distortion or evisceration of those trademarks via oversized GHWs will hinder that fight[14]; illicit products not only are cheaper thus likely to encourage consumption but also expose consumers to unregulated products with no controls on hygiene standards and ingredients, or compliance with other product regulation including ceilings on tar, carbon monoxide and nicotine levels.

1.17 It is clear that a measure, which cannot be shown to be effective, and that would virtually extinguish the last means of communication between the manufacturer of a legitimate product and a consumer is manifestly unjustified and disproportionate.

1.18 **The Hong Kong Government will breach its international obligations**. The Proposal would violate Hong Kong's international obligations under World Trade Organisation ("**WTO**") Agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS Agreement**") and the Agreement on Technical Barriers to Trade ("**TBT Agreement**"), which are vital for the fair treatment of Hong Kong's exports. Further, certain companies within the BAT Group hold significant investments in Hong Kong that are protected under Investment Treaties and, as the implementation of the Proposal would violate these treaties, Hong Kong's international reputation would be

---

11 See Zerrillo Report, at paras 54 to 56.

12 See Zerrillo Report, at paras 47 to 58; and the expert report of Dr. Kevin K. Tsui and Dr. Kwok Ping Tsang "An Economic Analysis of Health Warning Labels on Cigarette Packets in Hong Kong", LC Paper No. CB(2)1808/14-15(43), at pp 9-11.

13 Illicit trade in tobacco is already estimated to account for 28% of the total market in Hong Kong and costs the Hong Kong government over HK$2.5 billion in lost tax revenues in the 2014/15 year Asia-16: Illicit Tobacco Indicator 2014, available at 3, at p.71. Available at https://www.oxfordeconomics.com/my-oxford/projects/328658.

14 See expert report of John Hector, a former investigator for the U.K. Her Majesty's Revenue and Customs and Fiscal Crime Liaison Officer at the UK Embassy in Beijing, Appendix 5 of BAT HK's 2015 Submission.

damaged thus putting the Government at risk of legal awards requiring it to repeal the legislation and/or pay substantial sums in compensation.

1.19 **The Proposal is not required nor authorised by the World Health Organisation ("WHO") Framework Convention on Tobacco Control ("FCTC")**. The Government wrongly relies on the WHO Guidelines to the FCTC as the basis for the Proposal. As explained in section 7 of BAT HK's 2015 Submission (enclosed as **Annex 1** to this submission), the FCTC neither requires nor authorises the increase in the size of GHWs to 85%. Hong Kong's existing GHWs of not less than 50% are already over and above the FCTC requirements. Accordingly, the Proposal is not necessary to meet the requirements of the FCTC.

1.20 **The Proposal overlooks the numerous technical problems and impracticalities scattered throughout the Proposal.** The proposed adaptation period of 6 months is wholly inadequate and unreasonable. The failure to take into account the necessary time that would be required to implement the changes to the packaging of BAT HK's products is demonstrative of the lack of industry consultation that the Government was directed to undertake by the Chairman of the Panel. The Government has also failed to provide detailed guidance on the technical requirements and address the concerns specifically raised by the tobacco industry at the 2015 Special Meeting on the technical difficulties and layout issues relating to the indication of nicotine and tar yields, colour, font size and the excessive size of the required GHWs. BAT HK submits that a longer adaptation period of at least 12 months would be required to ensure the industry has sufficient time to go through the laborious process, minimise market disruption and reduce the amount of economic loss that BAT HK will inevitably suffer as a result of the Proposal.

2. THE GOVERNMENT HAS FAILED TO FOLLOW A FAIR AND PROPER REGULATORY PROCESS

2.1 The regulatory process that has been undertaken to date in respect of the Proposal is fundamentally flawed and, in doing so, the Government has denied key stakeholders their legitimate expectation of procedural propriety and fairness. The Government has ignored the express recommendations made by the Chairman of the Panel to the Government; the recommendation made in the RIA undertaken in 2001 in respect of proposed amendments to the Smoking Ordinance and its Regulations; established international principles of Better Regulations to which Hong Kong has subscribed; and its own established consultation standards. Accordingly, the decision to proceed with the Proposal on this basis cannot be justified.

2.2 During the 2015 Special Meeting, a number of Legislative Council members urged the Government to communicate with the industry before introducing the Proposal. Similarly, when closing the meeting, the Chairman of the Panel expressly stated that the Government should revert after communicating with the tobacco industry and the relevant stakeholders having regard to their concerns[15]. However, the Government has chosen not to do so.

2.3 A proper RIA, which has been absent, would have facilitated thorough scrutiny of the Proposal. At the minimum, the Government should analyse all submissions from 2015 and respond to the concerns raised. The failure to undertake any impact analysis of the Proposal goes against the recommendation made in the RIA that was undertaken in 2001 in respect of proposed amendments to the Smoking Ordinance and its regulations, as well as internationally accepted principles of Better Regulation, such as those defined by the Organisation for Economic Co-operation and Development and the Asia-Pacific Economic Cooperation ("**APEC**") of which Hong Kong is a member (see BAT HK's 2015 Submission, section 8).

---

[15] LC Paper No. CB(2)373/15, available at http://www.legco.gov.hk/yr14-15/english/panels/hs/minutes/hs20150706.pdf.

2.4 Mr Stephen Gibson (SLG Economics Limited), formerly Chief Economist and Director of Economic Policy at Postcomm in the United Kingdom produced a report ("**Gibson Report**")[16] detailing an assessment of the Legislative Council paper on Progress of Tobacco Control Measures No. CB(2)1456/14-15(07) (the "**Legislative Council Paper**") with the following principal conclusions:

- failure to follow a proper process in developing proposals for larger GHWs;
- failure to conduct a public consultation and failure to undertake an RIA; and
- the development of the Tobacco Control proposals by the Secretary for Health and Welfare in 2001 included a formal consultation[17] inviting views and comments on the proposed legislative arrangements.

2.5 Hong Kong is also a key member of APEC and its Guidelines for Preparation, Adoption and Review of Technical Regulations stipulate "*that adequate consultation takes place*[18]*…at all stages of the process [of preparing, adopting and reviewing the proposals]*."[19] Similarly, the APEC paper *Supporting the TBT Agreement with Good Regulatory Practices* states that *"[c]onsultation should not be a discretionary part of regulating society.*"[20]

2.6 However, the Government has neither engaged in any communication with the industry nor addressed the industry concerns expressed at the 2015 Special Meeting.

2.7 Consultation involves the establishment of procedures that provide all public stakeholders with an early, proper and meaningful opportunity to comment on regulatory proposals[21]. To this end, the APEC Guidelines require that

---

16 Appendix 2 of BAT HK's 2015 Submission.

17 Refer to Smoking (Public Health) Ordinance Cap.371 Consultation Document, http://www.fhb.gov.hk/en/press_and_publications/consultation/Smoke2.HTM.

18 APEC Guidelines for Preparation, Adoption and Review of Technical Regulations, at section 1.

19 APEC Guidelines for Preparation, Adoption and Review of Technical Regulations, at section 9.

20 Supporting the TBT Agreement with Good Regulatory Practices, at p 52.

21 Supporting the TBT Agreement with Good Regulatory Practices, at p 55.

consultations should occur when the proposal concerned is at a formative stage and not after "*the [Government] has reached a decision on a draft*", otherwise such consultation would become merely "*a façade, in which the views of stakeholders do not really matter to the final decision.*"[22] In essence, the opportunity for comment by stakeholders should be provided in a way so that "*there is genuine dialogue and potential to affect policy development.*"[23] In spite of this, the Government's letter of 31 May 2016 only invited responses in relation to the technical aspects of the Proposal rather than the decision itself, i.e. the "*layout, adoption period of the amendments and other technical specifics regarding the [P]roposal*."

2.8 Given the absence of any proper and meaningful dialogue between the tobacco industry and the Government and any genuine potential to affect policy development, it appears that the letter Proposal "consultation" is a mere façade in disregard of APEC requirements and the recommendation by the Panel.

2.9 During the Special Meeting of the Panel held on 6 July 2015, the Under Secretary for Food and Health stated that the Government had only consulted the District Council and it would merely "*follow up with the industry on the technical issues concerned.*"[24] This goes against APEC Guidelines stipulating that consultations be open to all interested parties, and should not be limited to insiders.[25] In particular, it should "*never exclude anyone with valid interests.*"[26]

2.10 The Government's stated reliance on Article 5.3 of the Framework Convention on Tobacco Control ("**FCTC**")[27] for excluding the industry is also misconceived — there is no requirement in Article 5.3 or its non-mandatory guidelines that tobacco manufacturers be excluded from participating in the regulatory process for the implementation of new tobacco control regulations.

---

22 Supporting the TBT Agreement with Good Regulatory Practices, at p 54.
23 APEC-OECD Integrated Checklist on Regulatory Reform, at p 17.
24 Legislative council Panel on Health Services Minutes of special meeting held on Monday, 6 July 2015, LC Paper No. CB(2)373/15-16, at p 17.
25 APEC-OECD Integrated Checklist on Regulatory Reform, at p 17.
26 Supporting the TBT Agreement with Good Regulatory Practices, at p 56.
27 Legislative council Panel on Health Services Minutes of special meeting held on Monday, 6 July 2015, LC Paper No. CB(2)373/15-16, at p 16.

Article 5.3 only states that *"[i]n setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law*." The Guidelines also only recommend that interactions with the tobacco industry should be transparent and accountable. Therefore, Article 5.3 cannot be a basis for disregarding procedural proprietary and fairness in the regulatory process.

2.11 Consultation is particularly pertinent given the trade restrictive nature and the profound impact of the Proposal on the tobacco industry. The post-decision letter Proposal sent by the Government on May 31, 2016 seeking views from selected companies on technical aspects only is not an adequate process, nor is it fair to the tobacco industry. The Government failed to provide the tobacco industry with any genuine and meaningful opportunity to submit on the development of the Proposal and has failed to consider and/or address the concerns raised by the industry and other stakeholders.

2.12 In the absence of an RIA, is unjustified and not based on a clear understanding of its impact. An RIA is the cornerstone of internationally accepted principles of Better Regulation. According to APEC, in its paper *Supporting the TBT Agreement with Good Regulatory Practices*:

> "It is nearly impossible to regulate well if the consequences of government action are not understood in advance. Understanding consequences of various options for action more clearly is the main purpose of RIA."[28]

2.13 In the RIA that preceded the 2001 Tobacco Regulation proposals, the Government itself concluded that:

> "…any future requirements for pictorial and graphic contents take into account the likely financial and economic costs of implementation and

[28] Supporting the TBT Agreement with Good Regulatory Practices, at p 27.

that these be weighed against the likely health and economic benefits likely to arise."[29]

2.14 The assessment and response to issues raised by stakeholders is pivotal to the RIA process and not doing so would be major failure of transparency and process in policy development. Feedback to stakeholders closes the loop between the government and stakeholders[30], and APEC has stated that "*a lack of tangible results or feedback breeds public cynicism and undermines trust in government.*" [31] The Hong Kong Government's "Be the Smart Regulator" programme also provides that regulators should "*explain the rationale for positive and negative decisions before they are taken on board*"[32] which is a key component in the development of good regulatory policy[33]. However, there is no evidence that the Government has assessed the submissions made in respect of the Proposal in 2015 in any proper and meaningful way — it has not issued any consultation report even though one was issued in respect of the 2001 tobacco control proposals,[34] nor has it grappled with the evidence relating to the Proposal. However, the content of the Government's letter of 31 May 2016 is essentially the same as the Government's submission to the Panel in the 18 May 2015 letter; the only change being the mandatory warning message. This evidences that the Government did not take into account and/or address any of the industry's concerns, contrary to the express direction made by the Chairman of the Panel.

2.15 The Government's failure to hold a public consultation also deviates from established standards and consultation practices adopted by the Food and Health Bureau in recent years. As set out in the table below, the Government (i.e. the

---

29 Regulatory Impact Assessment, Proposed amendments to the existing smoking legislation, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, at p 107.

30 APEC Committee on Trade and Investment Committee on Standards and Conformance Good Regulatory Practices in APEC Member Economies - Baseline Study, 2011, at p 31.

31 OECD (2008), Mind The Gap: Fostering Open And Inclusive Policy Making: An Issues Paper.

32 Economic Analysis and Business Facilitation Unit, Be the smart regulator.

33 APEC Committee on Trade and Investment Committee on Standards and Conformance Good Regulatory Practices in APEC Member Economies - Baseline Study, 2011, at p 27.

34 Refer to Smoking (Public Health) Ordinance Cap.371 Consultation Document, http://www.fhb.gov.hk/en/press_and_publications/consultation/Smoke2.HTM.

Food and Health Bureau) has conducted detailed public consultation in similar circumstances involving proposed amendments to subsidiary legislation ("**Previous Legislative Proposals**"):

Year of Consultation	Proposed legislative changes	Legislative process
2013	Proposed amendments to Import and Export (General) Regulations (Cap. 60A) to prohibit the export of powdered milk formula to all places outside Hong Kong, except under an export licence or unless an exemption applied [35]	The Government conducted a public consultation in relation to the proposed legislative amendments from 7 to 18 February 2013. On 7 February 2013, it held a trade consultation session. At the close of the consultation period, it also summarised the opinions of various stakeholders.
2012	Proposed amendments to the Public Health (Animals and Birds) (Animal Traders) Regulations (Cap. 139B) to tighten regulation of animal breeders and	The Government conducted a public consultation from October to November 2012. During the consultation period, the Government invited views from the Legislative Council Panel on Food Safety and Environmental Hygiene and other interested stakeholders. The Government also organised 4 consultation forums with interested stakeholders and met with

[35] Refer to the Government's briefing paper to the Subcommittee on Import and Export (General) (Amendment) Regulation 2013 http://www.legco.gov.hk/yr12-13/english/subleg/brief/25_brf.pdf

	remove the exemption of private dog owners[36]	representatives of some animal welfare groups which raised suggestions after the consultation period and exchanged views with them.
2011	Proposed amendments to the Dutiable Commodities (Liquor) Regulations (Cap. 109B) to revise the liquor licensing regime[37]	The Government launched a 2 month public consultation in July 2011 to gauge public views on a review of the liquor licensing regime. As part of the process to engage relevant stakeholders, officials responsible for the subject attended a number of trade consultation forums, and presented the proposals to advisory bodies. It also went before the District Councils ("**DCs**") of the three districts with the largest number of liquor-licensed premises in Hong Kong.

[36] Refer to the Government's briefing paper to the Subcommittee on Public Health (Animals and Birds) (Animal Traders) (Amendment) Regulation 2016 and Specification of Public Offices (Amendment) Notice 2016 http://www.legco.gov.hk/yr15-16/english/subleg/brief/2016ln064_068_brf.pdf

[37] Refer to the Government's briefing paper to the Subcommittee on Dutiable Commodities (Liquor) (Amendment) Regulation 2015 and Dutiable Commodities (Liquor Licences) (Fees) (Amendment) Regulation 2015 http://www.legco.gov.hk/yr14-15/english/subleg/brief/20_21_brf.pdf

2.16 Accordingly, it is submitted that the Food and Health Bureau and the Government as a whole has, on this occasion, failed to conduct a proper and meaningful consultation by reference to its own standards and established practice.

2.17 In respect of the submissions made by stakeholders for the purposes of the 2015 Special Meeting and the Government's treatment of the views gathered, BAT HK also makes the following observations:

2.17.1 The written submissions in support of the Proposal lacked evidential substance.

2.17.2 The Government failed to consider the fact that almost 70% of the submissions amongst commercial groups do not support the Proposal[38]. This substantial and significant opposition cannot be ignored and ought to be properly considered by the Government before it proceeds with the Proposal any further.

2.17.3 The Government further failed to address and respond to the concerns raised by other bodies opposing the Proposal:

(A) The Association of Hong Kong Nursing Staff urged the Government to[39]:

i. consider the needs of smokers and ensure that there was sufficient trademark information and anti-counterfeit designs to enable smokers to make an appropriate decision; and

ii. suggested the Government liaise with the public and industry and conduct sufficient discussions to understand

---

[38] Such as the Tobacco Association of Hong Kong, Coalition on Tobacco Affairs and Hong Kong Federation of Tobacco Industries Limited and Hong Kong and Kowloon Tobacco Trade Workers General Union, and including BAT HK..

[39] Refer to the Submission by the Association of Hong Kong Nursing Staff http://www.legco.gov.hk/yr14-15/chinese/panels/hs/papers/hs20150706cb2-1862-3-c.pdf

the feasibility and operational difficulties so as to prevent the proposal from, inter alia, being counterproductive.

(B) The ICC-BASCAP expressed concerns that the imposition of an 85% GHW was an unjustified interference with intellectual property rights, trademarks and freedom of expression and that there was no evidence that GHWs would actually discourage or reduce tobacco use[40]. In particular, the ICC-BASCAP noted that any restriction to normal use of trademarks could:

(1) Increase the prevalence of counterfeit goods and reduce trademark owners' ability to take action;

(2) Exacerbate the illicit tobacco problem as restricting the use of trademarks would facilitate counterfeiters and hinder consumers' ability to differentiate genuine from counterfeit cigarettes;

(3) Increase the burden on the already overstretched public agencies working to enforce intellectual property right protection throughout Hong Kong and worldwide;

(4) Limit the use of private intellectual property rights and facilitate similar restrictions on intellectual property rights in other sectors;

(5) Compromise and undermine Hong Kong's intellectual property rights policies and the laws established to protect them, including international laws and trade agreements assuring protection of intellectual property rights; and

---

[40] Refer to the Submission by the ICC-BASCAP http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1808-81-e.pdf

(6) Undermine the ability of consumers to make informed purchasing decisions.

(C) The INTA stated that if left with only 15% of the front and back surfaces of a cigarette pack or the retail container, the function of trademarks would be impeded and this would represent a possible violation of Hong Kong law and international treaty obligations. The INTA was also concerned that the Proposal would lead to a loss of business opportunity and affect freedom of expression[41].

2.18 As explained in the Gibson Report,"**[o]verall the failures of process and lack of evidence mean that the proposals cannot be shown to be necessary, appropriate or proportionate**" and "**taking all the concerns raised in this report together, it would be manifestly inappropriate to rely on the LC Briefing Paper to proceed with larger [GHWs]**."[42] The Government has done nothing since the LC Briefing Paper to change this position.

2.19 In contrast, the U.S. FDA did carry out an analysis of the effectiveness of the proposed 50% GHWs in 2010 and 2011 – not only were they the most comprehensive analyses undertaken by any country to date but they also found no impact of GHWs on smoking prevalence. The regulatory process followed by the U.S. FDA included the preparation of a draft impact assessment (described as a "Preliminary Rule"), a comprehensive consultation process and the preparation of a final impact assessment (a "Final Rule"), including an assessment of the consultation responses that were received.

2.20 As explained in the Expert Report of Professor W. Kip Viscusi, the U.S. FDA also undertook two types of studies to test the effectiveness of the proposed 50% GHWs as part of its regulatory process:[43]

---

41 Refer to the Submission by INTA's http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1808-70-e.pdf

42 Appendix 2 of BAT HK's 2015 Submission.

43 Viscusi Report, at paras 34 to 43.

2.21 The first line of inquiry consisted of statistical analyses of the effect of GHWs on smoking prevalence rates. The other approach was a large scale experimental study of the effect of different types of GHWs. Neither study indicated that there would be an effect of GHWs on smoking behaviour.

2.22 The statistical analyses centred on the expected benefits of proposed GHWs on smoking behaviours in the United States by comparing the impact of similar warnings introduced in Canada in 2000. Based on this comparison, the U.S. FDA estimated that the use of GHWs on cigarette packages would lead to a decline in smoking rates of only 0.088% and thus the U.S. FDA concluded that it "…cannot reject, in a statistical sense, the possibility that the rule [requiring graphic warnings] will not change the US smoking rate."[44]

2.23 As a second level of analysis, the U.S. FDA commissioned the largest study of consumer responses to cigarette GHWs ever conducted[45]. The study measured consumer attitudes, beliefs, perceptions, and intended behaviours related to cigarette smoking in response to selected 50% graphic warning labels (the "**U.S. FDA Study**") by testing the efficacy of the 50% graphic warnings relative to a control of a text warning statement presented on the side of the packet in accordance with the current US standard warning. However, the authors were forced to concede that *"[t]he graphic cigarette warning labels did not elicit strong responses in terms of intentions related to cessation or initiation.*"[46]

2.24 When the existing warnings are already overwhelmingly seen by current smokers given they constitute 50% of a pack's two largest surface areas, it is even more unlikely that merely increasing the size of existing warnings would have any benefit — no evidence has been forthcoming that an increase in the size of GHWs to 85% would have any benefit in Hong Kong.

---

44 The U.S. Deptartment of Health and Human Services, Food and Drug Administration, "Required Warnings for Cigarette Packages and Advertisements – Final Rule", Federal Register, Vol. 76, No. 120, June 22, 2011, at p 36776.

45 The U.S. FDA Study included approximately 18,000 participants : U.S. FDA, Frequently Asked Questions: Final Rule "Required Warnings for Cigarette Packages and Advertisements", available at http://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm259953.htm.

46 Nonnemaker, J., et al., Experimental Study of Graphic Cigarette Warning Labels: Final Results Report Prepared for Center for Tobacco Products, Food and Drug Administration, Contract No. HHSF-223-2009-10135G.

2.25 Whilst the U.S. FDA did proceed to introduce the warnings, the regulation was overturned by the U.S. Court of Appeals for the D.C. Circuit in 2012, having held there is a consistent lack of evidence in support of the efficacy of GHWs and implementing them would be unconstitutional:

> *"FDA has not provided a shred of evidence—much less the "substantial evidence"' required by the APA [Administrative Procedures Act]—showing that the graphic warnings will "directly advance'" its interest in reducing the number of Americans who smoke.*
>
> …
>
> *FDA's Regulatory Impact Analysis ("RIA") essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates…. In light of the number of foreign jurisdictions that have enacted large graphic warning labels, the dearth of data reflecting decreased smoking rates in these countries is somewhat surprising, and strongly implies that such warnings are not very effective at promoting cessation and discouraging initiation."*[47]

2.26 As for Hong Kong, Dr. Kevin K. Tsui and Dr. Kwok Ping Tsang (as submitted in the 2015 Special Meeting) concluded that increasing the size of warnings has not had any beneficial effect above smaller warnings (including those used in the U.S.) among the local population, and may have actually led to an increase in consumption by some smokers[48]. Similarly, the evidence provided in a letter from BAT HK's legal counsel dated 20 July 2015 to the Panel (the "**July 2015 Letter**") (enclosed as **Annex 2** to this submission) demonstrates the lack of

---

47 *R.J.Reynolds Tobacco Company, et al., Appellees* v *FDA, et al.*, Appellants, No. 11-5332, Appeals from the United States District Court for the District of Columbia (No. 1:11-cv-01482)

48 Expert report of Dr. Kevin K. Tsui and Dr. Kwok Ping Tsang " An Economic Analysis of Health Warning Labels on Cigarette Packets in Hong Kong", LC Paper No. CB(2)1808/14-15(43), available at http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1808-43-e.pdf.

effectiveness of larger warnings in other jurisdictions[49]. Accordingly, if the Government had undertaken a proper evidence-based analysis it would have reached a similar outcome to the U.S. FDA, namely that increasing the size of the existing warnings would not be effective in reducing smoking prevalence (which is already one of the lowest in the world at 10.2%), particularly given the existing awareness of the current warnings and of the health risks of smoking in Hong Kong[50].

2.27 In summary, the continued absence of any meaningful and adequate consultation and the absence of a proper evidence based RIA, which would serve to facilitate proper scrutiny of the Proposal, demonstrates that the Government's actions are arbitrary and without justification.

---

[49] LC Paper No. CB(2)1951/14-15(01), available at http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150706cb2-1951-1-e.pdf

[50] As explained in the Viscusi Report, the high level of awareness includes youth, as demonstrated by the independent 2009 Global Youth Tobacco Survey (GYTS) data for Hong Kong which found that 95.4% of respondents answered 'Definitely Yes' (89.8%) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?', Viscusi Report, at paras 27 to 29.

3. **THE PROPOSAL IS UNLAWFUL**

(A) A VIOLATION OF FUNDAMENTAL RIGHTS PROTECTED UNDER HONG KONG LAW

3.1 The Basic Law expressly protects property rights under the following provisions:

> Article 6
>
> *The Hong Kong Special Administrative Region shall protect the right of private ownership of property in accordance with law.*
>
> Article 105
>
> *The Hong Kong Special Administrative Region shall, in accordance with law, protect the right of individuals and legal persons to the acquisition, use, disposal and inheritance of property and their right to compensation for lawful deprivation of their property.*
>
> *Such compensation shall correspond to the real value of the property concerned at the time and shall be freely convertible and paid without undue delay.*
>
> *The ownership of enterprises and the investments from outside the Region shall be protected by law.*

3.2 In *Michael Reid Scott v The Government of HKSAR* (HCAL 188/2002), the court found that property (for the purposes of Article 105) is a very wide concept and requires a "wide and purposive interpretation." Accordingly, it is clear that intangible rights including intellectual property, business goodwill and reputation rights are protected under Article 105 of the Basic Law. Section 10(1) of the Trade Mark Ordinance (Cap. 559) also provides that a "*registered trade mark is a property right obtained by the registration of the trade mark under this Ordinance*" and section 27(1) provides that a "*registered trademark is personal property*." By virtue of paragraph 3 of Article 105 of the Basic Law, the protection of trademark rights and other intellectual property rights extends

to those owned and invested in by legal persons including foreign companies such as the BAT group.

3.3 The concept of "use" of a trademark involves use on or in relation to goods in order to distinguish between competitors' goods. However, the Proposal would make it impossible to use a number of trademarks as they include logos and other devices that must be placed at certain positions on the pack (including, but not limited to, position marks and entire pack marks) and eliminating the ability to use these trademarks would eviscerate the essential role of trademarks. In other words, the impact of the proposed 85% GHWs on the use of other trademarks is so severe that they would effectively deprive owners of the "use" right.

3.4 Article 105 was considered in the Hong Kong case of *Fine Tower Associates Ltd v Town Planning Board* [2008] 1 HKLRD 553, where the Court of Appeal held that action adversely affecting use of property, despite falling short of formal expropriation, may in certain circumstances properly be described as deprivation. The Court of Appeal held that **"*deprivation*" in this context contemplates the removal or denial of all meaningful use, or all economically viable use, of the property**.

3.5 The following special features of the tobacco products further exacerbate the manufacturers' vulnerability to deprivation of their property rights as a result of the Proposal:

3.5.1 The advertising of tobacco products has already been banned in Hong Kong and retail packaging is one of the last limited remaining channels of communication between the manufacturer and the consumer;

3.5.2 The physical size of tobacco products is small and the use of the packaging is already severely limited by the existing warnings that occupy 50% of the front and back surfaces of tobacco packaging; and

3.5.3 The manner of purchase of cigarette products at their points of sale, where a whole host of different brands are grouped and displayed together (which is unique to cigarette sales), makes it imperative for a

packet to be readily recognisable by both the brand name and display of the trade dress, both of which necessitate reasonably sufficient space on the packaging.

3.6 It is submitted that the 15% surface area that remains on the pack is patently insufficient to effectively differentiate the product from the competition — it leaves the trademark without its function as an identifier of commercial origin and quality of the underlying product.

3.7 **In other words, the Proposal would deny all meaningful use or all economically viable use of the trademarks and, as held in *Fine Tower Associates Ltd v Town Planning Board* [2008] 1 HKLRD 553, it thereby constitutes a deprivation of the property of the trademark owners**.

3.8 As explained by Professor Zerrillo:

> *"With GHWs covering 85% of the package it would be impossible to effectively include all the desired information on the package. Increasing the size of the GHWs to 85% will prevent consumers' from being able to perceive the brand on cigarette packages. Without distinctive packaging to make the trademark elements stand out, a brand becomes undifferentiated from competing brands. Trademarks will not be able to effectively differentiate, and identify the origin and quality of products, which are essential functions of trademarks.* ***The consequence of this is that the trademarks and their related brands are practically destroyed and the goodwill inherent in the trademarks and their related brands will be lost, along with the decades of significant investment it took to generate such goodwill.***"[51] (emphasis added)

3.9 The practical sterilisation of the manufacturers' property amounts to a deprivation of intellectual property rights and the associated goodwill that manufacturers have cultivated over years of investment, of which these rights

---

[51] Zerrillo Report, at para 48.

are protected under the Basic Law. Given the commercial value of BAT's brand portfolios, the loss caused by the Proposal would be substantial.

3.10 The Proposal is inconsistent with the Basic Law and thus the Government is precluded from implementing this proposed change.

(B) THE PROPOSAL EXCEEDS THE SCOPE OF THE POWER AND AUTHORITY UNDER SECTION 18(2) OF THE SMOKING (PUBLIC HEALTH) ORDINANCE (CAP 371)

3.11 The power to prescribe health warnings is vested with the Secretary for Food and Health (the "**Secretary**") pursuant to section 18(2) of the Smoking (Public Health) Ordinance (Cap 371) but the power conferred upon the Secretary under section 18(2) is restricted to the "form (including specifications)" of the health warning — it does not confer a power to violate rights protected under the Basic Law which is higher law.

3.12 As explained above, the Proposal would deprive BAT HK of the very substance of the protections provided under the Basic Law. It is thus beyond the scope of power and authority of the Secretary under section 18(2).

4. TECHNICAL PROBLEMS WITH THE PROPOSAL

(A) INSUFFICIENT ADAPTATION PERIOD FOR IMPLEMENTATION

4.1 The Tobacco Association has already advised the Government that the proposed period of 6 months for adaptation is wholly unreasonable and fails to take into account the necessary time that would be required to implement the changes, but these concerns have been ignored. Based on its past experience, it has been repeatedly stated that the whole manufacturing and logistics process is complicated and time-consuming. A longer adaptation period of at least 12 months would be required to ensure the industry has sufficient time to go through the laborious process, minimise market disruption and reduce the amount of economic loss that BAT HK will inevitably suffer as a result of the Proposal.

4.2 As indicated in the table below, an adaptation period of 6 months as currently proposed by the Government is technically impractical and imposes a significant economic burden for the following reasons:

4.2.1 Taking into account the estimated time required for packaging redesign, printing, manufacturing, shipping, delivery and depletion of current stock, BAT HK considers that an adaptation period of at least 12 months would be required.

4.2.2 BAT HK estimates it will incur costs of approximately £10 million (i.e. approximately HK$102 million) if the Government were to insist on a 6 month adaptation period, which will impose a significant economic cost on BAT HK as opposed to a compliance cost of around £ 2.3 million (i.e. approximately HK$ 23 million) for a 12 month adaptation period but excluding the cost of the goodwill attached to the registered trademarks as a result of the irreparable harm to the branding. Much of this reduction would be attributable to the lost duty paid on the cigarettes and costs associated with loss of sales due to the inadequate adaptation period and write-off of stock and raw materials. Therefore,

whilst BAT HK would still incur compliance costs, these would be reduced with the introduction of a longer adaptation period.

For the Government's ease of review and consideration, BAT HK has summarised the standard procedures and estimated time needed in the table below:

Procedure for implementing the new GHWs on all BAT HK SKUs

Procedure	**Estimated time required (minimum)**
Packaging re-design on all of the 37 SKUs to accommodate the Proposed Changes on the health warning requirements BAT HK would need to redesign all cigarette packs and the Hong Kong cigarette market features 208 Stock Keeping Units ("**SKUs**"). Although BAT HK is only one of the industry players, alone, it manufactures a total of 37 different SKUs. Given the large number of packs to be redesigned and the laborious process involved, BAT HK estimates that this part of the process alone will take at least 3 months.)	At least 3 months
Printing and manufacturing from various sourcing countries BAT HK would need extra time to coordinate with overseas suppliers and printing houses, and finished goods would need to be shipped into Hong Kong from a number of different countries including from Singapore, Malaysia, South Korea, and Brazil.	At least 6 months
Delivery of finished goods from overseas factories to Hong Kong	At least 1 month
Depletion of current stock with health warnings based on existing requirements Time to exhaust current stock of SKUs bearing the existing 50% GHW, and launch the new cigarette packs with the larger GHW. Massive product recall would be necessary, leading to wasted costs and lost sales could ensue without adequate time for stock transition.	At least 2 months (at least 1 month for stock in warehouse and at least 1 month for stock in market)
Total Period	**At least 12 months**

4.3 For the reasons set out above, an adaptation period of 6 months from the date of publication of the Amendment Order is patently inadequate and technically impractical. Realistically, BAT HK would require an adaptation period of at least 12 months from the official release of an Adobe Illustrator format of final artwork to fully comply with the Proposal.

4.4 In response to the current suggested adaptation period of 6 months, BAT HK also makes the following observation:

4.4.1 An adaptation period of 12 months was provided for the implementation of the 50% GHW requirement under the Smoking (Public Health) (Amendment) Ordinance 2006.

4.4.2 At least 12 months were provided for similar implementation in other countries yet the Government claims that it took into account overseas experience in its letter of 31 May 2016. However, the overseas examples set out in the table below all point to support a minimum of 12 months adaptation period for implementation of any change of GHWs.

4.4.3 The Guidelines to the FCTC, which are relied on by the Government to support the Proposal, also contemplates an adaptation period of 12 months from the enactment of the legal measures[52].

Adaptation periods for tobacco related legislative proposals

Country/ Year	**Tobacco related legislative proposals**	**Adaptation period**
Hong Kong, 2006	Introducing 50% GHW in the Smoking (Public Health) (Amendment) Ordinance 2006	12 months
UK, 2008	Introducing GHWs in The	12 months for cigarettes

[52] Paragraph 59 of the Guidelines for implementation of Article 11 of the FCTC.

	Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007	24 months for other tobacco products
European Union, 2014	Introducing 65% GHWs in the Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.	13 months for member states to adopt provisions, plus 12 months sell through period from 20 May 2016 for existing stock.
The Philippines, 2015	Introducing 50% GHWs in the Graphic Health Warnings Law, Republic Act No. 10643	12 months
South Korea, 2015	Introducing 50% GHWs (including a 30% pictorial warning and a 20% textual warning) under the National Health Promotion Act	18 months

(B) OTHER TECHNICAL DIFFICULTIES

4.5 In order to properly consider the implications and practicalities of the Proposal, clarification on some of the requirements contained in Annex A of the Government's letter dated 31 May 2016 is required, and these are set out in the table below:

Aspect	**Existing Requirements**	**Proposed Requirements**	**BAT HK comments/ clarifications sought**

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
General principles			
Size of the health warning	The Chinese and English version of the health warnings shall be of a size that covers at least 50% of the area of the 2 largest surfaces on which that version appears[53].	The coverage of the health warning, the tar and nicotine yield exclusive, will be 85% of the area of the 2 largest surfaces on which the health warning appears.	The size of the GHWs should ensure sufficient room for brand recognition and trademark protection whilst still communicating the required public health messages. The current GHWs are sufficiently prominent for the purposes of effective communication of health messages to consumers. There is no substantive basis or empirical evidence that proves a direct link between increasing the size of GHWs and reducing the smoking prevalence rate in Hong Kong. The proposed requirement in Annex A, when read together with the Government's briefing paper to the Panel dated May 2015 [54] appears to suggest that the tar and nicotine yields should no longer be set out in the

[53] Indication of tar and nicotine yields included in determining the size of the health warning.

[54] Paragraph 17 of the Government's briefing paper to the Panel dated May 2015 states that "*(a) the area of the GHW shall be of a size that covers at least 85% of the 2 largest surfaces of the packet and of the retail container*" and "*(d) the indication of tar and nicotine yields should be printed on a side adjacent to a typical flip flop lid of a cigarette packet, excluding the portion which forms part of the lid and the two largest surfaces presented in a conspicuous place of such side of the packet*'.'

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
			GHW. If that is the case, BAT HK would have even less than 15% of the packaging space to display its branding elements of which trademarks are key. This would effectively eviscerate the role of trademarks and thus deprive BAT HK of highly valuable property. There are currently 559 trademarks, either applied for or registered in Hong Kong by the affiliated companies of the BAT Group, a large proportion of which will no longer be able to be displayed on cigarette packs. They include, but are not limited to, the following: (1) 3D or pack shot trademarks; (2) Trademarks featuring special lid designs; and (3) Trademarks that would otherwise not be possible or practicable to display on a narrow strip of a cigarette pack with only 15% space on the two largest surfaces. Please refer to section 4(C) below for an example of a current cigarette pack of a BAT HK brand currently sold in Hong Kong with the proposed 85% GHWs on

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
			the right. This image clearly demonstrates that an 85% GHW would prevent BAT HK from using its trademarks, and effectively destroy the "visual equity" of these trademarks, as noted by Professor Zerrillo in his report which was included as Appendix 4 of the 2015 Submission.
Forms of health warning	Six	Twelve	BAT HK has no objection to this proposal, provided that the industry has at least 12 months from the issuance of the final form of the health warnings to implement the proposed changes. Moreover, the proposed graphics would have to be both consistent with the law and the local culture. Currently, no indication has been given by the Government as to when the 12 new forms of health warnings would be released. BAT HK is of the view that an adaptation period of 6 months would be: (1) Insufficient for BAT HK to perform all the steps set out in paragraphs 4.1 and 4.2 above; and (2) Impracticable to comply and would impose a significant

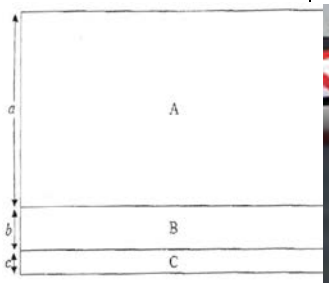
Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
			economic burden on BAT HK in terms of resources and costs.
Health warning message	“香港特區政府忠告市民” / “HKSAR GOVERNMENT WARNING”	Incorporate the following health warning message together with the existing statement “HKSAR GOVERNMENT WARNING" / “香港特區政府忠告市民” "QUIT SMOKING FOR FUTURE GENERATIONS" /“請為你的下一代戒煙” **and** “QUITLINE: 1833 183; 戒煙熱線 1833 183”	The Proposal, in its current form, lacks the technical specificity required for implementation of the proposed changes. For example, the Government should clearly set out the text size and colour of each health warning message as well as how big the text warning should be vis-a-vis the GHWs.
Layout of the health warning	Each form is rectangular in shape and surrounded by a black line as demarcation.	Remains rectangular in shape but different orientation and surrounded by a black line as demarcation.	In respect of the layout of the health warning, BAT HK observes that: (1) The requirement of "different orientation" is also unclear; and (2) The Government has also failed to address concerns specifically raised by the tobacco industry, at the 2015 Special Meeting, on the technical difficulties and layout issues relating to soft packs, drum containers, and the cigar boxes etc.

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
Packet or retail container of cigarettes[55] and retail container of cigar, pipe tobacco or cigarettes tobacco (Other than retail container containing one cigar)			
Indication of tar and nicotine yields[56]	The top side of the area containing the Chinese or English version of the health warning and indication of tar and nicotine yields shall be no more than 12 millimetres from the top of the surface on which that version appears.	The indication of tar and nicotine yields must appear on a surface of the packet and of the retail container other than the lid, the portion of a surface that forms part of / covered by the lid or the 2 largest surfaces.	This requirement is contrary to the recommendations of the Guidelines to the FCTC which the Government relies on, which state that parties shall not require such statements (see Paragraph 34 of the Guidelines for implementation of Article 11 of the FCTC). From the prescribed requirements, it appears that: (1) The tar and nicotine indications can only appear on the sides of the packets or on the bottom panel. Please confirm whether our interpretation is correct; and (2) The characters, letters and numbers must be printed in not less than 8 point font size and 100% black for black. However, the Government has failed to specify how the tar and nicotine yields should be printed and presented. For example, it is unclear

[55] Applies to any packet of cigarettes containing 20 or more cigarettes and any retail container of cigarette packets containing any number of cigarettes.

[56] Applies to packet or retail container of cigarettes only.

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
			from the proposed requirements: (1) Whether there are any specific requirements in relation to the background colours; (2) Whether the characters, letters and numbers can be printed in any colour other than black; and (3) Whether the characters, letters and numbers should be surrounded by a white line, as required under the specifications for the health warning. Putting the indication of tar and nicotine yields to the side or bottom panel will unfairly reduce the space which otherwise could be used for bar code printing, authentication features, consumer hotline information for product quality etc.

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
Specifications of printing of health warning for **packet or retail container of cigarettes**	In relation to area A • The characters and letters are printed in white • The graphic is printed by 4-colour printing with a minimum resolution of 300 dpi In relation to areas B and C • The background colour is white • The characters, letters and number are printed in ▪ 100% black for black; and ▪ 100% yellow plus 100% magenta for red.  	• The health warning form is no longer required to be divided into three areas (i.e. Areas A, B, C); • The characters, letters and numbers are printed in – ▪ White; ▪ 100% black for black; and ▪ 100% yellow plus 100% magenta for red • The characters, letters and numbers should be surrounded by either a black line or white line; • The graphic is printed by 4-colour printing with a minimum resolution of 300 dpi. Example:  	As the image in Annex A is only an example, the Government has failed to clearly set out : (1) Whether there are any requirements on the size of the health warning message or other texts vis-a-vis the overall GHWs; (2) The font size of the characters, letters and numbers to be printed; (3) Unless the Government provides an official Adobe Illustrator format file of all final artwork with the specific colour of each of the letters, characters, numbers to be printed, font size and other printing requirements etc. BAT HK is unable to give full comments on the feasibility of complying with the proposed technical requirements. For example, there is no guidance on (1) whether the font colour can be the same as the border colour; and (2) what the background colour of the pack should be; and

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
			(4) Whether the existing arrangement of the same graphic being displayed on each of the 2 largest surfaces remains unchanged.

Aspect	Existing Requirements	Proposed Requirements	BAT HK comments/ clarifications sought
Specifications of **indication of tar and nicotine yields**	Please refer to the specifications in "Specifications of printing of health warning for packet or retail container of cigarettes" above.	• The characters, letters and numbers are printed in – ▪ Not less than 8 point font size; ▪ 100% black for black.	See BAT HK's comments in the section on "Indication of tar and nicotine yields" above.

(C) AN EXAMPLE OF ONE CURRENT CIGARETTE PACK CARRYING A PACK SHOT REGISTERED TRADEMARKIN HONG KONG WITH THE PROPOSED 85% GHW ON THE RIGHT

[111] 商標編號: Trade Mark No.: 303517984

狀況: Status: Registered

[540] 商標: Mark: KENT

[550] 商標種類: Mark Type: Ordinary

5. CONCLUSION

5.1 For the reasons set out above and in BAT HK's 2015 Submission, the Proposal should not proceed.

5.2 The issues raised by BAT HK and others in the 2015 Special Meeting in respect of the Proposal raise fundamental concerns that the Government has failed to address including:

5.2.1 The Government has failed to adhere to the express directions made by the Chairman of the Panel, its own recommendation and established consultation standards and international principles in failing to undertake any meaningful consultation, address the issues raised by stakeholders in 2015 or conduct an RIA.

5.2.2 The Proposal is unlawful and contrary to the express rights protected under the Basic Law in Hong Kong.

5.2.3 The Proposal is manifestly disproportionate and fundamentally flawed in that it is not necessary nor could it achieve its stated objectives. The Government has not provided any evidence, nor can it, that increasing the size of the existing warnings would be effective in reducing smoking prevalence.

5.2.4 The Proposal would violate Hong Kong's international obligations under the TRIPS Agreement, Paris Convention, TBT Agreement and Bilateral Investment Treaties.

5.2.5 The proposed adaptation period of 6 months is inadequate, unreasonable and unfair and fails to take into account the necessary time that would be required to implement the changes to the packaging required by the Proposal, or any relevant past local experience.

5.2.6 There are a number of technical difficulties and layout issues that would render the compliance of the Proposal impractical or infeasible, if not impossible.

5.3 In failing to address any of these issues the Government cannot lawfully proceed with the Proposal.

5.4 The enactment of effective and evidence-based regulation that meets public health objectives and respects Hong Kong's legal framework and international obligations is central to the rule of law, good governance and Hong Kong's reputation as a top international trade and investment hub.

5.5 However, the increase of the GHWs to 85% would contradict the Basic Law, the principles and obligations set forth above and thus would expose the Hong Kong Government to a number of potential domestic and international claims and legal costs, arising from the unfair process undertaken by the Government in order to bring into effect the unlawful Proposal. BAT HK therefore urges the Government to reject the Proposal and instead to focus on alternative policies, such as those set out in section 5.31 of BAT HK's 2015 Submission[57], which are both lawful and would better achieve the Government's public health objectives.

57

Including, for example, (1) implementing more targeted youth education programmes; (2) implementing a consistent and moderate tax policy; (3) increasing measures to prevent the trade of illicit tobacco; and (4) using targeted warnings to address any perceived information deficits.

HERBERT SMITH FREEHILLS

Clerk to Panel on Health Services
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
D +852 2101 4629
DX 009028
E dominic.geiser@hsf.com
www.herbertsmithfreehills.com

Our ref
6461/15904/30975151
Your ref

Date
23 June 2015

By email

Dear Sirs,

Special Meeting on 6 July 2015 - Legislative proposals to strengthen tobacco control

We represent British American Tobacco Company (Hong Kong) Limited ("**BATHK**").

We enclose a Written Submission together with appendices in respect of the captioned meeting, on behalf of BATHK.

Please do not hesitate to contact us should you have any queries.

Yours faithfully,

Herbert Smith Freehills

Herbert Smith Freehills

RESPONSE OF BRITISH AMERICAN TOBACCO COMPANY (HONG KONG) LIMITED TO THE GOVERNMENT'S PROPOSAL TO INCREASE THE SIZE OF THE GRAPHIC HEALTH WARNINGS FOR PACKETS AND RETAIL CONTAINERS OF CIGARETTES TO 85%

23 JUNE 2015

TABLE OF CONTENTS

TABLE OF APPENDICES

1. INTRODUCTION

1.1 This submission by British American Tobacco Company (Hong Kong) Limited ("**BAT (HK)**") (the "**Response**") responds to the Hong Kong Government's proposal to amend the area of the graphic health warnings and messages for packets and retail containers of cigarettes under the Smoking (Public Health) (Notices) Order (Cap 371B) (the "**Order**"), by requiring that the area of the graphic health warning shall be of a size that covers at least 85% of two largest surfaces of the packet or of the retail container (the "**Proposal**"). The Proposal would substantially and impermissibly expand the size of graphic health warnings for packets and retail containers of cigarettes from the current size of at least 50% to at least 85% which is beyond what is necessary or permissible.

1.2 BAT (HK) is a member of the British American Tobacco group of companies and is responsible for the importation, distribution and sale of tobacco products in the Hong Kong. BAT (HK) has an approximate 24% share of the Hong Kong market. BAT (HK) currently supplies 11 brands in Hong Kong, including VICEROY, PALL MALL, KENT, CAPRI, CASTAN, DUNHILL, HILTON, WINFIELD, and LUCKY STRIKE. There are also currently plans to continue the investment into new brands.

1.3 As explained in detail in this Response, BAT (HK) is strongly opposed to the Proposal to increase graphic health warnings on tobacco packaging in Hong Kong to at least 85%.

2. EXECUTIVE SUMMARY

2.1 BAT (HK) opposes to the Proposal to increase the size of graphic health warnings to 85% on a number of grounds, including:

2.1.1 **The Proposal is unlawful.** The Proposal would deprive BAT (HK) of its property rights and the right to use its trademarks as protected under Articles 6 and 105 of the Basic Law in Hong Kong. The Proposal is therefore contrary to existing laws and thus there is no legal or valid basis upon which the Government can make these regulations.

The Proposal would represent a fundamental shift in Hong Kong's attitude towards intellectual property and property rights generally. Adopting the Proposal would diminish the reputation of Hong Kong as an international trading centre which supports and protects intellectual property and investment. Its implications would also extend beyond the tobacco industry. Industries that sell other consumer products that are perceived to pose health risks would consider that in time they will also become targets for similar labelling policies.

According to the Economic Freedom Index 2015, Hong Kong is ranked no.1 in the world. Rule of law and the degree by which the law protects private property is one of the criteria. The strong rule of law that exists in the territory is a principal reason why Hong Kong is attractive to investors and thus all efforts should be made to uphold and fortify that reputation. If the Government's actions damage the right to property or it does not protect property to the greatest possible extent envisaged by the law, as would be the case if the Proposal is adopted, then Hong Kong's status as an international centre for investment will be diminished, contrary to the Government's obligation under Article 109 of the Basic Law to: "*provide an appropriate economic and legal environment for the maintenance of the status of Hong Kong as an international financial centre.*"

2.1.2 **The Proposal is also manifestly disproportionate**. The interference resulting from the Proposal goes to the very essence of the fundamental rights of property and so the requisite thresholds for justification and proportionality are at their highest. The burden imposed by the 85% graphic health warning requirement would manifestly outweigh any illusory benefit. The Proposal is not necessary. There is already universal awareness of the risks of smoking. Evidence also demonstrates that further increasing the size of the graphic health warnings would not be more effective in increasing awareness (which is already effectively universal) or reducing smoking. In addition, the proposed size of 85% graphic health warnings is entirely arbitrary and has no evidential basis at all.

The Proposal is also likely to have serious adverse consequences which undermine the public health objective, including:

- exacerbating a serious illicit trade problem in Hong Kong;
- stimulating price competition leading to down trading to cheaper products, which may in turn lead to an increase in consumption;
- distorting competition and raising barriers to entry; and
- stifling innovation.

The Proposal must also be considered against the background of the existing comprehensive ban on tobacco advertising and promotion in Hong Kong. Packs, and the trademarks used on them, are to all practical purposes the only means by which manufacturers can identify and differentiate their products from those of their competitors. It is clear that a measure, which cannot be shown to be effective, and that would virtually extinguish this last means of communication for a lawfully available product, while resulting in adverse consequences in respect of pricing, the illicit market and public health, cannot be justified or proportionate.

2.1.3 **The Proposal would place the Hong Kong Government in breach of its international obligations**. The Proposal would violate Hong Kong's international obligations under World Trade Organization ("**WTO**") Agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS Agreement**") and the Agreement on Technical Barriers to Trade ("**TBT Agreement**"), or which are vital for the fair treatment of Hong Kong's exports. Further, certain companies within the BAT Group hold significant investments in Hong Kong that are protected under Investment Treaties. The Proposal would breach these treaties, damaging Hong Kong's international reputation and putting the Government at risk of legal awards requiring it to repeal the legislation and/or pay substantial sums in compensation.

2.1.4 **The Proposal is not required nor authorised by the World Health Organisation ("WHO") Framework Convention on Tobacco Control ("FCTC")**. The current graphic health warnings that already occupy 50% of the front and back of tobacco product packages are already over and above the FCTC requirement. Accordingly, the Proposal is not necessary to meet the requirements of FCTC.

2.1.5 **The Government has not undertaken any regulatory impact analysis ("RIA").** The failure to undertake any impact analysis of the Proposal goes against the recommendation made in the Regulatory Impact Analysis undertaken in 2001 in respect of proposed amendments to the then existing smoking

legislation, that: "*any future requirements for pictorial and graphic contents take into account the likely financial and economic costs of implementation and that these be weighed against the likely health and economic benefits likely to arise.*" [1] The Legislative Council paper on Progress of Tobacco Control Measures No. CB(2)1456/14-15(07) (the "**Legislative Council Paper**") doesn't address these issues at all. The lack of a proper evidence-based regulatory impact analysis means that Legislative Council cannot properly scrutinise the Proposal under the negative vetting procedure to ensure that it is justified.

[1] Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, page 107 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

3. THE PROPOSAL WOULD EVISCERATE THE ESSENTIAL ROLE OF TRADEMARKS

3.1 Trademarks are used by manufacturers as an essential tool to distinguish their goods from similar products. The function of trademarks is to indicate the source of the product and to identify the product by distinguishing it from its competitors. Trademarks are essential for product differentiation and thus for competition in the market. They are an important tool to permit market penetration and trademarks facilitate local and international trade. Trademarks can only perform these functions if they can be effectively used as they were registered.

3.2 Trademarks are often the most valuable asset that a manufacturer possesses and are at the centre of the global economy, as recognized by a recent report of the World Intellectual Property Organization, World Intellectual Property Report 2013: Brands – Reputation and Image in the Global Marketplace.[2] According to this report, the "public good" of trademarks exists in their functional use as a communication tool. The report notes that "the trademark system provides the legal framework underpinning [consumer] confidence", and "trademarks play an important role in preventing market failure". It concludes that "society is bound to be worse off" without the "market-enabling role of trademarks" as, without protected trademarks, consumers can no longer gain access to the product reputation mechanism to guide their purchases and producers have a reduced incentive to invest in product differentiation, thus undermining product quality and diversity. This would gravely damage the interests of consumers in general.

3.3 It is clear that the Government accepts the value and sanctity of trademarks as a key type of intellectual property. The website of the Government's Intellectual Property Department, states:

> *"Protection of intellectual property rights protects creativity…*
>
> *Hong Kong, China is a creative place. Our…graphical design and production skills are known world-wide and…Hong Kong, China is an international trading centre, we need to provide the necessary intellectual property rights protection to our investors to assure them of a free and fair environment in which to do business. Thus it is in our very interest to protect intellectual property rights…*
>
> *The Government…attaches great weight to the contribution that the creation of intellectual property makes to the economy. We have been involved in an on-going effort to ensure that Hong Kong, China people and overseas investors in Hong Kong, China can be assured of intellectual property protection as good as and even better than in any other economy in the world."*[3]

---

[2] Available at http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2013.pdf.
[3] Available at http://www.ipd.gov.hk/eng/intellectual_property/ip_hk.htm

3.4 The right of manufacturers to use their trademarks and the requirement to allow sufficient space on packaging for trademarks, was confirmed in a 2014 decision of the Court of Appeal of Sri Lanka, in which the court held that 80% graphic health warnings on cigarette packages would not allow sufficient space to display trademarks and directed that the size of the graphic health warnings should only occupy a space of 50% to 60% of the pack. The Court stated:

"*Having considered the size of the packs and other relevant facts, I am of the view that 20% of the space is not reasonably sufficient to present and exhibit a trademark. 20% of the space is not exclusively left for the trademark. It may carry other information as well. In such a space, the presentation of the trademark necessarily becomes comparatively very small. The owner of a trademark cannot reach the consumers with his mark which is hidden in the health warning. The consumers will also not be able to see and identify the trademark properly and consequently the source of the respective goods. They have to make extra efforts to see or identify the trademark, when they buy the goods. Such a situation will unreasonably interfere with the statutory right of the owner of the trademark to use it frustrating the whole purpose of a trademark and of the trademark law*"; and

"*This court observes that a balance need [sic] to be maintained, having considered the case of either party. Health of each and every citizen of our country and all those living in Sri Lanka permanently or in a temporary capacity is paramount and need to be protected. On the other hand a legally established business/industry cannot be denied its legitimate rights, flowing from the laws of our country. If 80% of the space is covered by health warnings the remaining space would not be sufficient to display the manufacturers' trade mark.*" A copy of the decision of the Court of Appeal of Sri Lanka is submitted with this Response (see Appendix 1).[4]

3.5 BAT (HK) submits that the factual observations made by the Court in Sri Lanka would equally apply in respect of the Proposal and a Court in Hong Kong would apply the same reasoning and reach the same result, namely that 85% graphic health warnings would provide insufficient space for display of trademarks on tobacco product packaging.

3.6 BAT (HK) also submits the Expert Report of Professor Philip Zerrillo, Ph.D. Professor Zerrillo is a Full Professor in the Marketing department at Singapore Management University and Dean of Post Graduate Professional Programmes. He is also the Executive Chairman of the Board for the Masters in Marketing (MIM) programme at Thammasat University in Thailand. Professor Zerrillo has taught graduate level courses in marketing channels and marketing strategy for 17 years in this programme. He also teaches a

[4] BAT (HK) notes that the subsequent decision of the Sri Lankan Government to introduce 80% graphic health warnings and circumvent the decision of the Court of Appeal is contrary to the rule of law, and would clearly not be countenanced in Hong Kong.

doctoral level seminar at Thammasat University. Professor Zerrillo's report (the "**Zerrillo Report**") is submitted with this Response (see Appendix 4).

3.7 In his Report, Professor Zerrillo describes the importance of trademarks and the brands that they represent, and how they affect consumers, manufacturers, competition in the marketplace, and international trade. He also opines upon the ramifications to trademarks and brands that will result from the requirement to increase the size of the graphic health warnings on cigarette packages in Hong Kong to cover not less than 85% of the package surface, and the resulting impact on consumers, manufacturers and the marketplace.

3.8 A summary of Professor Zerrillo's opinions are, as explained in his Report[5]:

3.8.1 Trademarks (such as words, logos, images, designs or combination of these elements) and packaging are vital to brands.

3.8.2 Trademarks perform valuable functions for both consumers and the firms that own them. A trademark identifies the brand and differentiates the product performing important navigation and reassurance functions for consumers. It signals the source or origin of the product and, as such, aids the consumer's navigation among competing products. Trademarks also symbolize a product's quality and features, and guarantee that the goods or services measure up to expectation. The existence of trademarks, and the brands they represent, is particularly important for effective market competition, as they enable firms to uniquely identify and differentiate their products other than on the basis of price alone. For manufacturers, the protection of the intellectual property rights afforded to trademark owners means that the firm can invest in the trademark and the associated brand with confidence. In addition to the firm's ability to obtain the benefits of its valuable asset sustained over time, it provides an incentive for the firm to create greater value for all stakeholders including consumers.

3.8.3 Increasing the size of GHWs to cover 85% of the cigarette packages will make it impossible for manufacturers to use some trademarks as registered (including logos and labels) and for them to use other trademarked elements effectively. Trademarks will not be able to adequately serve their essential functions of differentiating products and uniquely identifying their origin and quality.

3.8.4 In Hong Kong, the extensive ban on advertising and sponsorship of cigarettes means that the limited space available on cigarette packs for trademarks is the only tool manufacturers have to identify and differentiate their products from other competitive offerings. A further reduction in this already limited space will minimize or even eliminate any meaningful use of trademarks and, in doing so,

---

5 Zerrillo Report at para 12.

destroy their value. As a result, decades of investment in brands and their related trademarks, along with their inherent goodwill, will be lost.

3.8.5 Brands including trademarks play an important role in the cigarette market, and their erosion or elimination changes the nature of the market. In general, markets without brands become price-driven commodity markets.

3.8.6 Commodity markets produce lower prices that encourage more consumption. Commodity markets also make the market inhospitable to firms trying to enter the market and for existing brands, particularly small brands, to compete for a greater market share. Commoditization of the cigarette market in Hong Kong and a shift to pure price driven competition could also lead to an increase in illicit trade because without the added value of brands, legitimate products will be less clearly differentiated from illicit products.

3.9 Professor Zerrillo includes in his Report images below of current cigarette packs of BAT (HK)'s brands sold in Hong Kong with the proposed health warning covering 85% of the packages on the right. As noted by Professor Zerrillo these images clearly illustrate that the graphic health warnings covering 85% of the packages would destroy the "visual equity" of BAT (HK)'s relevant trademarks.[6]

[6] Zerrillo Report at para 46.


香港特區政府忠告市民
吸煙引致肺癌
焦油： 5 毫克 尼古丁：0.4 毫克
PALL MALL
FAMOUS AMERICAN BLEND
CHILLED
戒煙熱線：1833 183
吸煙帶來痛苦，
生不如死
CHILLED
香港特區政府忠告市民
吸煙禍及家人
焦油： 8 毫克 尼古丁：0.7 毫克
R.A. PATTERSON TOBACCO COMPANY
LUCKY STRIKE
EST RICH'D. VA. USA
戒煙熱線：1833 183
吸煙帶來痛苦，
生不如死
EST RICH'D. VA. USA
吸煙可加速皮膚老化
焦油：13 毫克 尼古丁：1.0 毫克
RICH TOBACCOS · FILTER KINGS
VICEROY
AMERICAN BLEND
戒煙熱線：1833 183
吸煙帶來痛苦，
生不如死
AMERICAN BLEND

4. THE PROPOSAL IS UNLAWFUL

(A) THE PROPOSAL WOULD VIOLATE FUNDAMENTAL RIGHTS PROTECTED UNDER HONG KONG LAW

4.1 The Proposal to increase the area of the graphic health warnings on tobacco packaging in Hong Kong to cover at least 85% of two largest surfaces of the packet and of the retail container, is a violation of BAT (HK)'s fundamental property rights which are protected under the Basic Law of Hong Kong. Indeed, by eviscerating the essential role of trademarks as highlighted in preceding section 3, the Proposal would deny all meaningful use or all economically viable use of the trademarks. It would thereby deprive BAT (HK) of its extremely valuable intellectual property rights; namely, its trademark rights together with the goodwill arising in their brands. The Basic Law expressly protects property rights under the following provisions:

> Article 6
>
> *The Hong Kong Special Administrative Region shall protect the right of private ownership of property in accordance with law.*
>
> Article 105
>
> *The Hong Kong Special Administrative Region shall, in accordance with law, protect the right of individuals and legal persons to the acquisition, use, disposal and inheritance of property and their right to compensation for lawful deprivation of their property.*
>
> *Such compensation shall correspond to the real value of the property concerned at the time and shall be freely convertible and paid without undue delay.*
>
> *The ownership of enterprises and the investments from outside the Region shall be protected by law.*

4.2 The concept of protected property rights under Hong Kong law includes tangible rights as well as intangible rights. This was specifically determined by the Hong Kong court in *Michael Reid Scott v The Government of HKSAR* (HCAL 188/2002) in which the court found that that property (for the purposes of Article 105) is a very wide concept and requires a "wide and purposive interpretation". In light of this judgment, it is clear that intangible rights including intellectual property, business goodwill and reputation rights are protected under Article 105 of the Basic Law. Section 10(1) of the Trade Mark Ordinance (Cap. 559) also provides that a "*registered trade mark is a property right obtained by the registration of the trade mark under this Ordinance*" and section 27(1) provides that a "*registered trademark is personal property*". By virtue of paragraph 3 of Article 105 of the Basic Law, the protection of trademark rights and other intellectual property rights extends

to those owned and invested in by legal persons including foreign companies such as the BAT group.

4.3 The concept of "use" of a trademark involves use on or in relation to goods to distinguish them from competitors' goods. The Proposal would make it impossible to use a number of trademarks consisting of logos and other devices placed at certain positions on the pack (including, but not limited to, position marks and entire pack marks). The right to use these trademarks would be eliminated. In addition, the proposed 85% graphic health warnings would have such a severe impact on the use of other trademarks that they would effectively deprive owners of the 'use' right. As explained in section 3 the Proposal would eviscerate the essential role of trademarks.

4.4 In *Fine Tower Associates Ltd v Town Planning Board* [2008] 1 HKLRD 553, the Court of Appeal in Hong Kong considered Article 105 of the Basic Law and held that action adversely affecting use of property, despite falling short of formal expropriation, may in certain circumstances properly be described as deprivation. The Court held that "*deprivation*" in this context contemplates the removal or denial of all meaningful use, or all economically viable use, of the property.

4.5 The following special features of the tobacco products further exacerbate the manufacturers' vulnerability to deprivation of their property rights:

4.5.1 The advertising of tobacco products has already been banned in Hong Kong, such that one of the last remaining channels of communication between the manufacturer and the consumer is through the packaging of the product for retail sale;

4.5.2 The physical size of the packaging of tobacco products is small and the use of the packaging is already severely limited by the existing warnings that occupy 50% of the front and back surfaces of tobacco packaging;

4.5.3 The likely manner of purchase of cigarette products at their points of sale where a whole host of different brands are grouped and displayed together (which is unique to cigarette sale), making it imperative for a packet to be readily recognisable not only by its brand name but by the display of the trade dress in a reasonably sufficient space on the packaging.

4.6 Although there may still be room left for applying some word and device trademarks, the space left for displaying the trademarks being a maximum of 15% of the two largest surfaces of the packet and retail container, is patently insufficient to effectively differentiate the product from the competition. This leaves the trademark without its function as an identification of the commercial origin and the quality of the underlying product. In order to serve as a source-identifier, a sign must be easily identifiable and widely visible on the pack space. Where only 15% of the packet is left for the display of trademarks and the

package is dominated by oversized graphic health warnings, this requirement cannot be fulfilled and the essential role of trademarks is eviscerated. The decision of the Court of Appeal of Sri Lanka, discussed in section 3 above, demonstrates that when graphic health warnings become too large, as would be the case with 85% graphic health warnings, trademarks can no longer serve their essential functions and the right to use is infringed.

4.7 The Proposal would therefore remove or deny all meaningful use or all economically viable use of the trademarks and thereby constitutes a deprivation of the property of the trademark owners.

4.8 As explained by Professor Zerrillo:

> *"With GHWs covering 85% of the package it would be impossible to effectively include all the desired information on the package. Increasing the size of the GHWs to 85% will prevent consumers' from being able to perceive the brand on cigarette packages. Without distinctive packaging to make the trademark elements stand out, a brand becomes undifferentiated from competing brands. Trademarks will not be able to effectively differentiate, and identify the origin and quality of products, which are essential functions of trademarks.* ***The consequence of this is that the trademarks and their related brands are practically destroyed and the goodwill inherent in the trademarks and their related brands will be lost, along with the decades of significant investment it took to generate such goodwill."***[7] (emphasis added)

4.9 In addition to trademark rights, the goodwill associated with the packaging of BAT's products and used in connection with their sale, including the main panels of the packaging of the product which make up its trade dress, would be adversely affected. Generally, the longer a trade dress has been in use, the more valuable it will be as a tool to help visually distinguish the product from those manufactured or marketed by competitors. This is all the more important given that the effect of the Proposal will be to allow a maximum of only 15% of cigarette packaging to bear the relevant trademark, logo and reflect the trade dress.

4.10 The practical sterilization of the manufacturers' property, by reason of the requirement to print warnings covering over 85% of the surfaces of the packaging amounts to a deprivation of intellectual property rights and the associated goodwill that manufacturers have cultivated over years of investment, of which these rights are protected under the Basic Law. Given the commercial value of BAT (HK)'s trademarks and valuable goodwill built over the years in their brand portfolios, the loss caused by the Proposal would clearly be very substantial.

---

7 Zerrillo Report at para 48.

4.11 Accordingly, the Proposal is inconsistent with the Basic Law and thus the Government is precluded under the law from implementing this proposed change.

(B) THE PROPOSAL EXCEEDS THE SCOPE OF THE POWER AND AUTHORITY UNDER SECTION 18(2) OF THE SMOKING (PUBLIC HEALTH) ORDINANCE (CAP 371)

4.12 The power to prescribe health warnings is vested with the Secretary for Food and Health (the "Secretary") pursuant to section 18(2) of the Smoking (Public Health) Ordinance (Cap 371). The power conferred upon the Secretary under section 18(2) is restricted to the "form (including specifications)" of the health warning and does not confer a power to violate rights protected under the Basic Law which is higher law.

4.13 As explained above, the Proposal would deprive BAT (HK) of its property rights and the right to use its trademarks as protected under the Basic Law in Hong Kong. This deprives BAT (HK) of the very substance of the protections provided under the Basic Law, including Article 105. The Proposal is therefore beyond the scope of power and authority of the Secretary under section 18(2).

5. THE PROPOSAL IS DISPROPORTIONATE AND THEREFORE CANNOT BE JUSTIFIED AS A PUBLIC HEALTH MEASURE

5.1 The principles of proportionality require administrative acts to meet a three-pronged test, as set out in the Hong Kong Court of Appeal decision in *Mok Charles v Tam Wai Ho*[8], namely:

5.1.1 The restrictions or limitation must pursue a legitimate aim;

5.1.2 The restrictions or limitations must also be rationally connected to that legitimate aim; and

5.1.3 The restrictions or limitations must also be no more than is necessary to accomplish that legitimate aim.

5.2 The Government has the burden of showing that the Proposal meets the above requirements. As discussed below, the Government has not prepared an RIA in relation to the Proposal. Absent this analysis, it cannot be demonstrated that the above requirements have been met.

5.3 The Proposal must also be considered in context, namely that the current graphic health warnings already occupy 50% of the front and back sides of cigarette packs. The Government has not adduced any evidence to show either (a) that the current size of graphic health warnings are inadequate or insufficient to achieve their intended purpose, namely to inform the public of the health risks involved by smoking, or (b) that the further increase in the size of the graphic health warnings from 50% to 85% will more effectively achieve that purpose than the current size of 50%.

(A) THERE IS NO LEGITIMATE PURPOSE THAT REQUIRES THE PROPOSAL

5.4 The first essential step in an impact analysis is to identify and establish the problem that the measure is intended to solve. The Government must be able to identify a specific and addressable problem before it can show why the proposed increase in warnings size from 50% to 85% is required and how it will address the problem identified.

5.5 There is no problem that requires further increasing the size of graphic health warnings from 50% to 85% because:

5.5.1 Public awareness in Hong Kong about the risks of smoking cigarettes is effectively universal. BAT (HK) has commissioned an expert report from Professor Viscusi, the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University (the "**Viscusi Report**") (see Appendix 3). As explained in the Viscusi Report the public, including youth in Hong Kong are well informed about the risks of smoking. Statistics reflect the widespread

[8] (2010) 13 HKCFAR 762.

exposure of the public to anti-smoking messages, and indicate universal awareness of the potential health consequences of smoking. The youth are often taught about the dangers of smoking in schools, and are targeted in media campaigns that warn of possible health risks. Warnings on cigarette packets have reinforced the media coverage of smoking risks. The high level of awareness includes the youth, as demonstrated by the independent 2009 Global Youth Tobacco Survey (GYTS) data for Hong Kong which found that 95.4% of respondents answered 'Definitely Yes' (89.8%) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?'[9] Professor Viscusi states:

> *"Given that the public are aware of the risks of smoking, there is no beneficial informational role for increased warnings. In the absence of any effect of additional warnings on risk beliefs, one would not expect that warnings that reiterate what consumers already know would alter smoking behavior. It is well documented that reminder warnings do not alter consumer or worker behavior. Independent studies have also demonstrated that further attempts to modify consumer behavior are misguided if they are premised on the notion that people lack adequate information about smoking."*[10]

5.5.2 Branded packaging also does not neutralise consumers' existing awareness of the risks of smoking or prevent consumers from seeing and assimilating the health warnings. Accordingly the removal of trademarks from packaging is not required to increase the effectiveness of health warnings.

5.5.3 The existing cigarette packages in Hong Kong, which already carry large graphic health warnings that cover 50% of the two largest surfaces of packages, do not mislead consumers about the harmful effects of smoking as demonstrated by the universal awareness of the risks of smoking as highlighted above.

5.5.4 Furthermore, existing laws are sufficient to meet any demonstrable concerns regarding deceptive packaging. The existing protections against false or misleading trade descriptions on goods including tobacco products under sections 6 and 7 of the Trade Descriptions Ordinance (Cap.362), in addition to the extensive restrictions on sale, advertising and on misleading descriptors of tobacco products under the Smoking (Public Health) Ordinance (Cap.371), are sufficient to address any allegedly misleading elements of packaging, while also respecting the choices and rights of adults who choose to use tobacco products

---

9 Viscusi Report at paras 27-29.
10 Viscusi Report at para 30.

and allowing tobacco manufacturers, as a part of a legal industry, to communicate with consumers about product information.

5.5.5 It is also clear from numerous studies that factors other than a deficit of information or branded packaging are the real drivers of smoking initiation. According to leading public health authorities, a wide variety of psychosocial risks factors are related to the initiation of tobacco use among adolescents. They include low socioeconomic status, tobacco accessibility, sibling use, peer use, normative expectations, academic achievement, social support, problem behaviours, expected utility, self-esteem and self-image, personality factors, and psychological well-being[11]. In a 2008 paper, James Heckman, a Nobel Prize-winning economist who specializes in research regarding why young people behave as they do, reviewed a vast amount of literature on the causes of youth smoking and concluded that:

> *"The available evidence in the developing literature on adolescent risky behavior, including smoking, supports a multi causal model for youth smoking, as many factors have been empirically linked to youth smoking in this literature. These factors include price, parental influences, risk preferences, peer influences, and access."*[12]

5.6 Given the absence of any problem requiring the increase in graphic health warnings, the Proposal is plainly disproportionate as it cannot be necessary or serve any legitimate objective

(B) FURTHER INCREASING THE SIZE OF GRAPHIC HEALTH WARNINGS FROM 50% TO 85% IS INADEQUATE AS A PUBLIC HEALTH MEASURE.

Increasing the size of graphic health warnings to 85% would not reduce smoking.

5.7 A proper evidence-based analysis demonstrates that graphic health warnings do not reduce smoking prevalence. The Government has not cited any existing studies or commissioned any studies to support its assertion that increasing the size of graphic health warnings from the current 50% to 85% will meet these aims.

---

11 See, *e.g.*, US Department of Health and Human Services. "Preventing tobacco use among young people: A report of the Surgeon General" (1994) (summarizing approximately 160 studies on the subject of the psychosocial risk factors associated with underage tobacco use). *See also* US Department of Health and Human Services, "Preventing tobacco use among youth and young adults: A report of the Surgeon General" (2012), at Ch. 4 (reinforcing findings of 1994 Surgeon General's report with added emphasis on individual cognitive processes).

12 James Heckman, "An Assessment of Causal Inference in Smoking Initiation Research and a Framework for Future Research," Economic Inquiry, (2008).

5.8 The Viscusi report contains a detailed review of the empirical evidence regarding the effect of graphic cigarette warnings on smoking behaviour. A summary of Professor Viscusi's conclusions is [13]:

5.8.1 Analysis of smoking trends in Canada, the U.K., and Australia fails to indicate any beneficial effect of graphic warnings when assessed either on a within country basis or in comparison to trends in the U.S. Empirical evidence also indicates that the introduction of 50% graphic warnings in Hong Kong in October, 2007 has similarly had no impact on reducing smoking prevalence. The downward smoking prevalence trend is similar to the U.S., which does not have graphic health warnings but only a small text warning. Neither increasing the warning size nor the use of graphic health warnings has been effective in reducing smoking prevalence rates.

5.8.2 Evidence demonstrates that the risks of smoking have been well publicized over the last several decades and that the youth are well informed about the risks of smoking. Given that consumers are aware of the risks of smoking, there is no beneficial role for increased warnings. However, if there are concerns regarding the current warnings being worn out and lower levels of awareness of specific illnesses, these can be met by changing the current warning content. Increasing the size or format of the warnings is not needed and will not have any improved benefit in terms of reducing smoking rates.

5.8.3 The U.S. Food and Drug Administration (the "FDA") undertook a substantial statistical analysis to estimate the effect of the Canadian graphic warnings on smoking prevalence rates. In its preferred analysis that accounted for U.S. smoking trends and cigarette tax levels, the FDA found that the effect of graphic warnings on prevalence rates was less than one-tenth of 1 percentage point. In all of its statistical analyses all effects of graphic warnings on smoking prevalence were statistically equivalent to a zero effect.

5.8.4 The FDA also funded a large scale experimental survey that compared the efficacy of a wide variety of graphic warnings relative to text warnings that did not include the graphic information. There was no evidence of efficacy of graphic warnings in influencing smoking decisions of adults or younger age groups for any of the nine smoking risks that were studied.

5.8.5 Nevertheless, the FDA proceeded with a proposed graphic warnings regulation. However, the U.S. courts overturned this regulation in 2012 in R.J. Reynolds Tobacco Co. v. Food and Drug Admin. because, in the view of the Court: *"FDA*

---

[13] Viscusi Report at paras 3.1-3.8.

has not provided a shred of evidence—much less the 'substantial evidence' required by the APA [Administrative Procedures Act]—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke."

5.8.6 The preponderance of other studies of graphic warnings is not informative as these studies typically ask people if the warnings provided information to them, or would alter their behaviour, rather than assessing how warnings actually affect their risk beliefs and influence their smoking behaviour. While there have been many claims of efficacy of graphic cigarette warnings, there is a profound gap between these claims and any concrete evidence that graphic warnings are more effective than text warnings in altering risk beliefs or smoking behaviour.

5.8.7 There is no sound basis in experimental data, survey data, or data on smoking behaviour to conclude that larger graphic warnings are more effective in increasing risk awareness or reducing smoking behaviour. It therefore cannot be expected that increasing the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviours.

5.9 As noted above, the Government has not undertaken any assessment to establish if further increasing the size of graphic health warnings from 50% to 85% would in some shape or form address an information deficit that has not been demonstrated to exist. This renders the Proposal totally arbitrary and irrational. Further, it must be considered that even if the Government had undertaken a proper evidence-based analysis it would have reached a similar outcome to the FDA, namely that increasing the size of the existing warnings would not be effective in reducing smoking prevalence. The FDA analysis is the *state of the art* when it comes to assessing the impact of graphic health warnings, which nevertheless failed to find any impact of graphic health warnings on smoking behaviours. This is particularly telling in the present case where graphic health warnings in Hong Kong already cover 50% of the pack. In these circumstances further increasing the graphic health warnings to 85%, when there is no information deficit to be addressed and no evidence that (i) consumers do not understand the current warnings covering 50% of the pack and that (ii) the increased warnings would reduce smoking prevalence, is clearly arbitrary and an improper use of power.

Further increasing the size of graphic health warnings from 50% to 85% would distort competition and drive down prices which may lead to an increase in consumption contrary to the public health objective.

5.10 In view of the prohibition of all forms of advertising and existing restrictions on tobacco packaging, the principal, if not sole remaining competitive levers available to tobacco manufacturers are product differentiation and price.

5.11 As explained by Professor Zerrillo, increasing the size of graphic health warnings to 85% would effectively prevent manufacturers from being able to differentiate their products and will make the packages all look largely the same. To the limited extent that trademarks can be squeezed onto the remaining space on the pack, they will be unable to effectively perform their function of identifying and differentiating products, signalling the source or origin of the product and indicating a product's quality and characteristics[14].

5.12 Without the ability to differentiate or offer the quality and value attributes created by trademarks and the brands they represent, tobacco products will become increasingly standardised and manufacturers would only be able to compete on price. As such, price competition, which is already extremely vigorous in the tobacco market, will become even more intense leading to further price reductions.

5.13 Professor Zerrillo opines that:

> *"The elimination or minimization of cigarette brands will also impact the market structure and market dynamics. First, competition will shift from brand competition to price competition. In the short term, a lack of competitive dimensions could lead to market rigidity, with little switching by consumers among brands. This market rigidity will further discourage innovation and investment and will hasten competition on price alone. It will also give an advantage to domestic brands that are likely to be able to compete more effectively on price.*
>
> *The impact of the loss of brand differentiation in the Hong Kong tobacco market will differ among firms depending upon the extent to which they have already established their market position and depending upon the nature of their business model. Firms for which the business model depends upon the use of diversity so as to appeal to the niche tastes and firms that are currently seeking to enhance their market position by winning market share from the leading firms stand to suffer more than firms relying on one dominant brand – indeed, the latter may gain in the short run (in terms of market share) because they will still benefit from being known as a market leader and will be subject to less competitive pressure from other firms. Nonetheless, even as their market share increases, margins on these brands will decrease and eventually be eroded more or less completely, as the market evolves to pure price competition.*
>
> *As cigarettes become commodity products resulting in competition on price alone, price conscious smokers will likely navigate toward low value, non-premium brands. The focus on commodity pricing likely will result in lower prices*

[14] Zerrillo Report at para 12(c).

to consumers, a result which could also lead to increased purchases and consumption."[15]

5.14 The impact of reduced prices is likely to increase in consumption, especially among price-sensitive consumers, as tobacco products become more affordable. This would undermine the public health objective of reducing smoking prevalence.

5.15 By implementing measures that distort competition, the Proposal would also betray a policy of Hong Kong to facilitate fair competition, as inferred from the Competition Ordinance (Cap. 619) ("An Ordinance to prohibit conduct that prevents, restricts or distorts competition in Hong Kong") and Articles 109[16] , 115[17] and 119[18] of the Basic Law. We refer again to Hong Kong's long-standing reputation for economic freedom and a supportive business friendly environment which will be damaged by measures such as the Proposal that undermine competition and business investment.

5.16 Professor Zerrillo also explains that:

"*One of the benefits of brands to market structure is that they can make it possible for new competitors to enter the marketplace and differentiate themselves from their competitors. In an unbranded commodity market, new entrants to the marketplace have a very difficult time encouraging consumers to try their product except on the basis of price. Given that they cannot effectively differentiate their products through communication about the brand, the only way to encourage trial is to compete on price. However, in a market like cigarettes where incumbents have significant scale advantages, competing on price is not likely to be an attractive option for new entrants. In contrast, in a market with brands, it is possible for a new brand to establish itself in consumers' minds as something different from existing brands and, therefore, as something worthy of switching to. One of the keys to ensuring that a market functions efficiently is ensuring that incumbents feel a continuous threat that new entrants may enter the market and therefore continue to try to improve the quality of their products and brand*

---

15 Zerrillo report at paras 54-56.

16 Article 109 provides: "The Government of the Hong Kong Special Administrative Region shall provide an appropriate economic and legal environment for the maintenance of the status of Hong Kong as an international financial centre."

17 Article 115 provides: "The Hong Kong Special Administrative Region shall pursue the policy of free trade and safeguard the free movement of goods, intangible assets and capital."

18 Article 119 provides: "The Government of the Hong Kong Special Administrative Region shall formulate appropriate policies to promote and co-ordinate the development of various trades such as manufacturing, commerce, tourism, real estate, transport, public utilities, services, agriculture and fisheries, and pay regard to the protection of the environment."

reputation. In essence it ensures a "best behavior" practice on the part of market participants."[19]

Further increasing the size of graphic health warnings from 50% to 85% would further incentivise the illicit trade

5.17 The illicit trade in tobacco is a major concern to society in undermining public health attempts to reduce smoking prevalence and the financing of organised crime.

5.18 A 2013 International Tax and Investment Center and Oxford Economics report on the illicit tobacco trade in 14 selected Asian markets estimated that 33.6% of tobacco consumption in Hong Kong is illicit.[20] Of the 14 Asian countries surveyed, Hong Kong had the third largest percentage of illicit consumption in the region. It was estimated that illicit trade in tobacco would cost the Hong Kong government HK$3.2 billion in lost tax revenues in the fiscal year 2013/2014.

5.19 This growing illicit market is becoming increasingly problematic for Hong Kong. Cross border criminal syndicates are often behind illicit cigarette trade, and the illicit trade is a source of violent crime, economic losses, and counterfeit smuggling. It also poses a threat to Hong Kong's international reputation as a leading international city.

5.20 Further increasing the size of graphic health warnings to 85% would exacerbate the already significant illicit trade in tobacco products in the following ways:

5.20.1 Removing the incentive to pay premiums for products that no longer look or feel premium would drive prices down across all cigarette market segments, conferring a competitive advantage to those able to supply the lowest cost product – i.e. the illicit trader. As a Morgan Stanley research note on tobacco and illicit trade points out:

"…to the extent that brand equity is degraded over time, it could result in lower tobacco prices than would otherwise have been the case (presumably resulting in higher tobacco consumption), and a potential substantial increase in illicit volumes."[21]

5.20.2 The market in illicit fully branded products would grow in response to demand from those consumers who would rather continue using the fully branded product they are used to. This is likely to be sourced either through illegal supply from other countries or by suppliers of counterfeit branded products.

---

19 Zerrillo Report at para 39.

20 Asia-14: Illicit Tobacco Indicator 2013, at p. 63, available at http://www.oxfordeconomics.com/asia14

21 Tobacco – Legitimate Manufacturers or Illicit Trade? A Stark Choice", Morgan Stanley Research, July 2, 2012.

5.21 As part of this Response, BAT also submits the expert report of Mr John Hector, a recently retired former UK Her Majesty's Revenue and Customs officer nearly 45 years' experience, including acting as the Fiscal Crime Liaison Officer at the UK Embassy in Beijing from 2006 to 2011 where his role was to combat the flow of illicit trade in tobacco product to the UK and Europe in conjunction with Chinese Law Enforcement agencies. Mr Hector sets out his observations on the illicit trade of tobacco products in Hong Kong and the likely impact of increasing the size of graphic health warnings to 85% on the illicit trade, based on his many years of experience in tackling the illicit tobacco market. Mr Hector's report (the "**Hector Report**") is submitted with this Response (see Appendix 5).

5.22 Mr Hector explains that:

> "*The impact of further regulation on the illicit trade must be carefully considered given the existence in Hong Kong of a well-established and accessible illicit market. Consumers can easily find and purchase illicit products if they want to. Given the high price of legal cigarettes in Hong Kong compared to neighbouring countries there is already a greater incentive for illicit trade in Hong Kong. This situation will only be made worse by the introduction of further measures that incentivise the illicit market, such as making legal products less recognisable or increasing the product range that the illicit market can provide consumers. Cigarette smugglers can readily provide whatever type of packaging that smokers of any age want.*"[22]

5.23 Mr Hector concludes:

> *"In my view, increasing the size of graphic health warnings from 50% to 85% will only make the significant illicit problem in Hong Kong worse by incentivising consumers' willingness to purchase the cheapest products available rather than pay the increasingly higher price for legal products which no longer look and feel like premium products. It will provide the illicit tobacco trader with an additional advantage in that they can provide packaging without large graphic health warnings if that is what consumers want*."[23]

5.24 Not only would this increase in illicit trade severely undermine the public health objectives – i.e., the proliferation of cheap illicit products would stimulate demand for tobacco products rather than reduce it – but, it would also have a significant impact on government revenues and society in general through increased criminal activity, and would further undermine public health by:

5.24.1 increasing youth access to tobacco products; and

---

[22] Hector Report at para 16.

[23] Hector Report at para 17.

5.24.2 exposing consumers to unregulated products with no controls on hygiene standards and ingredients, or compliance with other product regulation including ceilings on tar, carbon monoxide and nicotine levels.

(C) FURTHER INCREASING THE SIZE OF GRAPHIC HEALTH WARNINGS FROM 50% TO 85% WOULD NOT BE PROPORTIONATE

5.25 The interference resulting from the Proposal goes to the very essence of the fundamental rights of property and so the requisite thresholds for justification and proportionality are at their highest. As explained above, the Proposal would deprive BAT (HK) of its extremely valuable intellectual property rights; namely, its trademark rights together with the goodwill arising in their brands. Given the commercial value of BAT (HK)'s trademarks and valuable goodwill built over the years in their brand portfolios, the loss caused by the Proposal would clearly be very substantial.

5.26 The burden imposed by the 85% graphic health warning requirement would manifestly outweigh any possible illusory benefit. The Proposal is also disproportionate for the following further reasons.

85% graphic health warnings go beyond what is necessary to effectively warn* consumers*.

5.27 Large graphic health warnings that effectively rebrand cigarette packs, such as the 85% graphic health warnings proposed, are also unnecessary for the purpose of effectively conveying warnings to consumers. There is no evidence that consumers are unable to comprehend the current warnings which already occupy 50% of the front and back of the pack.

5.28 Furthermore, concerns that the current 50% warnings are worn out, which would have to be substantiated by evidence that has not been presented, and that there are lower levels of awareness of specific illnesses—evidence of which the Government has not identified -- can be met by changing the current warning content and do not require increasing the size of the warnings. Accordingly, 85% graphic health warnings would go beyond what is necessary to effectively warn consumers.

There are a number of more effective and less intrusive measures

5.29 Existing laws that prevent false or misleading trade descriptions of goods are sufficient to meet any demonstrable concerns regarding packaging while also respecting the choices and rights of adults who choose to use tobacco products and allowing manufactures, as a part of a legal industry, to communicate product information to consumers. Enforcement of these laws should be undertaken, if required, before introducing more unnecessary regulation.

5.30 Further, the existing 50% graphic health warnings are sufficient for the purpose of informing consumers about the hazards of tobacco use. Such warnings comply with the

obligations under the FCTC, while minimising the violation of the rights of manufacturers and obligations under other international agreements.

5.31 There are also a number of alternative regulations that are more effectively targeted to reducing youth smoking. For example:

5.31.1 Reducing youth access, by for example:

(A) Rigorous enforcement of existing laws forbidding retailers to sell to minors and/or the implementation of additional age verification measures;

(B) Creating an offence of proxy purchase. Such a measure would directly target minors' access to cigarettes and would close off a significant avenue through which minors obtain cigarettes; and

(C) Creating an offence of youth purchase. As in the case of a proxy purchasing offence, criminalising purchases by minors is a targeted measure. The risk of criminal prosecution may also act as a deterrent for minors. Similar measures have been adopted in relation to the purchase of alcohol, and evidence suggests that such measures are effective in reducing sales.

5.31.2 Implementing more targeted youth education programmes aimed at preventing young people from taking up smoking. A significant body of research, including research by the Nobel prize-winning economist James Heckman, establishes that early childhood interventions that affect personality traits and cognitive skills supportive of health can be effective policy tools in preventing unhealthy behaviour, such as smoking;[24]

5.31.3 Implementing a consistent tax policy that discourages youth uptake of smoking while disincentivising adult consumers from purchasing illicit products;

5.31.4 Increasing measures to prevent the trade of illicit tobacco. In light of the rampant illicit trade situation in the Hong Kong market, we strongly urge the Government to focus its efforts on making Hong Kong a place without illicit cigarettes as a far more effective means of reducing the criminality and other harms associated with illicit trade while also increasing tax revenue.

5.31.5 Using targeted warnings to address any perceived information deficits. To the extent that the Government is concerned about any specific information deficits relating to the health risks of smoking (despite the well-established nature of the public's awareness of these risks), it can remedy these concerns through

[24] Heckman J. "Skill formation and the economics of investing in disadvantaged children" Science, 312(5782), 1900-1902 (2006); Feeny T. "The case for investing in early childhood. A snapshot of research by Professor James Heckman (University of Chicago, USA) and Dr. Richard Tremblay (University of Montreal, Canada)", (April 2006).

focussed warning messages that would provide the appropriate, purportedly "unknown" information to targeted populations.

6. THE PROPOSAL WOULD VIOLATE HONG KONG'S INTERNATIONAL OBLIGATIONS.

World Trade Organization Agreements

6.1 The increase in size of graphic health warnings to 85% of pack surfaces is entirely inconsistent with Hong Kong's obligations under several WTO Agreements, namely: (i) the TRIPS Agreement (and the related Paris Convention for the Protection of Industrial Property ("**Paris Convention**")), and (ii) the TBT Agreement. It is unquestionably in Hong Kong's interests to comply, and ensure compliance by other States, with these WTO Agreements. They are vital for the fair treatment of Hong Kong's exports.

6.2 The proposed 85% graphic health warnings would undermine intellectual property rights by adversely affecting the use of trademarks on the packaging of tobacco products and the enforcement of trademark rights. As a result of their impact on internationally protected trademark rights, the graphic health warnings must be analysed under the provisions of the TRIPS Agreement. In particular, the 85% graphic health warnings would impose special requirements that encumber the use of trademarks, including preventing the use of certain validly registered trademarks, thus violating Articles 15, 16, and 20 of the TRIPS Agreement and several trademark-related provisions of the Paris Convention, such as Articles 6*quinquies* and 10*bis*.

6.3 Article 20 of the TRIPS Agreement provides that use of trademarks in the course of trade shall not be "*unjustifiably encumbered by special requirements, such as ... use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings*".

6.4 The proposed increase to 85% graphic health warnings would constitute a "special requirement" because it would be mandatory; and the requirement is specifically limited to certain tobacco products and the position and size of the graphic health warnings on the tobacco packaging is specifically regulated (thus constituting "special" requirements).

6.5 The 85% graphic health warnings would encumber the use of trademarks by requiring their use in a manner that is detrimental to the capability of the trademarks to distinguish products. The 85% graphic health warnings would prevent the use of trademarks registered for the entire pack and impair trademarks' identification and distinguishing functions. The Proposal also prescribes the use of trademarks in a special form as those limited trademarks which could still be used have to be adapted to fit the limited remaining space on the pack.

6.6 Article 20 of the TRIPS Agreement confirms that a measure that requires use in a special form or use in a manner that is detrimental to the capability of the trademarks to distinguish products is *ipso facto* an "*unjustifiable*" encumbrance. This means that the Proposal cannot

be justified under TRIPS. However, even if the measure could be justified, the absence of any contribution to the reduction of smoking rates, let alone a material reduction, and the availability of less trademark-restrictive alternative measures that are equally or more effective, confirms that the encumbrances resulting from the 85% graphic health warnings are not "necessary" and thus certainly not "justifiable" under Article 20 of the TRIPS Agreement.

6.7 The proposed 85% graphic health warnings would also violate the basic principles that protect the function of trademarks and the minimum guaranteed rights that are reflected in Articles 15 and 16 of the TRIPS Agreement:

6.7.1 Article 15.1 provides that "*[a]ny sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark*". The ordinary meaning of a "trademark" is a sign used to distinguish products. Article 15.1 thus requires Members to allow "any distinctive sign" to be capable of constituting a "trademark" irrespective of the form or category of the sign. Where graphic health warnings are of such a size that they make the use of a specific sign (*e.g.*, logo or combination marks) impossible (as would be the result from increasing the size of graphic health warnings to 85%), these signs would no longer be capable of constituting a trademark as properly defined under the TRIPS agreement.

6.7.2 Article 15.4 provides that "*[t]he nature of the goods or service to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark*". Article 15.4 confirms therefore that the nature of the product cannot be an obstacle to registration. It also confirms that trademarks are intellectual property rights that must be examined and protected independently of the product or service to which they are applied.

6.7.3 Article 16.1 of the TRIPS Agreement provides an exclusive right to the owner of a trademark to prevent others from using identical or similar signs on identical or similar goods, when such use is likely to cause confusion. Article 16.3 provides additional protection to owners of well-known marks from unauthorized use of similar signs even on dissimilar goods, if such use indicates a connection and is likely to cause damage to the interests of the trademark owner. A mark obtains and maintains this well-known status as a result of frequent and widespread use in the relevant market. The more intensive use of the mark, the stronger the mark becomes and the greater scope of protection it enjoys because of an increased likelihood of confusion between marks. Increasing the size of graphic health warnings to 85% would prevent or impair trademarks from being used on

the product packaging, thereby undermining the ability of registered trademark owners to maintain the distinctiveness and associations between the trademark and the product that are required to exercise these rights effectively and to establish "confusion" in any infringement proceeding. A well-known mark that can no longer be properly used will lose its special status and extended scope of protection under Article 16.3. Increasing the size of graphic health warnings to 85% would therefore violate the obligation to guarantee a minimum level of protection for registered trademarks and well-known marks under Articles 16.1 and 16.3 of the TRIPS Agreement.

6.8 Furthermore, increasing the size of graphic health warnings to 85% would not only violate the provisions of the TRIPS Agreement discussed above but also violate Articles 10*bis* and 6*quinquies* of the Paris Convention because they mandate confusion that causes unfair competition and fail to ensure protection of the trademark "*as is*" registered and protected in other countries that are parties to the Paris Convention. As opposed to protecting against unfair competition and prohibiting acts that create confusion, 85% graphic health warnings would allow for the kind of confusion and unfair competition that a WTO Member is under an obligation to prevent. Such confusion and unfair competition are, in effect, mandated because the 85% graphic health warnings would make all cigarette packs look almost identical and will suggest that all products are essentially the same in terms of their characteristics. Accordingly, by requiring the confusion that it was obligated to prevent under Article 10*bis*, increasing the size of graphic health warnings to 85% would violate Hong Kong's obligation under Article 10*bis* of the Paris Convention.

6.9 Furthermore, increasing the size of graphic health warnings to 85% would be inconsistent with Article 2.2 of the TBT Agreement as it would create an unnecessary obstacle to trade because it would:

6.9.1 significantly limit market entry for imported tobacco products;

6.9.2 reduce product differentiation and lower the value of imported products; and

6.9.3 strongly disincentives exports to Hong Kong because of the required adaptation costs and the potential risk of penalties for non-compliance.

6.10 The trade restrictive nature of the proposed increase in the size of graphic health warnings to 85% cannot be justified. First, as discussed below, there is no evidence to suggest that increasing the size of graphic health warnings would make a material contribution to the achievement of their legitimate public health objective (given the evidence that graphic health warnings do not actually reduce smoking prevalence). In light of this, there is no need to consider if less trade restrictive alternative measures are available. However, as explained above, there are a number of alterative measures which would be more effective than increasing the size of graphic health warnings to 85%.

Bilateral Investment Treaties

6.11 Increasing the size of graphic health warnings to 85% could also expose Hong Kong to claims from foreign investors under Bilateral Investment Treaties (BITs). Invariably, intellectual property is specifically included in the definition of investments protected by such treaties and increasing the size of graphic health warnings to 85% would inevitably breach several of the usual protections afforded by BITs including those prohibiting expropriation of investments (including goodwill and intellectual property) without the payment of compensation, as well as those requiring fair and equitable treatment.

6.12 The 'fair and equitable' standard requires the Hong Kong Government to act towards foreign investors consistently and to respect their legitimate expectations. Every legal business has a legitimate expectation of its continuity without unlawful or arbitrary impairment or obstruction, and that it will be able to use its registered trademarks and other intellectual property which it has used for decades in accordance with Hong Kong legislation.

6.13 The Government must also act proportionately and not discriminate unjustifiably. Tobacco is a legal product and the tobacco industry is a legitimate industry. The Proposal would frustrate the legitimate expectation of BAT Group companies that they will be able to continue to use long-established trademarks.

6.14 Given the commercial value of BAT (HK)'s trademarks and valuable goodwill, the Hong Kong Government would be exposed to a substantial damages award.

7. THE PROPOSAL IS NEITHER REQUIRED NOR AUTHORISED BY THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

7.1 The Legislative Council Paper relies on WHO Guidelines to the FCTC as the basis for the Proposal. However, the FCTC neither requires nor authorises the increase in the size of graphic health warnings to 85%. Hong Kong's existing graphic health warnings of not less than 50% are already over and above the FCTC requirements. Paragraph 15 of the Legislative Council Paper is incorrect.

7.2 Article 11 of the FCTC requires that a Party shall "*adopt and implement, in accordance with its national law, effective measures to ensure that*" tobacco product packaging carries health warnings in the form of text warnings covering "*no less than 30% of the principal display areas*" of packages. The FCTC only suggests that such warnings "should" (not "shall") cover 50% or more of the principal display areas and "may" (not "shall") be in the form of or include pictures or pictograms.

7.3 Furthermore, the WHO Guidelines to Article 11 of the FCTC which call for parties to consider warnings that cover no less than 50% and to use pictures, do not impose any binding obligations. The WHO Guidelines to the FCTC are only "*intended to assist Parties in meeting their obligations*" under the FCTC and do not create legally binding obligations.

7.4 Accordingly, in order to comply with its binding legal obligations under the FCTC, a Party must issue a notification or law, consistent with national law, so as to adopt and implement "effective" textual warning labels on tobacco packaging covering not less than 30% of the principal display area. Hong Kong's existing graphic health warnings of not less than 50% are already over and above the FCTC requirements. Accordingly, there is nothing in the FCTC that requires increasing the size of graphic health warnings to 85%

7.5 Importantly, the FCTC does not authorise Parties to implement or issue measures that breach national law-making criteria or procedures, which is the case with the graphic health warnings of not less than 85% required under the Proposal. Article 11 of the FCTC expressly states that the implementation of measures shall be: "*in accordance with [a Party's] national laws*". Article 5(2) of the FCTC, which sets out the general obligations of parties, similarly acknowledges that the implementation of tobacco control measures must be in "*accordance with [Parties'] capabilities*". As explained in section 4 of the Response, the Proposal is inconsistent with the Basic Law and beyond the scope of the power and authority under Section 18(2) of the Smoking (Public Health) Ordinance (Cap 371), and therefore is contrary to the FCTC.

7.6 Article 2.1 of the FCTC also confirms Parties' obligations to comply with international laws in respect of the implementation of any measures that exceed a party's obligations under the FCTC. It provides that: "*nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are <u>in</u>*

accordance with international law" (emphasis added). Thus, the graphic health warnings of not less than 85% required under the Proposal, which go far beyond the requirement in the FCTC to impose a textual warnings covering 30%, must be "in accordance with international law." However, as explained above, the 85% graphic health warnings required under the Proposal violate Hong Kong's international obligations under the TRIPS Agreement, the Paris Convention, and the TBT Agreement.

7.7 The Legislative Council Paper incorrectly relies on the FCTC to justify the increase in graphic health warnings from 50% to 85% when in fact the FCTC only obliges Hong Kong to maintain 30% textual warnings and the existing graphic health warnings of not less than 50% are already over and above the FCTC requirement. Accordingly, the Proposal is not necessary to meet the requirements of FCTC.

7.8 The Proposal also directly contravenes the WHO Guidelines in proposing to retain the requirement to print tar and nicotine yields on tobacco product packaging. The WHO Guidelines state that: "*Parties should prohibit the display of figures for emission yields (such as tar, nicotine and carbon monoxide) on packaging and labelling.*" [25]

[25] *Who Framework Convention on Tobacco Control* Guidelines for implementation, 2013 edition, page 63 http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf?ua=1

8. A PROPER IMPACT ASSESSMENT IS REQUIRED BEFORE PROCEEDING WITH THE PROPOSAL

8.1 An RIA that undertakes a thorough analysis of the Proposal, including whether it is necessary and whether there are less burdensome means of achieving the regulatory objective, ought to be undertaken to enable the Legislative Council to properly scrutinise the Proposal under the negative vetting procedure. As noted above, the failure to undertake any impact analysis of the Proposal goes against the recommendation made in the Regulatory Impact Analysis undertaken in 2001 in respect of proposed amendments to the Existing Smoking Legislation. The 2001 RIA recommended introducing an enabling provision to allow for health warnings to contain pictorial and graphic content, but stated: "*any future requirements for pictorial and graphic contents take into account the likely financial and economic costs of implementation and that these be weighed against the likely health and economic benefits likely to arise."*[26] The Legislative Council Paper doesn't address these issues at all.

8.2 An RIA is also the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the Organization for Economic Co-operation and Development and the Asia-Pacific Economic Cooperation of which Hong Kong is a member. The APEC paper *Supporting the TBT Agreement with Good Regulatory Practices*[27] states: "*it is impossible to regulate well if the consequences of government action are not understood in advance. Understanding consequences of various options for action more clearly is the main purpose of RIA*".

8.3 The failure to undertake a proper evidence based RIA violates these principles and also means that the measure cannot be shown to comply with the obligations under WTO TBT Agreement or the TRIPS Agreement which mandate that requirements do not constitute an "unnecessary obstacle to trade" or a violation of internationally protected intellectual property rights.[28]

---

[26] Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, page 107 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

[27] *Supporting the TBT Agreement with Good Regulatory Practices,* APEC, March 2012 http://publications.apec.org/publication-detail.php?pub_id=1266

[28] WTO Members that failed to undertake such impact assessments have been heavily criticized for failing to conduct the necessary impact assessment, including an examination of less trade-restrictive alternatives. For example, the EU questioned Brazil over whether it had properly conducted an impact assessment of its regulation to ban certain ingredients in tobacco products (G/TBT/M/54 (20 September 2011), p. 54).

8.4 The first step in the analysis must be clearly to identify the inadequacies in the existing state of affairs which need to be rectified.[29] A problem must be identified which specifically requires larger graphic health warnings as opposed to other tobacco control measures. It is manifestly irrational to proceed with larger graphic health warnings when it is not necessary to address a legitimate objective.

8.5 The Legislative Council Paper does not identify a problem with the existing 50% graphic health warnings or provide any evidence to demonstrate that increasing the size of graphic health warnings from the current size of 50% to 85% is necessary. As outlined in section 5 of this Response, increasing the size of graphic health warnings from the current size of 50% to 85% is neither necessary, including because there is already universal awareness of the risks of smoking, nor adequate as a public health measure. The proposed size of 85% graphic health warnings in the Legislative Council Paper is entirely arbitrary and has no evidential basis at all.

8.6 The Legislative Council Paper also fails to consider whether the Proposal is lawful. As explained in section 4 above, the Proposal is inconsistent with, inter alia, Articles 6 and 105 of the Basic Law. The Proposal is therefore illegal.

8.7 BAT (HK) also submits the expert report of Mr Stephen Gibson (SLG Economics Limited), formerly Chief Economist and Director of Economic Policy at Postcomm in the United Kingdom, who specialises in competition and regulatory economics (the "**Gibson Report**"). The Gibson Report is submitted with this Response (see Appendix 2). The Gibson Report assesses the proposals for larger graphic health warnings contained in the Legislative Council Paper and considers whether they are in line with better regulatory principles, and to what extent they are necessary, appropriate or proportionate. As explained by Mr Gibson, the Legislative Council Paper does not include the necessary evidence or analysis to support the implementation of the proposed policy; it does not provide proportionate evidence-based policy recommendations. It has not shown that the proposed increase in GHWs from 50% to 85% is necessary, appropriate or proportionate. Mr Gibson notes that the Legislative Council Paper:

---

[29] This is reflected in the APEC Guidelines for the preparation, adoption and review of technical regulations, which state: "*The first step in the development process should be to clearly identify the problem that needs to be addressed*" and "*accurate problem definition reduces the risk of choosing inappropriate options for government action or ignoring more effective solutions, and reduces the likelihood of over regulation.*" *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC, available at http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

- Fails to include a public consultation;
- Fails to include a Regulatory Impact Assessment;
- Fails to follow the recommendations of the 2001 Tobacco Regulation RIA;
- Fails to follow the principles of better regulation;
- Fails to recognise that the current tobacco controls are already more than is required under the WHO Framework Convention on Tobacco Control;
- Fails to analyse the baseline or identify any problems with the current 50% GHWs that might need further regulation;
- Fails to properly specify the objectives of the proposals;
- Fails to provide any evidence for the proposals;
- Sets out proposals that are arbitrary and gold-plated;
- Sets out proposals that directly contravene the FCTC Guidelines;
- Fails to consider alternative policies or identify the policy with the greatest net benefits;
- Fails to estimate the costs of the proposals; and
- Fails to estimate the benefits of the proposals.

8.8 Taking the factors outlined above into account, Mr Gibson concludes that: "**it would be manifestly inappropriate to rely on the [Legislative Council] Paper to proceed with larger graphic health warnings.**"[30]

8.9 Accordingly, a proper impact assessment should be carried out before proceeding further with the Proposal.

30 Gibson Report at p14, emphasis in original.

9. CONCLUSION

For the reasons set out above, BAT (HK) believes that the Proposal should be rejected. In summary, those reasons include:

9.1 The enactment of effective and evidence-based regulation which meets public health objectives and respects Hong Kong's legal framework and international obligations is central to its reputation as the top international trade and investment hub.

9.2 However, the Proposal completely disregards the current levels of awareness of the risks of smoking in Hong Kong, which renders it totally unjustified. The Proposal is proceeding without any analysis or evidence demonstrating that: (a) that the current size of graphic health warnings are inadequate or insufficient to achieve their intended purpose, namely to inform the public of the health risks involved by smoking; or (b) that the further increase in the size of the graphic health warnings from 50% to 85% will more effectively achieve that purpose than the current size of 50%.

9.3 The Proposal is unlawful. The Proposal would deny all meaningful use or all economically viable use of trademarks and thereby deprive BAT (HK) of its extremely valuable intellectual property rights; namely, its trademark rights together with the goodwill arising in their brands, as protected under the Basic Law in Hong Kong.

9.4 The Proposal is also manifestly disproportionate. The Proposal is fundamentally flawed in that it is not necessary and would not achieve its stated objectives. The Government has failed to undertake any analysis or provide any evidence demonstrating that further increasing the size of the health warnings from 50% to 85% is necessary and appropriate to materially contribute to the protection of health, and proportionate. Evidence also demonstrates that increasing the size of the warnings would not be more effective in increasing awareness (which is already effectively universal) or reducing smoking. The Proposal would also distort competition, drive down prices leading to increased consumption, and incentivise illicit trade which would undermine the public health objective. The Proposal would cause substantial losses to BAT (HK) and other manufacturers, and there are a number of more effective alternatives.

9.5 In addition, the Proposal is neither required nor authorised by the FCTC and it would violate Hong Kong's international obligations under the TRIPS Agreement, Paris Convention, TBT Agreement and Bilateral Investment Treaties.

9.6 The Government has not undertaken a regulatory impact assessment in order to properly consider the impacts, costs and benefits of the Proposal. It must be considered that if the Government had undertaken a proper evidence-based analysis it would have reached a

similar outcome to the U.S. FDA, namely that increasing the size of the existing warnings would not be effective in reducing smoking prevalence.

IN THE COURT OF APPEAL OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

Ceylon Tobacco Company PLC
No. 178, Srimath Ramanathan
Mawatha, Colombo 15.

PETITIONER

Vs.

C.A 336/2012 (Writ)

1. Hon. Maithripala Sirisena
Minister of Health
Ministry of Health.
"Suwasiripaya",
Colombo 10.

2. Dr. Nihal Jayathilaka
Secretary,
Ministry of Health.
"Suwasiripaya",
Colombo 10.

3. National Authority on Tobacco and Alcohol
"Suwasiripaya",
Colombo 10.

RESPONDENTS

BEFORE: Anil Gooneratne J. &
Malinie Gunaratne J.

COUNSEL: Faiz Musthapha P.C., with Ali Shabry P.C. and C.Wijesinghe, Faizer Marker, M. Bandara M. Careem, R. Cooray and Mohamed Imthiyas instructed by Sudath Perera Associates for the Petitioner

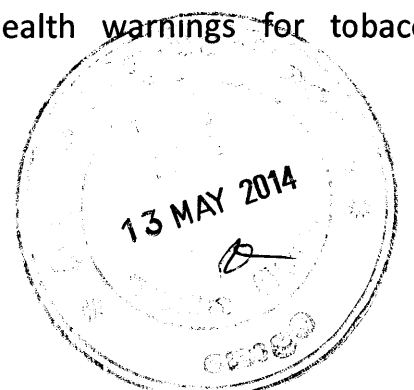
Janak de Silva D.S.G., with Suranga Wimalasena S.C. for the Respondents

ARGUED ON: 03.02.2014 & 07.02.2014

DECIDED ON: 12.05.2014

GOONERANTNE J.

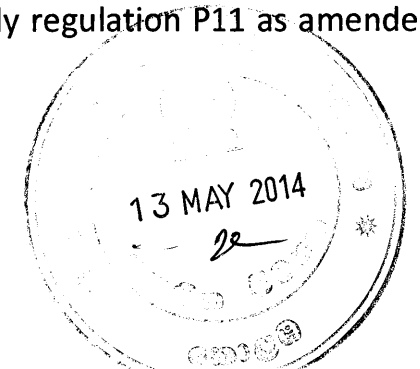
The Petitioner in this Writ Application is the Ceylon Tobacco Company PLC. A Writ of Certiorari is sought to quash the tobacco products (labeling and packaging) Regulation No. 1 of 2012, published in Gazette Notification marked P11 of 8.8.2012. A mandate in the nature of Writ of prohibition is also sought against the three Respondents, proceeding to make regulation prescribing health warnings for tobacco products containing



pictorials, graphics, images or any other non-textual content under Section 30 read with Section 34 of the National Authority on Tobacco and Alcohol Act No. 27 of 2006. Petitioner in terms of sub para (d) of the prayer to the petition has sought an interim order staying the operation of the above regulation referred to in Gazette marked P11. The learned President's Counsel for the Petitioner on 20.2.2013 supported this application for the issuance of interim relief. However the then Hon. President of this court by his order dated 22.2.2013 refused to grant and issue an interim order as prayed for in the prayer to the petition.

Petitioner Company sought Special Leave to Appeal from the order of the Court of Appeal dated 22.2.2013. However on a perusal of the record, I find that the state, at an early stage of the above leave to appeal application gave an undertaking to the Supreme Court that the impugned regulation will not be operationalised, and as such undertaking had been extended from time to time, and on 1.4.2013 Supreme Court ordered the status quo to be maintained. Such an order pronounced by the Supreme Court to maintain the status quo also had been extended periodically.

The Petitioner in this application is challenging the vires of regulation P11 as amended. More particularly regulation P11 as amended are ultra vires



of the powers of the Minister, of the National Authority on tobacco and Alcohol Act No. 27 of 2006 (hereinafter called NATA Act) and that Section 34(1) does not provide for pictorial health warnings. The Respondents with objections have filed Gazette Notification marked R3 and R15. Perusal of R3 and R15 it appears that regulation (P11) shall come into operation on 1st March 2013 and regulation No. 1 of 2012 (P11) is further amended according to R15 and regulation Nos. 5, 6 & 7 amended and a new regulation 11, added to regulation (P11). As such the Petitioner Company submits that the impugned regulations seek to:

(i) Introduce mandatory pictorial health warnings to be displayed on packets of cigarettes covering 80% of the total area of a pack.

(ii) Impose a descriptor ban (use of descriptions 'light' 'low' and 'mild'.

(iii) Print date of production on every cigarette stick.

(iv) Print of information on the relevant constituents and emissions of tobacco products, including formaldehyde and other toxic contents if any

(v) Print health warnings and other information in a font size of not less than 10 and in all 3 languages.

The learned President's Counsel for Petitioner raised numerous points and objections to favour the case of the Petitioner. The main argument advanced by the learned President's Counsel for the Petitioner and referred to inter alia, the following matters to demonstrate that the impugned subordinate legislation should be rejected since it is:

(a) Unreasonable and disproportionate to the main statute.

(b) Impossibility of compliance (time factor) and the insertion of multiple labels and the failure to prescribe dimensions of health warnings. The submission of impossibility of compliance was an argument advanced when supporting for interim relief. Petitioner did not hesitate to put forward this submissions also when the substantive matter was argued.

(c) To require the printing of constituents and emissions. Regulations is ambiguous resulting in varying interpretations

(d) A requirement to print the date of production and date of expiry on cigarette sticks. It is practically impossible to comply. Further Section 34(1) requires only a single label.

(e) To prescribe pictorial health warnings to cover 80% of the front and back surface areas, has by subsidiary legislation illegally subverted the statutory right of Petitioner to effectively use its intellectual property rights, recognized under the Intellectual Property Act.

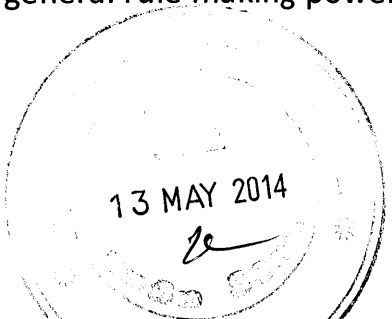
(f) Petitioner not heard before publication of impugned regulations. Breach of natural justice.

(g) Exclusion of the Beedi, cigars and white illicit whites from the application of the impugned regulations.

It is the position of the Petitioner that (a) to (F) above would make Regulation Nos. 5, 6, 7 and 8 and the added Regulation No. 11, ultra vires the provision of the NATA Act.

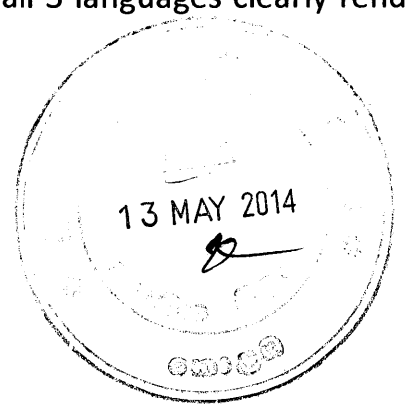
Learned President's Counsel was also critical of the Respondents stance of reading Section 34 of the NATA Act (an Act itself is to give effect to who Framework Convention on Tobacco Control (FCTC)) in harmony with FCTC obligations. FCTC does not require 80% pictorial warnings (Article 11 of FCTC) FCTC require only 50% or more. Further FCTC do not use pictorial, do not impose a binding obligation to use pictures.

Another argument advanced, was that the NATA Act does not empower the Minister to make regulation generally for carrying out the intention/purpose/principles in enacting the NATA Act. The Minister is only empowered to make regulations required to be prescribed or in which regulations are authorized or required by the Act. Minister cannot make regulations generally of any matter for carrying out the intention/purpose/principles in enacting the NATA Act. Attention of this court was drawn to several other statutes where a Minister is generally permitted, a general rule making power on all matters by the



use of legislative language e.g. Condominium Property Act, Employees Provident Fund Act, Employees Trust Fund Act, Inland Revenue Act, etc. Petitioner argues that the Minister does not have the power to grant a blanket rule making power.

President's counsel for Petitioner submitted that regulation Nos. 2 & 3are not authorized by Section 34 of the NATA Act. As such the regulation is ultra vires. The Consumer Authority Act No. 9 of 2003, already regulates on conduct that is misleading or deceptive. He referred to Section 30 of the Act No. 9 of 2003. As such Minister has no power to make regulations 2 & 3. It was also submitted that under Section 34 the required label shall contain a statement of the tar and nicotine content of the product and a health warning. The printing of information relating to other constituent and emissions is not required or prescribed. As such requirement of printing information relating to constituent and emissions in regulation 6 is ultra vires. the phrase 'including its nicotine and tar cannot be read as only tar and nicotine in background of having 5,600 identified chemicals in cigarette smoke. Section 34 already contains provisions on same. As such there is no need for delegated regulations. NATA Act does not require the date of manufacture and or the expiry date to be printed thereon and regulation 7 is also ultra vires . Further printing in a font size of 10 in all 3 languages clearly renders the regulations practically impossible to perform.



The learned Deputy Solicitor General on behalf of the Respondents submitted in his oral submissions, at the very outset to the evidence of harmful effects of tobacco smoking and invited court to, document R8, (pg. v) mainly to the material contained in the foreword. He also referred to the preamble of the WHO Framework Convention on Tobacco Control more particularly to 3rd para which state about the serious concern about increase in the worldwide consumption and production of cigarettes. Article 8 (pg. 8 of R8) refer to scientific evidence has unequivocally established that tobacco smoke cause death, decease and disability. He also invited us to R6, the S.C. Determination 13-22/05 on National authority on Tobacco & alcohol Bill especially Clause 34 which have the objective of enhancing health and the quality of life. The objectives cannot be reconciled with the harmful effects of tobacco and alcohol products and the objectives of the bill are not inconsistent with the Constitution. Learned Deputy Solicitor General referred to document R11 (pg. 5) to emphasis on the death rate as a consequence of smoking cigarettes. (inclusive of passive smoking) R12 on regional situation of tobacco control in the South East Asia Region and the figures of deaths and decease.

Learned Deputy Solicitor General in his address to court referred to packaging and labeling of tobacco products, more particularly to Article 11(1) b

11(1) (iv) of R8 to emphasis on international standards that Sri Lanka, is bound to adopt and follow in its national legislation, since our country was a signatory to the Who Framework Convention on Tobacco Control. Reference was also made to R4 cigarette package health warnings (pg. 7) i.e effectiveness of warnings, increase with larger size, and use of pictures. R10 (para 14) refer to use of pictorials. Para 15 of R10 gives details of evidence when compared with text only health warnings and messages those with pictures.

- Are more likely to be noticed;
- Are rated more effective by tobacco users;
- Are more likely to remain salient over time;
- Better communicate the health risks of tobacco use;
- Provoke more thought about the health risks of tobacco use and about cassation
- Increase motivation and intention to quit; and
- Are associated with more attempts to quit.

By a gradual process the learned Deputy Solicitor General drew the attention of this court to the preamble of the National Authority on Tobacco and Alcohol Act No. 27 of 2006. It was the position of the Respondents that the above act of Parliament envisage a variety of matters to protect public health. He drew the attention of this court to letter R9 by the Chairman of the National Authority on Tobacco and Alcohol to the Minister of Health. We have noted the contents of

R9, along with Section 15 (J) of the Act. section 15(J) reads thus (clearly explains adherence to International Treaties).

> To recommend adherence to such International Treaties and Conventions dealing with Tobacco and Alcohol as the Government may ratify and accede to;

It was the contention of the learned Deputy Solicitor General that reading Section 30 and 34 of the above Act, should not be construed in the absence of International Treaties and Conventions which had been ratified and signed by Sri Lanka. Section 30 is the enabling section to frame regulations and Section 34 impose a prohibition on sale of tobacco products without health warnings etc. We were also invited on behalf of the Respondents to consider a purposive construction and referred to several rules of interpretation/constructions relevant to the National Authority on Tobacco and Alcohol Act No. 27 of 2006, especially as regards Section 30 and 34 of the Act.

The Petitioner Company is one of the oldest business establishments engaged in the manufacture, export and distribution of cigarettes in our country. There is no total prohibition placed on the tobacco industry, but it is and has to be subject to certain restrictions and controls imposed by statute. It is so all over the world. The Respondents in this application as well as the Government of the day and any successive governments are duty bound to protect the civil society and its

citizens from all possible health hazards, caused due to cigarette smoking, and tobacco products. Scientific evidence prove and establish that smoking of cigarettes and use of tobacco cause death, illness and disability. Even the Petitioner does not dispute this aspect which cause all bad health effects to the people and its consumers.

The subject matter of this Writ Application cannot be considered in isolation of data and material gathered from other jurisdictions. Though the challenge before court is more or less focused on subordinate legislation, all necessary and relevant background facts need to be ascertained not only from within our country, but from also a global point of view since pictorial warnings on cigarette packs are accepted displayed and adopted all over the world, both in developed and developing countries as well as in 3rd world countries. The prime necessity all over the world being to protect all from health hazard, death, decease and disabilities. As such I do consider it essential to examine initially whatever available research, studies around the world and the attitudes of the authorities concerned with reference to case law in favour and against tobacco packaging warning messages and pictorial/graphic warnings, before giving my mind to the vires of the regulations (P11) framed under NATA Act.

13 MAY 2014

I would include the following in this judgment, an excerpt of a report from the University of Waterloo, Canada : (though it is somewhat prolex)

Health warnings on tobacco packages:
Summary of evidence and legal challenges

Prepared by:

David Hammond PhD
Department of Health Studies,
University of Waterloo Canada
200 University Ave West
Waterloo, ON
CANADA N2L, 3G1
January 2008

www.global.tobaccofreekinds.org
Website visited on 2nd May 2014

To date, more than 17 countries have passed legislation requiring large pictorial health warnings on cigarette package: Dozens of other jurisdictions are currently preparing similar legislation in response to the international labeling regulations under Article 11 of the World Health Organization Framework Convention on Tobacco Control. The evidence on effective packaging and labeling practices has grown rapidly over the past decade to keep pace with theses regulatory developments. A consistent pattern of findings has emerged from this body of research:

- Package health warnings are among the most prominent and cost-effective health communications available
- Health warnings have high awareness and visibility among non-smokers and youth.
- Obscure text warnings have little impact

- Large, pictorial warnings can increase health knowledge, motivation to quit, and cessation behavior.
- Pictorial warnings are especially important for reaching low-literacy smokers and children
- Messages that depict health risks in a vivid and emotionally arousing manner are most effective.
- "Graphic" information should be accompanied by supportive cessation information.
- There are no adverse effects in response to pictorial warnings.
- Large pictorial warnings are credible and have high levels of public support.

This report also includes a review of legal challenges to health warning regulations in Canada and the European Union. In both jurisdictions, national courts have ruled against tobacco manufacturers and have upheld comprehensive labeling regulations including requirements for large pictorial health warnings on packages.

Background: Tobacco Packaging

Packaging is an important component in the overall marketing strategy of consumer goods. Packaging helps to establish brand identity in competitive markets and serves as an effective form of promotion both at the point of purchase and while the product is being used. Packaging is particularly important for consumer products such as cigarettes, which have a high degree of social visibility. Unlike many other consumer products, Cigarette packages are displayed each time the product is used and are often left in public view between uses. Cigarette packages also serve as an important link to other forms of tobacco advertising. Package designs help to reinforce brand imagery that is communicated through other media, and play a central role in point of purchase marketing, which now accounts for a majority of the industry's promotional spending in Canada and the US.

Health warnings: Evidence

This section provides a review of the scientific literature and research on health warning labels. The section begins with a review of general evidence on health communications, followed by evidence specifically related to tobacco warning labels on packages.

2.1 The use of pictorial information in health communications

A wide variety of research has clearly demonstrated the effectiveness of using pictures and imagery in health communications.

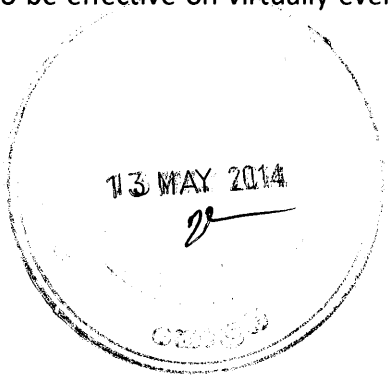
- Warnings with pictures are significantly more likely to draw attention and result in greater information processing.
- Pictures improve memory for the accompanying text and encourage individuals to imagine health consequences.
- Health warnings with pictures are also more likely to be accessed when on individual is making relevant judgments and decisions.

Experimental Research

Experimental research on cigarette warnings has also found that picture-based warnings are more likely to be rated as effective versus text-only warnings both as a deterrent for new smokers and a means to increase cessation among current smokers.

Populations-surveys and impact evaluation

A series of population-based surveys have compared the effectiveness between text and pictorial warnings. To date, surveys have been conducted in Brazil Thailand, Singapore, Uruguay, Mexico, Canada, New Zealand, Australia, the United Kingdom and the United States. These findings are consistent with both the experimental and government commissioned research: graphic warnings are more likely to be effective on virtually every



outcome that has been evaluated. The following provides a brief summary of the evidence key area.

Pictorial warnings are more likely to be noticed and read than text-only warnings including by non-smokers

- Health warnings on cigarette packages are among the most prominent sources of health information: more smokers report getting information about the risks of smoking from packages than any other source except television.
- Findings from Thailand and elsewhere, indicate that considerable proportions of non-smokers also report awareness and knowledge of package health warnings.
- Picture help to minimize the "wear-out' of health warnings over time.

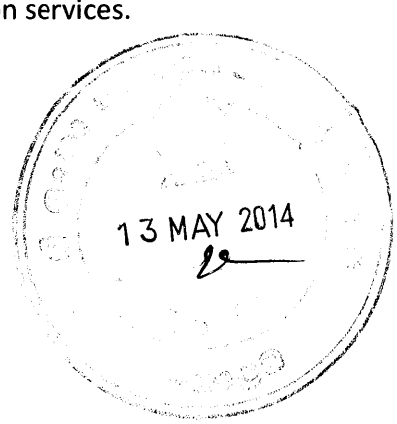
Picture warnings increase awareness and recall of the health effects from tobacco use

- The impact of warnings on health knowledge depends upon the prominence of warnings: obscure text warnings have little effect, large pictures warnings have the greatest effect.
- Pictorial warnings increase how often smokers think about the health effects.

Health warnings promote cessation behavior

- Significant proportions of adult and youth smokers report that large comprehensive warnings have reduced their consumption levels increased their motivation to quit and increase the likelihood of remaining abstinent following a quit attempt.

Prominent health warnings increase in the use of cessation services.



Research conducted in Brazil, the UK, the Netherlands, and Australia has examined changes in the usage of national telephone "helplines" after contract information was in package health warnings. Each of these studies reports significant increases in call volumes. For example calls to the tollfree smoking cessation helpline in the Netherlands increased more than 3.5 times after the number was printed on the back of one of 14 package warnings. Therefore while it is not possible to precisely quantify the impact of health warnings on smoking prevalence or behavior, all of the evidence conducted to date suggests that health warnings can promote cessation behavior and that larger pictorial warnings are most effective in doing so.

Picture warnings appear to be especially effective among youth

- More than 90% of Canadian youth agree that picture warnings on Canadian packages have provided them with important information about the health effects of smoking cigarette, are accurate, and make smiling seem less attractive. Other national surveys of Canadian youth suggest similar levels of support and self reported impact.
- A recent study with Australian school children found that students were more likely to read , attend to think about, and talk about health warnings after the pictorial warnings were implemented in 2006. Experimental and established smokers were more likely to think about quitting and to forgo a cigarette, while intention to smoke was lower among those students who had talked about the warning labels and had forgone cigarettes.

Pictorial health warnings are essential in countries with low literacy and multiple languages

- Text-only health warnings have little or no effect among those who cannot read. This includes illiterate individuals, individuals who may be literature but only in a language other than that used for text warnings. As well as young children.

- Text-only health warnings, therefore, can increase health disparities across socio-economic groups
- The most effective way to reach low-literacy smokers is to include pictures., which can be universally understood,, including by young children.
- Preliminary evidence suggests that countries with pictorial warnings demonstrate fewer disparities in health knowledge across educational levels.

~~Prominent health warnings have the potential to undermine~~ brand appeal ~~and the impact of~~ package displays at retail outlets

- A Quebec Supreme Court Judge in Canada remarked upon this phenomenon in a ruling regarding the industry's challenge to pictorial warnings in Canada:
  "Warnings are effective and undermine tobacco companies' efforts to use cigarette packages as badges associated with a life style.

In the United States in the year 2009 the congress passed the Family Smoking and Tobacco Control Act (Tobacco Control Act) 21 USCA. In that Act among many powers delegated to the Food and Drug Administration (FDA), the congress mandated the FDA to adopt a Rule requiring new graphic warnings on cigarette packages and advertisements. In June 2011 the FDA Rule required that coloured graphic warnings cover fifty percent (50%) of the front and back of each cigarette package sold in the U.S. This regulation is consistent with required warning label on cigarette packages in a number of other countries including

Canada, Australia, Brazil and Thailand. In consequence of publishing these regulations by the FDA, tobacco companies filed the following cases where courts expressed different views

On August 31, 2009, five tobacco manufacturers and one retailer filed suit in U.S District Court for the Western District of Kentucky to challenge several provisions of the Tobacco Control Act. This case, Discount Tobacco City & Lottery v. Food and Drug Administration (Discount Tobacco) upheld the graphic warning requirements. This decision was upheld on appeal to the U.S. Court of Appeals for the Sixth Circuit. On August 16,2011, five tobacco manufacturers filed suit in the U.S. District Court for the District of Columbia to challenge the FDA's final regulation governing graphic warning labels for cigarettes. In this case, R.J. Reynolds Tobacco Co. v. Food and Drug Administration (RJ. Reynolds), the court found that the graphic warning rule unconstitutionally limited the tobacco companies' right to freedom of speech. On appeal, the U.S. Court of Appeals for the D.C. Circuit upheld the district court's finding that the graphic warning requirement was unconstitutional. The federal government has decided not to appeal this decision to the U.S. Supreme Court.

Overview of the above two cases

Discount Tobacco

In Discount Tobacco, the Sixth Circuit upheld the provisions of the Tobacco Control Act that authorized and directed the FDA to issue a rule requiring large, graphic warnings to be placed on cigarette packages and advertisements. The Act requires color pictorial images showing the health effects of smoking to appear on the top half of all cigarette packs, and twenty percent (20%) of the upper portion of cigarette advertisements, along with new textual warnings. The companies argued that these provisions were overly restrictive and infringed upon their free speech rights under the First Amendment.

In January 2010, Judge Joseph H. McKinley, Jr. of the U.S. District Court for the Western District of Kentucky upheld the graphic warning label requirements, along with other key provisions of the Tobacco Control Act. Judge McKinley found that the "content and format" of the warning labels were justified in light of evidence that consumers do not pay attention to current warnings, and ruled that the warnings were not too burdensome because the companies retain half of the space on the cigarette packs and eighty percent (80%) of cigarette advertisements for their own speech. The tobacco companies appealed this ruling to the U.S. Court of Appeals for the Sixth Circuit. In March 2012, a three-judge panel upheld Judge McKinley's ruling on the graphic warning label requirements. The appeals court ruled that the graphic warnings do not "impose any restrictions on the (tobacco companies') dissemination of speech, nor do they touch upon plaintiff's core speech." The court also held that the textual warnings mandated by the Tobacco Control Act were "reasonably tailored to overcoming the informational deficit regarding tobacco.

R.J Reynolds

In contrast, the U.S. Court of Appeals for the D.C. Circuit found in R.J. Reynolds that the graphic warning rule created by the FDA pursuant to the Tobacco Control Act did violate the tobacco companies' First Amendment rights.

In June 2011, the FDA issued its final rule mandating graphic warning labels on cigarette packages and advertisements. Nine graphic warning images were selected by the FDA, and the tobacco companies were required to display these warnings on a rotating basis. Among these images were a man smoking through a hole in his throat, and ac cadaver with chest staples. Two months after the rule was issued, five major tobacco companies filed suit, challenging the FDA's graphic warning label rule arguing that it forced them to convey the government's message about smoking and advocate against their own product.

In February 2012, U.S District Judge Richard J. Leon held that the FDA's graphic warning label rule violated the tobacco companies' First Amendment rights. The court took issue with the size of the mandated warning labels and concluded that the government has other means of discouraging smoking at its disposal. The FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. In a split ruling, the appeals court found that the rule violated the First Amendment. Two members of the panel ruled that the warning labels exceeded the proper scope of government authority to "force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest." The majority also ruled that the FDA failed to prove that the labels would "directly cause" a decrease in smoking rates in the United States.

(The above material obtained – Tobacco Control Legal Consortium 875 Summit Avenue, Saint Paul, MN 55105.3076 www.publichealthlawcenter.org 651.290.7506

Website visited on 2nd May 2014)

Apart from the above material included in this judgment which demonstrate contrary decisions of the US courts, the research undertaken by those authorities and the initiatives taken by very many countries to protect health of all persons by taking a step to include pictorial, health warnings/graphics in cigarette packets, I am unable to gather from the material made available, whether in our local scene the National Authority on Tobacco and Alcohol, on its own took the trouble to conduct research programmes prior to enacting Act No. 27 of 2006? As a passing comment I would also like to observe, as to whether the authorities concerned in the same way as "Tobacco' thought it fit to apply the same standards for 'Alcohol ' and endeavored to prescribe

regulations for 'Alcohol' also since both tobacco and alcohol are injurious to health and the resulting consequences are very much the same?

The relevant sections of the statute in question are Sections 30 & 34. Section 30 reads Thus:

(1) The Minister may make regulations in respect of any matter required by this Act to be prescribed or in respect of which regulations are authorized or required by this Act to be made.

(2) without prejudice to the generality of the powers conferred by subsection (1), the Minister may make regulations –

(a) identifying the tobacco products that are harmful or injurious to human health;

(b) specifying the types or categories of tobacco products which do not generate smoke.

(3) Every regulation made by the Minister shall be published in the Gazette, and shall come into operation on the date of such publication or on such later date as may be specified in such regulation.

(4) Every regulation made by the Minister shall after thirty days of its publication in the Gazette, be brought before Parliament for approval. Any regulation which is not so approved shall be deemed to be rescinded as from the date of such disapproval but without prejudice to anything previously done thereunder.

(5) Notification of the date on which any regulation made by the Minister is deemed to be rescinded shall be published in the Gazette

Section 34 reads thus:

(1) A manufacturer of a tobacco product shall cause to be displayed, conspicuously and in easily legible print, on every packet containing tobacco products manufactured by such manufacturer, a label of such dimensions as may be prescribed containing a statement of the tar and nicotine content in each tobacco product in such packet and such health warnings as may be prescribed. Different dimensions may be prescribed in respect of packets of different sizes.

(2) A person shall not sell or offer for sale, a packet containing tobacco products unless there is displayed on such packet, a label of the prescribed dimensions containing a statement of the tar and nicotine content in each tobacco product in such packet and the prescribed health warning.

(3) Any person who contravenes the provisions of subsection (1) or subsection (2) shall be guilty of an offence under this Act, and shall on conviction after summary trial before a Magistrate be liable to a fine not exceeding two thousand rupees or to imprisonment for a period not exceeding one year or to both such fine and imprisonment.

I observe that the Minister could in terms of the enabling Section 30, of the NATA Act make regulations on matters required by the Act to be prescribed. That would be the 1st limb that surface from Section 30(1). If one looks at Section 34(1) and 34(2) the matters and material that need to be prescribed could be understood and identified. Then the other limb of Section 30(1), contemplate of making regulations by the Minister, where the Act authorize or require to be done under the Act. Even Section 33(1) connects the

word 'prescribed'. Then subsection (2) of Section 30 seems to bestore on the Minister something more and an additional power from what is given in Section 30(1). As such I do agree with the learned Deputy Solicitor General that if by a narrow interpretation pictorial health warnings are ousted or ruled out, by resorting to Section 30(2) (a) the Minister may make regulations identifying the tobacco products that are harmful or injurious and thereby inclusion of pictorial health warnings could be permitted by regulations. Further I observe that Sections 30(1) and 30(2) are somewhat inter connected by the use of the words "without prejudice to the generality of the powers conferred by sub Section (1)". As such I could safely conclude based on the above interpretation that the regulation in question (P11 as amended by R3 & R15) could be presented by the Minister, subject to views expressed by this court. In the instant case, the regulations have been presented by the Minister in terms of Section 30 read with Section 34 of the NATA Act.

The basic and general rule of interpretation is that it must be construed in the ordinary and natural meaning of the word and sentence. However this rule is subject to well accepted exceptions. Having this in mind, when I peruse Section 34 of the above Act in its entirety it appears to me that the

choice is between two interpretations. Section 34(1) envisage a prohibition on sale of tobacco products without health warnings and the tar and nicotine content. There is no specific reference to 'pictorial' health warnings in Section 34 of the Act. Petitioner puts more emphasis on the words 'easily legible print. Learned President's Counsel also relies on the Sinhala version and Section 44 of the Act. It was strongly argued that it is nothing but written letters or words and the health warning could be described accordingly in letters or words. On a plain reading of the Section it appears to be so. However I cannot in the instant case give a narrow meaning and it is the duty of court to give an interpretation in keeping with the intention of the legislature.

A 'health warning' in the context of the statue and applicable to the subject matter of the Writ Application before us, cannot be given a narrow restricted meaning. The term health warning cannot be narrowly interpreted since a warning in today's context and society could be expressed by words, texts, pictures or even by use of symbols. The use of symbols in health communication could attract attention of the consumers. E.g. uses of skull and crossbones as the universal symbol for toxic substances. As such a health warning could attract a variety of meanings inclusive of pictorial health

warnings. It would never have been the intention of Parliament to exclude pictorial health warning since such a pictorial warning need to reach all category of persons. i.e the poor, rich, middle class, literate and illiterate, disabled and as well as children. Petitioner attempts to interpret the above terms differently be referring to various documentation and material, but I am compelled to reject and dismiss such views, since the intention of Parliament gathered from all the material placed before court by the Respondents and the hansard favour the view that health warning referred to in Section 34 could be very comfortably extended to pictorial health warnings.

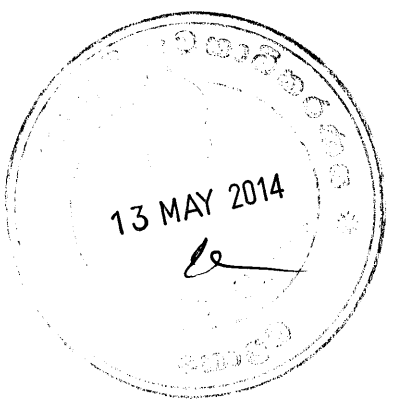
In the Sinhala version of Section 34 of the words clearly readable. (**පහසුවෙන් කියවිය හැකි අකුරින්**) would also have to be construed and applied to both the health warnings and statement of nicotine and tar contents. I do agree by perusing extracts from the Malalasekera English-Sinhala Dictionary (5th Ed 2007) produced as A11 & A12 and the Gunasena Maha Sinhala Shabdakoshaya (2008) produced as A13 the word 'letter' to include certain, forms of pictures. Even the Sinhala version should be read in the context of words which state ..... **නිකොටින් හා තාර ප්‍රමාණය දැක්වෙන හා සෞඛ්‍යයට හානිකර බවට අනතුරු ඇඟවීමක් ඇතුලත් නියම කරනු ලැබිය හැකි ආකාරයෙන් වූ හා** ..... It is understood as a health warning in the prescribed manner. As such

13 MAY 2014

the same interpretation stated above need to be adopted and applied since the primary purpose of statutes is to purpose justice and avoid absurd unacceptable interpretations. Statutory language is not read in isolation, but in its context. This court has been invited to peruse the following extract from Bindra Interpretation of Statutes – 10th Ed pg. 275-6

"It is a well known principle of interpretation of statutes that a construction should not be put upon a statutory provision which would lead to manifest absurdity or futility, palpable injustice, or absurd inconvenience or anomaly. To avoid absurdity or incongruity grammatical and ordinary sense of the words can, in certain circumstances, be avoided. There is no obligation on a court of law to construe a clause as would lead to a clear absurdity which would not possibly be regarded as contemplated by the legislating authority or agency. Since the basic and underlying purpose of all legislation, at least in theory, is to promote justice, it would seem that the effect of the statute should be of primary concern. If this is so, the effect of a suggested construction is an important consideration and one which the court should never neglect. As a result, the court should strive avoid a construction which would tend to make the statute unjust, oppressive, unreasonable, absurd, mischievous or contrary to public interest. One should avoid construction which would result in absurdity and give a harmonious construction so as to avoid making one provision of the Act conflict with the other."

At this point in this judgment I would prefer to refer to some rules of interpretation of Statutes which fortify my views and which enabled me to express the above observations.



Construction ut res magis valeat quam pereat

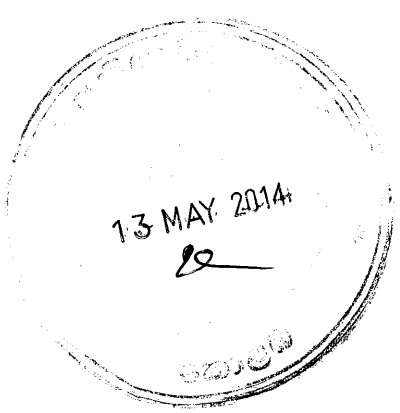
"If the choice is between two interpretations, the narrower of which would fail to achieve the manifest purpose of the legislation, we should avoid a construction which would reduce the legislation to futility and should rather accept the bolder construction based on the view that Parliament would legislate only for the purpose of bringing about an effective result", "Where alternative constructions are equally open, that alternative is to be chosen which will be consistent with the smooth working of the system which the statute purports to be regulating; and that alternative is to be rejected which will introduce uncertainty, friction or confusion into the working of the system."

Maxwell on The Interpretation of Statutes 12th Ed. Pg. 45

CONSTRUCTION MOST AGREEABLE TO JUSTICE AND REASON

At pg. 199.....

In determining either the general object of the legislature, or the meaning of its language in any particular passage, it is obvious that the intention which appears to be most in accord with convenience, reason, justice and legal principles should, in all cases of doubtful significance, be presumed to be the true one. "An intention to produce an unreasonable result is not to be imputed to a statute if there is some other construction available." Where to apply words literally would "defeat the obvious intention of the legislation and produce a wholly unreasonable result" we must "do some violence to the words" and so achieve that obvious intention and produce a rational construction. The question of inconvenience or unreasonableness must be looked at in the light of the state of affairs at the date of the passing of the statute, not in the light of subsequent events.



MODE OF ASCERTAINING MEANING IF OBSCURE

Pgs. 94/95..

CRAIES ON STATUTE LAW

> If (as is often the case) the meaning of an enactment, whether from the phraseology used or otherwise, is obscure, or if the enactment is, as Brett L.J. said in The R. L. Alston, "unfortunately expressed in such language that it leaves it quite as much open, with regard to its form of expression, to the one interpretation as to the other," the question arise, "What is to be done? We must try and get at the meaning of what was intended by considering the consequences of either construction." And if it appears that one of these constructions will do injustice, and the other will avoid that injustice, "it is the bounden duty of the court to adopt the second, and not to adopt the first, of those constructions." However "difficult, not to say impossible," it may be to put a perfectly logical construction upon a statute, a court of justice "is bound to construe, it, and, as far as it can, to make it available for carrying out the objects of the legislature, and for doing justice between parties."

Bindra, Interpretation of Statutes, 10th Ed., pg. 277

> "When there is doubt or a patent absurdity and the grammatical construction fails to give effect to the plain intention of the Act, as gathered from the preamble, then the courts are competent to and should rewrite the section in such a way so as to give effect o the Act".

As observed above adherence to such International Treaties and conventions is provided in terms of Section 15(J) of the NATA Act. Having perused R8 (WHO Framework Convention on Tobacco Control – referred to as FCTC) refer to inclusion of pictures or pictograms, in Article 11. It considers the harmful effect of tobacco and promote health warnings to be included in packaging and labeling. Space to be occupied within a ratio of 50% or more but not less than 30%.

13 MAY 2014

According to rule of construction of statutes, legislature is presumed not to enact rules contravening international law or common law of realm.

The Judges may not pronounce an Act ultra vires as contravening international law, but may recoil, in case of ambiguity, from a construction which would involve a breach of the ascertained and accepted rules of international law. (Bindra Interpretation of Statutes. 10th Ed. Pg. 204.

Our Supreme Court in decided cases emphasized the need to interpret domestic law in harmony with Sri Lanka's international commitments even in cases where no specific domestic law had been enacted to give effect to its international obligations.

In Weerawansa Vs. A.G 2000 (1) SLR 387 at 409

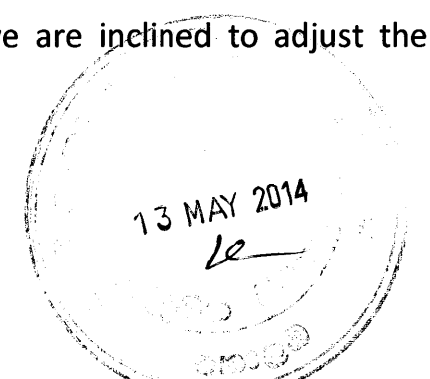
"Should this court have regard to the provisions of the Covenant? I think it must. Article 27(15) requires the State to "endeavor to foster respect for international law and treaty obligations in dealings among nations". That implies that the State must likewise respect international law and treaty obligations in its dealings with its own citizens, particularly when their liberty is involved. The State must afford them the benefit of the safeguards which international law recognizes.

In the background it would be wrong to attribute to Parliament an intention to disregard those safeguards. The PTA cannot be interpreted as dispensing, by implication or inference, with the safeguard of prompt production before a judicial officer under and in terms of Article 13(2) ".

13 MAY

Having read FCTC (R8) and the guidelines for implementing of Article 11 (R10) of the FCTC there cannot be any prohibition to convey the message by pictorial health warnings. As such apart from the matters stated in this judgment as regards inclusion and interpreting health warning to cater to pictorial health warning more support is lent, to do so from documents R8 and R10. Our courts recognize international commitments and articles 27(15) of the Constitution, endeavor to foster respect for international law and treaty obligation. As such I reject the argument that Section 34(1) of the NATA Act provide only for textual warnings. Health warnings in the context of said section and the NATA act need to be interpreted in a meaningful and purposive way and not so narrowly as the Petitioner argues. It may be essential to do some violence to the words to achieve the intention of the legislature. It is so because the message need to reach all category of persons in our country inclusive of children as observed above. Words of a section of a statute should be interpreted harmoniously to avoid conflict, friction, absurdity and inconvenience.

On behalf of the Petitioner Company, we also had the benefit to hear the submissions of Mr. Ali Sabry, President's Counsel, on the aspect of Petitioner's Intellectual Property Rights. We find some substance in those submissions of learned President's Counsel. As such we are inclined to adjust the 20% space



allocated to the Petitioner Company in a more reasonable and a meaningful way for the following reasons.

In view of Sections 121(1) and 121(2), of the Intellectual Property Act the rights of the registered owner of a trademark take both positive and negative forms in the sense that section 121(1) allows the registered owner to use the trademark, assign or transmit the mark and conclude licence agreements in respect of the trademark and 121(2) allows the registered owner to preclude third parties from using the trademark or a sign misleadingly similar to the trademark. (S.N. Silve J. in Leelananda v. Earnest de Silve (1990 (2) Sri LR 237-240-241).

These rights are subject to the limitations recognized under section 122 of the IP Act. These limitations restrict the right of the registered owner to preclude third parties from using the mark in certain specified circumstances. They do not restrict the positive rights of the registered owner – the right to use the trademark etc.

Even section 35(1)(a) of NATA Act recognizes the right of the registered owner to use the trademark. Section 35(1) of NATA Act prohibits the advertisements involving tobacco but section 35(1)(a) expressly permits the use of trademarks in respect of tobacco.

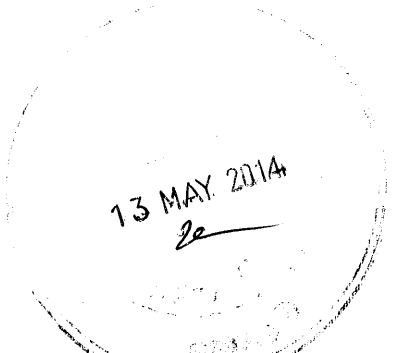
These statutory provisions clearly indicate that the registered owner of a trademark has the right to use the trademark. A trademark is used in trade and commerce. The use is intended to achieve the owner's reasonable business objectives – to reach the consumers and promote the commercialization of the concerned goods.

Consequently, the petitioners should have a reasonable opportunity to exercise the rights attached to their registered trademarks such as the use of the trademarks to reach the consumers and promote the commercialization of their goods. It is noted that the law does not prohibit the sale of tobacco. The petitioners can sell etc. tobacco subject to the lawful restrictions. They have the right to sell tobacco using their trademarks.

Where 80% of the pack is covered with the health warning, the practical issue that arises is whether the remaining 20% is reasonably sufficient to present and exhibit the mark or in other words to use the mark. Having considered the size of the packs and other relevant facts, I am of the view that 20% of the space is not reasonably sufficient to present and exhibit a trademark 20% of the space is not exclusively left for the trademark. It may carry other information as well. In such a space, the presentation of the trademark necessarily becomes comparatively very small. The owner of a trademark cannot

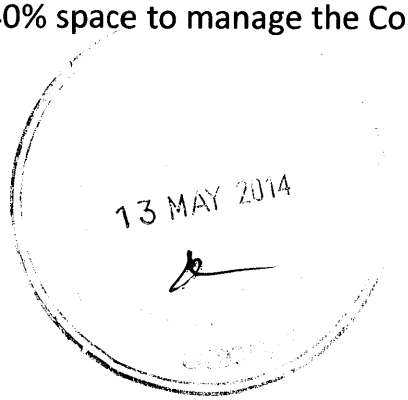
reach the consumers with his mark which is hidden in the health warning. The consumers will also not be able to see and identify the trademark properly and consequently the source of the respective goods. They have to make extra efforts to see or identify the trademark, when they buy the goods. Such a situation will unreasonably interfere with the statutory right of the owner of the trademark to use it frustrating the whole purpose of a trademark and of the trademark law.

Moreover, the Trademark Law, while protecting the rights of the owners of the registered trademarks, attempts to safeguard the interests of the consumers as well. In a market where there are several brands or trademarks in respect of same or similar goods the protected trademarks enable the consumers to make their choice. The consumers can identify the goods and the source of the goods that they actually want to buy through trademarks and brands without being misled to purchase the goods of wrong sources and wrong quality. Where only 20% of the space is available for the presentation of the trademark and other information, the consumers will not be able to see the trademark properly and make their choice properly and effectively. The packs of each manufacturer may look the same where 80% of the space is covered with the health warning. When the trademarks are not obviously and clearly presented, the unscrupulous traders



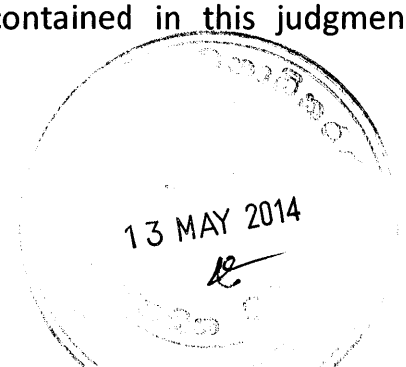
may even misuse such situation to mislead the consumers by selling products from wrong sources rather than selling what actually the consumer wants to buy.

This court observes that a balance need to be maintained, having considered the case of either party. Health of each and every citizen of our country and all those living in Sri Lanka permanently or in a temporary capacity is paramount and need to be protected. On the other hand a legally established business/industry cannot be denied its legitimate rights, flowing from the laws of our country. If 80% of the space is covered by health warnings the remaining space would not be sufficient to display the manufacturers trade mark. At the oral hearing of this application, the learned Deputy Solicitor General very correctly conveyed to this court that the authorities concerned would be agreeable and willing to allocate 75% of the space for health warnings. However at that point of time of the hearing the learned President's Counsel for the Petitioner Company was not prepared to act on the above ratio of 75%, as he may have thought that to accept the suggestion of learned Deputy Solicitor General would not be in the best interest of his client. However it is the view of this court that warnings/pictorial health warning should cover a space between 50% to 60%. Thus giving the Petitioner Company at least 40% space to manage the Companies



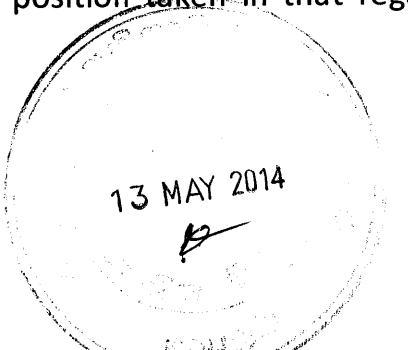
Trade Mark rights, within that space. The authorities concerned are directed to suitably amend the regulation to allocate a ratio anything between 50% to 60% for health/pictorial warnings.

We have also noted the contents of motion dated 14th March 2014, filed by the registered Attorney-at-Law for the Respondents. The said motion indicates that regulations marked P11, R3 & R15 had been placed before Parliament and same had been approved by Parliament on 19.2.2014. Section 30(4) of the NATA Act requires the regulations to be placed before Parliament after 30 days of its publication in the Gazette for approval. Regulations not so approved deemed to be rescinded. As such after a lapse of the 30 day period, as stated in section 30(4) the regulation, need to be placed before Parliament. I cannot see a prohibition as regards the provisions conferred in Section 30(4) to place the regulations before Parliament at any time after 30 days of publication in the Gazette. Now that regulation P11, R3 & R15 are approved by Parliament as subordinate legislation it remains valid for all purposes which has a quasi – Parliamentary validity subject to the views expressed by this court, as regards regulation No. 5 of P11 as amended by regulation R15. The space to be occupied for pictorial health warnings should only occupy a space in the ratio anything between 50% to 60% for the reasons contained in this judgment. The 1st



Respondent is directed to suitably amend the above regulation in keeping with the direction given by this court. The above requirement in the circumstances of this case would not offend the principle of proportionality. The attempt to introduce pictorial health warnings is only to minimize the harmful health consequences of smoking cigarettes. There is no total prohibition or ban on the Tobacco Industry or to engage in its business by the Petitioner Company. The regulations only attempt to impose a valid restriction or exercise some control for the benefit of safeguarding health of our people and as such the principles of proportionality cannot be offended.

In all the facts and circumstances of this Writ Application, we are of the view as stated in this Judgment and subject to the view expressed by this court as regards regulation No. 5 of P11 as amended by regulation R15, challenge to the regulation in question by the Petitioner on the several grounds urged by the Petitioner is a futile attempt. The regulation in question is not ultra vires the statute. However having regard to the Petitioner's rights flowing from Intellectual Property Act as regards the rights of the registered owner of a trade mark the positive rights of the registered owner, the right to use the trade mark, and the recognition given in terms of Section 35(1) (a) of the NATA Act, this court is mindful of same and as such accepts the position taken in that regard by the



Petitioner. On that account we direct the 1st Respondent to adjust the particular regulation referred to above, accordingly.

The remedy sought by the Petitioner Company are the prerogative Writs of Certiorari and Prohibition which are discretionary remedies of court. The granting of a Writ is a matter for the discretion of court, and court is bound to take into consideration the consequences which by the issue of the writs sought will entail. A Petitioner seeking a prerogative writ is not entitled to relief as a matter of course, as a matter of right or as a matter of routine. In the circumstances, subject to the views expressed by this court application of the Petitioner is refused and dismissed without costs.

Application dismissed.

Sgd../

JUDGE OF THE COURT OF APPEAL

13 MAY 2014

13 MAY 2014

W.M.M. Malinie Gunaratne J.

I agree.

Sgd../-

JUDGE OF THE COURT OF APPEAL

I do hereby certify that the foregoing is a true copy of the Judgment dated 12.05.2014 filed of record in C.A. No. 336/2012.(Writ).

Typed by:..

Comp'd with :....

Chief Clerk of the Court of Appeal

J/22 352925 2014/05/12

Chief Clerk of the Court of Appeal

SLG Economics Ltd

Economics, Regulation, Competition

Review of Proposals for Larger Graphic Health Warnings in Hong Kong

SLG Economics Ltd

June 2015

www.SLG-Economics.co.uk

Review of Proposals for Larger Graphic Health Warnings in Hong Kong

Table of Contents

Review of Proposals for Larger Graphic Health Warnings in Hong Kong

1 Introduction

The Legislative Council Secretariat has put forward a briefing paper[1] ('**LC Briefing Paper**') and updated background brief,[2] relating to the progress of tobacco control measures for the meeting of the Panel of Health Services on 18 May 2015. It proposed to strengthen tobacco control measures by amongst other things[3]:

- Increasing the area covered by graphic health warnings from 50% to at least 85% of the two largest surfaces of the packet;
- Increasing the number of health warnings from six to twelve;
- Changing the health warning message to: "*Tobacco kills up to half of its users, Quitline 1833 183*" (or the Cantonese equivalent); and
- The indication of tar and nicotine yields to be printed in a conspicuous place on a side of the packet adjacent to its flip-top lid.

This report assesses the proposals for larger graphic health warnings ('**GHW**'s) contained in the LC Briefing Paper and considers whether they are in line with better regulatory principles, and to what extent they are necessary, appropriate or proportionate. It has been commissioned by British American Tobacco Company (Hong Kong) Limited.

2 Executive Summary

The LC Briefing Paper:

- Fails to include a public consultation;
- Fails to include a Regulatory Impact Assessment ('**RIA**');
- Fails to follow the recommendations of the 2001 Tobacco Regulation RIA;
- Fails to follow the principles of better regulation
- Fails to recognise that the current tobacco controls are already more than is required under the WHO Framework Convention on Tobacco Control ('**FCTC**')

[1] LC Paper No. CB(2)1456/14-15(07) http://www.legco.gov.hk/yr15-16/english/panels/hs/papers/hs_a.htm
[2] LC Paper No. CB(2)1456/14-15(08) http://www.legco.gov.hk/yr15-16/english/panels/hs/papers/hs_a.htm
[3] There are also proposals to designate bus interchange facilities as non-smoking areas and to regulate electronic cigarettes, but these are not the subject of this report.

- Fails to analyse the baseline or identify any problems with the current 50% GHWs that might need further regulation;
- Fails to properly specify the objectives of the proposals;
- Fails to provide any evidence for the proposals;
- Sets out proposals that are arbitrary and gold-plated;
- Sets out proposals that directly contravene the FCTC Guidelines;
- Fails to consider alternative policies or identify the policy with the greatest net benefits;
- Fails to estimate the costs of the proposals; and
- Fails to estimate the benefits of the proposals.

Overall the failures of process and lack of evidence mean that the proposals cannot be shown to be necessary, appropriate or proportionate. The LC Briefing Paper does not identify any problem with the existing 50% GHWs, establish why the proposed increase in size from 50% to 85% is necessary, or what benefits it would provide over and above existing regulation or alternative measures. Taking all the concerns raised in this report together, it would be manifestly inappropriate to rely on the LC Briefing Paper to proceed with larger graphic health warnings.

3 SLG Economics

SLG Economics is an economics consultancy set up in 2011 by Stephen Gibson providing specialist micro-economic policy advice to regulated companies, regulators and government. Mr Gibson has over 25 years' experience of leading major economic and strategy projects across a broad range of industries from both sides of the regulatory fence.

Mr Gibson has been Chief Economist at Postcomm – the independent regulator of postal services in the UK, Principal Economist at Ofcom – the communications sector regulator and Head of Economics at Network Rail – the UK rail infrastructure owner, as well as a number of other senior economics positions.

Mr Gibson has been a lecturer at City University, London on their MSc in Competition and Regulation and is a lecturer at Birkbeck University on their undergraduate and postgraduate Industrial Economics courses. He has lectured widely on economic regulation at national and international industry conferences and seminars and is regularly interviewed on BBC TV and Radio, ITV and Sky News about economic issues. He was the external supervisor for a PhD in rail regulation at Cambridge University. He has an MA in Economics and Management Studies from Sidney Sussex College, Cambridge University and postgraduate

qualifications in: Computer Science from Cambridge University; Accounting and Finance from the ACCA; and Corporate Finance from London Business School. He has published papers on regulatory and competition economics issues in peer reviewed books and journals.

4 The Process for developing proposals for increasing graphic health warnings from 50% to 85%

The LC Briefing Paper fails to follow proper process in developing proposals for larger GHWs. It fails to:

- Conduct a public consultation;
- Undertake a RIA;
- Follow the recommendation of the 2001 Tobacco Regulation RIA; and
- Follow the principles for better regulation.

4.1 Failure to conduct a public consultation

Consultations are an important part of policy development. They allow the policy maker to gather the views and preferences of stakeholders (including members of the public), understand the possible unintended consequences of a policy and obtain a better perspective on implementation. Consultation increases the level of transparency and engagement with interested parties and improves the quality of policy making by bringing to bear expertise and alternative perspectives, and identifying practical problems.

The Secretary for Health and Welfare issued proposals in 2001 for a series of tobacco control measures[4] (the '**2001 Tobacco Control proposals**'). The development of these proposals included a formal consultation[5] inviting views and comments on the proposed legislative arrangements. The consultation responses identified and highlighted problems with the affordability of the proposals for hawkers and small businesses. As a result, the final legislation contained an exemption to the restriction on the display of tobacco advertising for hawkers and small businesses with a turnover less than HK$500,000.

Hong Kong is a member of the Asia-Pacific Economic Cooperation (APEC). The APEC-OECD checklist on regulatory reform[6] is clear on the importance of consultation, recommending:

[4] Including proposals to: expand the statutory no smoking areas, restrict the size of price boards and price markers, prohibit the sale of tobacco products with other merchandise, restrict tobacco sponsorship and allow health warnings to contain graphic content.
[5] Smoking (Public Health) Ordinance Cap.371 Consultation Document, http://www.fhb.gov.hk/en/press_and_publications/consultation/Smoke2.HTM
[6] APEC-OECD Integrated Checklist on Regulatory Reform, *a policy instrument for regulatory quality, competition policy and market openness*, 2005 http://www.oecd.org/regreform/34989455.pdf

- *"Public consultation should not be limited to insiders, such as already established businesses, but should be open to all interested parties"*[7]*;* and

- *"Consultation with stakeholders is considered to be fundamentally important for a well-managed regulatory system*"[8].

The APEC *Guidelines for the preparation, adoption and review of technical regulations*[9] (which are defined as mandatory government regulations put in place to achieve health, safety, consumer information and environmental objectives) require that the administration:

- "*ensure that adequate consultation takes place*".

Similarly, the APEC paper *Supporting the TBT Agreement with Good Regulatory Practices*[10] states:

- "*The importance of public consultation is widely recognised*"; and

- "*Consultation should not be a discretionary part of regulating society*".

It is therefore a failure of process that (unlike the 2001 tobacco control proposals) the current proposals have not been subject to a proper public consultation process. As well as not following better regulation principles, the lack of public consultation means that the proposals do not take account of stakeholder feedback and fail to consider the practical consequences of the proposals.

4.2 Failure to undertake a Regulatory Impact Assessment

The 2001 Tobacco Regulation proposals were also supported by a detailed (214 page) RIA[11] of the proposed amendments. RIAs are a structured process for collecting and using evidence to better solve policy problems. They are an important part of policy development that enables the government to understand the costs, benefits and risks of its proposed actions and policy alternatives and to thereby choose the solution that best achieves the policy goals at lowest cost. The APEC paper *Supporting the TBT Agreement with Good*

---

[7] Ibid, page 17
[8] Ibid, page 17
[9] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg
[10] *Supporting the TBT Agreement with Good Regulatory Practices, APEC,* March 2012 http://publications.apec.org/publication-detail.php?pub_id=1266
[11] Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

Regulatory Practices[12] states: "*it is impossible to regulate well if the consequences of government action are not understood in advance. Understanding consequences of various options for action more clearly is the main purpose of RIA*". The APEC Good Practice Guide on Regulatory Reform[13] comments: "*as parliaments realise the importance of RIA, they can provide invaluable support for its use*."

It is therefore a further failure of process that (unlike the 2001 Tobacco Control proposals) the current proposals have not been subject to a proper (or indeed any) RIA process (see also Section 7 below on the proportionality of the proposals).

4.3 Failure to follow the recommendation of the 2001 Tobacco Control RIA

The 2001 Tobacco Control RIA concluded that: "*it is recommended that the proposed amendment be enacted, but that any future requirements for pictorial and graphic contents take into account the likely financial and economic costs of implementation and that these be weighed against the likely health and economic benefits likely to arise*" [14]. The lack of an RIA or any assessment of the costs and benefits of the current proposals totally disregards this recommendation.

4.4 Failure to follow the principles of better regulation

The APEC *Good Practice Guide on Regulatory Reform*[15] sets out a set of seven principles of better regulation that have been widely accepted as good practice and are intended to be applicable to any economy and any policy issue. It is remarkable that the LC Briefing Paper fails to comply properly with any of the principles. The APEC principles for better regulation are:

- *Clearly define the problem* – The LC Briefing Paper fails to identify any problems with the current 50% GHWs that might need to be rectified by new regulations (see Section 5.2) or specify the objectives of the proposals (see Section 5.3).
- *Justify government action* – The LC Briefing Paper fails to provide explicit evidence that government action is justified (see Section 6.1).
- *Consider a range of policy options* – The LC Briefing Paper fails to consider alternative policy options (see Section 7.1).

---

[12] *Supporting the TBT Agreement with Good Regulatory Practices,* APEC, March 2012 http://publications.apec.org/publication-detail.php?pub_id=1266

[13] *Good Practice Guide on Regulatory Reform*, APEC, August 2008 http://publications.apec.org/publication-detail.php?pub_id=1061

[14] Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, page 107 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

[15] *Good Practice Guide on Regulatory Reform, August 2008*, APEC, July 2010, paragraph 8 http://publications.apec.org/publication-detail.php?pub_id=1061

- *Weigh the benefits and the costs of the regulation* – The LC Briefing Paper fails to estimate the costs and benefits of the proposed regulations (see Sections 7.2 and 7.3) or weigh them together (see Section 7.1).

- *Consult with interested parties* - The LC Briefing Paper fails to consult with stakeholders (see Section 4.1).

- *Consider enforcement and incentives for compliance* - The LC Briefing Paper fails to assess the incentives and institutions through which the regulation will take effect and design implementation strategies that make best use of them.

- *Review mechanisms to ensure the continuing effectiveness of the regulation* - The LC Briefing Paper fails to consider review mechanisms (such as a post-implementation review) to check whether the regulations are working effectively and remain relevant.

5 Establishing whether increasing the graphic health warnings from 50% to 85% is necessary

The LC Briefing paper fails to show that increasing the size of the GHWs from 50% to 85% is necessary, in fact:

- The current 50% GHWs are more than is required under the FCTC;

- There is no analysis of the baseline to support further regulations; and

- The LC Briefing Paper fails to properly set out the objectives of the proposals. It is therefore impossible to assess what the proposals are intended to achieve and whether they will meet those objectives.

5.1 The current tobacco control regulations are more than is required under the Framework Convention on Tobacco Control

The LC Briefing Paper justifies the proposed increase in GHWs solely on the basis of recommendations in the WHO Guidelines. These state that: "*the size of the health warnings and messages should cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible*."[16] However, the WHO Guidelines[17] quote Article 11.1(b)(iv) of the FCTC which provides that that health warnings and messages on tobacco product packaging and labelling: "*should be 50% or more, but no less than 30%, of the principal display areas*" and "*may be in the form of or include pictures or pictograms*." Therefore the FCTC only requires Parties to implement 30% text warnings, and the current

[16] LC Briefing Paper, paragraph 15

[17] *Who Framework Convention on Tobacco Control* Guidelines for implementation, 2013 edition, http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf?ua=1

regulations in Hong Kong that require 50% GHWs are already more than is required under the FCTC. This is not recognised in the LC Briefing Paper and means that larger GHWs are not necessary to meet the requirements of Article 11 of the FCTC.

5.2 Failure to assess the problem against a baseline

In order to properly make a case for further tobacco control regulation, the LC Briefing Paper should assess the efficacy of the current tobacco control regulations to provide a baseline and identify any problems that might need to be rectified by new regulations. There is no analysis of the baseline or the need for further regulations. The LC Briefing Paper doesn't identify any problem with the existing 50% GHWs or establish why an increase in size from 50% to 85% is necessary or what benefits it might bring. As the APEC *Guidelines for the preparation, adoption and review of technical regulations*[18] state: "*The first step in the development process should be to clearly identify the problem that needs to be addressed*" and "*accurate problem definition reduces the risk of choosing inappropriate options for government action or ignoring more effective solutions, and reduces the likelihood of over regulation.*"

5.3 Failure to properly specify the objectives of the proposals

The LC Briefing Paper does not set out the objectives of the proposals – it simply proposes them to "*strengthen our tobacco control efforts*". This is in contrast to the 2001 tobacco control proposals which set out two clear objectives to: "*reduce the exposure and impacts of second hand smoke, and to reduce the uptake of smoking and hence overall smoking rates"*[19].

Without a clearly framed objective(s), it is impossible to assess what the proposals are intended to achieve, whether the proposals are likely to deliver the objective(s), whether there are alternative less costly or more effective ways of delivering the objective(s) and to debate whether the objective(s) is a sensible goal for public policy. The APEC *Guidelines for the preparation, adoption and review of technical regulations*[20] are clear that "*it is essential to clearly specify policy goals. These goals or objectives should focus on outcomes, rather than means to achieve them, so that all possible alternatives can be considered"*. Similarly

---

[18] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

[19] Regulatory Impact Assessment, Proposed amendments to the existing smoking legislation, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, page 15 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

[20] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

the Hong Kong Department of Justice in their publication *How Legislation is made in Hong Kong*[21] state that Instructions for Bills and subsidiary legislation should include a general statement setting out "*the principal objectives to be achieved by the legislation*"[22] and the APEC *Good Practice Guide on Regulatory Reform*[23] states: "*A regulatory reform policy should have clear objectives*"

6 Establishing whether the evidence for increasing graphic health warnings from 50% to 85% is adequate

The LC Briefing Paper (and the WHO Guidelines on which it is based) does not demonstrate adequate evidence to support increasing the size of GHWs to 85%. It does not provide any evidence of an information deficit that requires larger warnings and fails to identify a problem with the existing 50% GHWs:

- It is solely based on a reference to the WHO Guidelines and does not set out any supporting evidence ;
- The choice of 85% is arbitrary and results in gold-plated regulations ; and
- The proposals directly contravene WHO Guidelines relating to printing tar and nicotine yields on packets.

6.1 Lack of evidence for proposals

The proposal for increasing the size of the GHWs from 50% to 85% is based solely on the non-binding recommendation in the WHO Guidelines that the size of the health warnings and messages should cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible. However, there is no indication of the source or quality of the evidence on which this recommendation is based. Without the evidence being properly set out, it is inappropriate to place any weight on recommendations stemming from it. Again, it must be remembered that the current regulations in Hong Kong that require 50% GHWs are already more than is required under the FCTC and meet the recommendation under the WHO Guidelines (see Section 5.1).

I have also reviewed the expert report of Professor W. K. Viscusi[24] which provides evidence which directly contradicts the assumption that increasing the size of graphic health warnings will have any impact on smoking behaviours. This evidence includes: statistical analysis by the U.S. Food and Drug Administration of Canadian data which found no evidence of a

[21] *How Legislation is made in Hong Kong, A Drafter's View of the Process*, Law Drafting Division, Department of Justice, June 2012, http://www.legislation.gov.hk/blis/eng/pdf/2012/drafting2e.PDF
[22] Ibid, Appendix to Chapter V, paragraph 8(c)
[23] *Good Practice Guide on Regulatory Reform, August 2008*, APEC, July 2010, paragraph 4 http://publications.apec.org/publication-detail.php?pub_id=1061
[24] *Expert Report on Proposals to Increase the Size of Graphic Cigarette Warnings in Hong Kong*, W. Kip Viscusi, June 2015

beneficial effect of graphic warnings on smoking behaviour; evidence that the introduction of 50% GHWs in Hong Kong in 2007 had no impact on reducing smoking prevalence; and evidence that GHWs in Canada, Australia and the UK had no effect on the trend in smoking prevalence rates in those countries. Professor Viscusi concludes that: "*There is no sound basis in experimental data, survey data, or data on smoking behavior to conclude that larger graphic warnings are more effective in increasing risk awareness or reducing smoking behavior. It therefore cannot be expected that increasing the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviors*". The LC Briefing Paper fails to consider any evidence or undertake any analysis of the type referred to in Professor Viscusi's report.

6.2 Arbitrary and gold-plated regulations

The WHO Guidelines are silent as to the basis on which graphic health warnings of any percentage above 50% are to be chosen. They do not provide any recommendations for 85% GHWs. The choice of 85% in the LC Briefing Paper is purely arbitrary and has no evidential basis at all. It effectively gold-plates the regulations – going well beyond the 30% text warnings required under the FCTC or indeed even the non-binding recommendation of 50% GHWs in the WHO Guidelines.

6.3 Proposals directly contravene WHO Guidelines relating to tar and nicotine yields

The WHO Guidelines clearly state that: "*Parties should prohibit the display of figures for emission yields (such as tar, nicotine and carbon monoxide) on packaging and labelling*" [25], because they are concerned that "*marketing of cigarettes with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful*". However the LC Briefing Paper proposes that: "*tar and nicotine yields be printed on a side adjacent to a typical flip-top lid of a cigarette packet … presented in a conspicuous place of such side of the packet*"[26] - in direct contravention of the Guidelines.

It is remarkable, given that the only justification put forward in the LC Briefing Paper for the proposals is to seek to follow WHO Guidelines, that they then directly contravene those Guidelines.

7 The proportionality of 85% graphic health warnings

The LC Briefing Paper does not demonstrate that increasing the size of GHWs from 50% to 85% would be a proportionate policy measure i.e. whether the benefits significantly outweigh the costs. In fact the LC Briefing Paper does not provide any quantified or even qualitative evidence on the impact of the incremental increase in the size of GHWs from

[25] *Who Framework Convention on Tobacco Control* Guidelines for implementation, 2013 edition, page 63 http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf?ua=1

[26] LC Paper No. CB(2)1456/14-15(07), paragraph 17(d) http://www.legco.gov.hk/yr15-16/english/panels/hs/papers/hs_a.htm

50% to 85% and fails to consider any of the costs or benefits that might arise as a result of the measure or possible alternative measures. The LC Briefing Paper fails to:

- Consider alternative policies or identify the policy with the greatest net benefit to society;
- Consider the costs of the proposals and in particular the impact on trademarks; and
- Estimate the benefits of the proposal.

7.1 Failure to consider alternative policies and identify the policy with the greatest net benefit

The LC Briefing Paper fails to consider any policy alternatives. The Hong Kong Department of Justice in their publication *How Legislation is made in Hong Kong*[27] states that the responsible Government agency is required to provide a clear statement of purpose for a proposed measure, demonstrating that "*legislation is necessary, in the public interest and that other options … cannot achieve the objective*"[28]

The APEC *Guidelines for the preparation, adoption and review of technical regulations*[29] similarly state that: "*In order to ensure that any government intervention brings the greatest possible net benefits, it is important to ensure that all the feasible options are identified and assessed. In addition to the imposition of technical regulations, there are a number of policy instruments available which should be considered*."

Without an estimate of the costs and benefits of the proposed measure, it is impossible to judge whether the proposal is proportionate, whether the benefits outweigh the costs and risks involved, and whether it provides the maximum net benefit compared to alternative policy options. The APEC *Guidelines for the preparation, adoption and review of technical regulations*[30] state: "*Each option should then be considered carefully in terms of costs and benefits. The option chosen should be the option which either provides the maximum net benefit or the least net cost to society. It is important to include the status quo in the set of options being considered, to ensure that no option is chosen which would in fact be worse for the economy than the status quo."*

---

[27] *How Legislation is made in Hong Kong, A Drafter's View of the Process*, Law Drafting Division, Department of Justice, June 2012, http://www.legislation.gov.hk/blis/eng/pdf/2012/drafting2e.PDF

[28] Ibid, Appendix 3, paragraph 451 (a)

[29] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

[30] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

This evidence on costs, benefits and risks of a range of policy options should have been provided through the RIA process (see Section 4.2) which would have allowed comparison of the proposal with the 'Do Nothing' option of maintaining existing GHWs and alternative options – for example using different warning messages.

7.2 Failure to estimate the costs of the proposals

The LC Briefing Paper does not even mention the potential costs of the measure. In contrast, the previous 2001 Tobacco Control RIA showed that the costs of tobacco control measures could be substantial – for example the costs of the previous amendments to restrict tobacco advertising and promotion were estimated at HK$555m. There are a wide range of costs that should be addressed, but are not considered at all in the LC Briefing Paper, including:

- One-off costs and running costs of changing health warnings;
- Loss of manufacturing industry profits - particularly through the impact on trademarks;
- The impact on the packaging industry;
- The cost of introducing the regulations;
- The impact on employment; and
- The impact on tax revenues and illicit trade.

7.2.1 The impact on trademarks

I have reviewed the expert report of Professor Zerrillo[31] which describes the importance of trademarks and the brands that they represent, how they affect consumers, manufacturers and competition in the marketplace, and the ramifications to trademarks and brands that will result from the requirement to increase the size of the GHWs to 85%. Professor Zerrillo explains that:

- Increasing the size of GHWs to cover 85% of the cigarette packages will make it impossible for manufacturers to use some trademarks as registered (including logos and labels) and for them to use other trademarked elements effectively. Trademarks will not be able to adequately serve their essential functions of differentiating products and uniquely identifying their origin and quality.
- In Hong Kong, the extensive ban on advertising and sponsorship of cigarettes means that the limited space available on cigarette packs for trademarks is the only tool manufacturers have to identify and differentiate their products from other competitive offerings. A further reduction in this already limited space will minimize

[31] Expert Report of Professor Philip Zerrillo, June 2015

or even eliminate any meaningful use of trademarks and, in doing so, destroy their value. As a result, decades of investment in brands and their related trademarks, along with their inherent goodwill, will be lost.

- Brands including trademarks play an important role in the cigarette market, and their erosion or elimination changes the nature of the market. In general, markets without brands become price-driven commodity markets.

- Commodity markets produce lower prices that encourage more consumption. Commodity markets also make the market inhospitable to firms trying to enter the market and for existing brands, particularly small brands, to compete for a greater market share. Commoditization of the cigarette market in Hong Kong and a shift to pure price driven competition could also lead to an increase in illicit trade because without the added value of brands, legitimate products will be less clearly differentiated from illicit products.

Professor Zerrillo concludes: "*In sum, it is my opinion that increasing the size of GHWs to 85% will preclude any effective or meaningful use of trademarks, thereby preventing them from performing their essential brand functions. Further, it is my opinion that the elimination of trademarks as a platform for brand communication has a number of important negative repercussions for consumers, manufacturers, and the market in general, including some unintended consequences that are at cross-purposes with the stated health goals of the initiatives.*"[32]

These impacts are not considered at all in the LC Briefing Paper. This is not only a failure of process, but as noted in Section 4.3 above, also goes against the recommendation made in the 2001 Tobacco Control RIA that: "*any future requirements for pictorial and graphic contents take into account the likely financial and economic costs of implementation and that these be weighed against the likely health and economic benefits likely to arise*." [33]

7.3 Failure to estimate the benefits of the proposals

The LC Briefing Paper does not estimate the extent of the benefits of its proposals in order to establish that some form of government intervention is warranted. The APEC *Guidelines for the preparation, adoption and review of technical regulations*[34] are clear that "*once the nature of the problem is established, the magnitude of the problem must be assessed*",

---

[32] Expert Report of Professor Philip Zerrillo, June 2015, Paragraph 56.

[33] Regulatory Impact Assessment, *Proposed amendments to the existing smoking legislation*, Environmental Resources Management Limited, LC Paper No. CB(2)1/02-03(04), Dec 2001, page 107 http://www.legco.gov.hk/yr02-03/english/panels/hs/papers/hs1025cb2-1-4e.pdf

[34] *Guidelines for the Preparation, Adoption and Review of Technical Regulations*, APEC http://www.google.co.uk/url?url=http://www.jsm.gov.my/documents/10180/86670/Guidelines%2Btechnical%2Bregulations.doc/8bce9281-59f4-4403-bc7d-5c9dbf35997f&rct=j&frm=1&q=&esrc=s&sa=U&ved=0CB4QFjABahUKEwio3e63sIfGAhXkKNsKHaTcAvA&usg=AFQjCNHe0Mkpx2A5xUFXEkebDHKg4cu_Yg

because "*the mere existence of a problem does not mean that Government intervention is warranted*". It warns about the danger of over regulation: "*Over regulation occurs where the extent and/or nature of regulation is greater than what is needed to address a problem. This results in additional costs to the economy, for example through increased production costs, reduced competition, reduced innovation, or reduced customer choice*."

8 Conclusion

The analysis in this report shows that the LC Briefing Paper does not include the necessary evidence or analysis to support the implementation of the proposed policy and does not provide proportionate evidence-based policy recommendations. It has not shown that the proposed increase in GHWs from 50% to 85% is necessary, appropriate or proportionate. **The LC Briefing Paper does not identify any problem with the existing 50% GHWs, establish why the incremental increase in size from 50% to 85% is necessary or what benefits it would provide over and above existing regulation or alternative measures. It fails to consider any evidence on the costs or benefits that might arise from the measure.**

Taking all the concerns raised in this report together, it would be manifestly inappropriate to rely on the LC Briefing Paper to proceed with larger graphic health warnings.

SLG Economics Ltd
June 2015

Expert Report on Proposals to Increase the Size of Graphic Cigarette Warnings in Hong Kong

W. Kip Viscusi

University Distinguished Professor of Law, Economics, and Management

Vanderbilt University

June 17, 2015

TABLE OF CONTENTS

Expert Report on Proposals to Increase the Size of Graphic Cigarette Warnings in Hong Kong

by Prof. W. Kip Viscusi

INTRODUCTION

1. My name is Professor W. Kip Viscusi. I am the University Distinguished Professor of Law, Economics and Management, Vanderbilt University, Nashville, Tennessee, United States. Further details of my qualifications and experience are outlined below.

2. I have been asked by British American Tobacco Company (Hong Kong) Limited to provide a report on the proposals that increase the size of existing graphic health warnings on cigarette packages in Hong Kong from 50% to 85% of the front and back surface area of cigarette packages. Specifically, I have been asked to provide a review of the empirical evidence and public health claims regarding the effect of graphic cigarette warnings on smoking behavior.

3. The principal sections of my report summarize my professional background, assess the effect of cigarette graphic warnings policies on trends in smoking prevalence in Hong Kong and other countries that have instituted such warnings, review the studies by the U.S. Food and Drug Administration of the effect of graphic warnings on smoking prevalence and on reported attitudes toward smoking, and consider the findings in the literature on surveys of the effect of graphic warnings on beliefs and intentions. The principal findings based on my assessment of the literature and available empirical evidence are summarized below.

3.1. The most meaningful test of the efficacy of graphic warnings for cigarettes is whether the graphic warnings policies that have been implemented have altered the temporal trend in smoking prevalence rates. Analysis of smoking trends in Canada, the U.K., and Australia fails to indicate any beneficial effect of graphic warnings when assessed either on a within country basis or in comparison to trends in the U.S. Empirical evidence also indicates that the introduction of 50% graphic warnings in Hong Kong in October, 2007 has similarly had no impact on reducing smoking prevalence. The downward smoking prevalence trend is similar to the U.S., which does not have graphic health warnings but only a small text warning. Neither increasing the warning size nor the use of graphic health warnings has been effective in reducing smoking prevalence rates.

3.2. Evidence demonstrates that the risks of smoking have been well publicized over the last several decades and that youth are well informed about the risks of smoking. Given that consumers are aware of the risks of smoking, there is no beneficial role for increased warnings. However, if there are concerns regarding the current warnings being worn out and lower levels of awareness of specific illnesses, these can be met by changing the current warning content. Increasing the size or format of the warnings is not needed and will not have any improved benefit in terms of reducing smoking rates.

3.3. The U.S. Food and Drug Administration (the "**FDA**") undertook a substantial statistical analysis to estimate the effect of the Canadian graphic warnings on smoking prevalence rates. In its preferred analysis that accounted for U.S. smoking trends and cigarette tax levels, the FDA found that the effect of graphic warnings on prevalence rates was less than one-tenth of 1 percentage point. In all of its statistical analyses all effects of graphic warnings on smoking prevalence were statistically equivalent to a zero effect.

3.4. The FDA also funded a large scale experimental survey that compared the efficacy of a wide variety of graphic warnings relative to text warnings that did not include the graphic information. There was no evidence of efficacy of graphic warnings in influencing smoking decisions of adults or younger age groups for any of the nine smoking risks that were studied.

3.5. To summarize, both the FDA's statistical analysis of the effect of graphic warnings in Canada and its large scale survey of the reported reactions to different graphic warnings discussed above found no evidence of a beneficial effect of graphic warnings on smoking behavior. These studies provide no evidence to support a claim that increasing the size of existing graphic warnings from 50% to 85% would have a beneficial effect on smoking behaviors.

3.6. Nevertheless, the FDA proceeded with a proposed graphic warnings regulation. However, the U.S. courts overturned this regulation in 2012 in *R.J. Reynolds Tobacco Co. v. Food and Drug Admin*. because, in the view of the Court: "FDA has not provided a shred of evidence—much less the 'substantial evidence' required by the APA [Administrative Procedures Act]—showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke."

3.7. The preponderance of other studies of graphic warnings is not informative as these studies typically ask people if the warnings provided information to them, or would alter their behavior, rather than assessing how warnings actually affect their risk beliefs and influence their smoking behavior. While there have been many claims of efficacy of graphic cigarette warnings, there is a profound gap between these claims and any

concrete evidence that graphic warnings are more effective than text warnings in altering risk beliefs or smoking behavior.

3.8. There is no sound basis in experimental data, survey data, or data on smoking behavior to conclude that larger graphic warnings are more effective in increasing risk awareness or reducing smoking behavior. It therefore cannot be expected that increasing the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviors.

EDUCATIONAL BACKGROUND AND PROFESSIONAL EXPERIENCE

4. I am the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University, where I hold tenured appointments in the Vanderbilt University Law School, the Department of Economics, and the Owen Graduate School of Management. I have previously held tenured full professor positions at Harvard University, Duke University, and Northwestern University. I hold a Bachelor's degree in Economics, a Master's Degree in Public Policy, a Master's degree in Economics, and a Ph.D. degree in Economics, all from Harvard University. I graduated *summa cum laude*, Phi Beta Kappa, and won awards at Harvard University for the best undergraduate thesis and the best doctoral dissertation in economics.

5. My research focuses on societal and individual responses to risk and uncertainty, with particular emphasis on risks to health and safety. I have published over 340 articles and 20 books dealing primarily with health and safety risks. Most of these articles and books have been peer reviewed. I have been ranked among the top 25 economists in the world based on citations and have been ranked as the leading contributor to the health economics literature by *Health Economics* and the leading contributor to the risk and

insurance literature by *Journal of Risk and Insurance*. My research has won numerous article of the year and book of the year awards from organizations such as the Royal Economic Society and the American Risk and Insurance Association. I am the founding Editor of the *Journal of Risk and Uncertainty*, which is the leading international journal in its field and which I continue to edit.

6. My research currently focuses on how consumers make decisions involving products such as cigarettes and drinking water that may pose precisely understood risks and less well understood hazards. Much of my research has analyzed hazard warnings and how they affect consumer behavior. I have worked extensively with the U.S. Environmental Protection Agency ("EPA"), on a continuous basis from 1983 to 2012, serving in several different roles. Much of my work for the EPA has focused on the development of guidelines for the Agency for hazard warnings for dangerous pesticides and chemicals. These studies involved an experimental structure in which consumers reviewed different warnings, assessed the implied risks, and indicated the precautions that they would take in using the product. This work has appeared in numerous articles, and much of it is summarized in two books with Wesley Magat: *Learning about Risk: Consumer and Worker Responses to Hazard Information* (Cambridge: Harvard University Press, 1987), and *Informational Approaches to Regulation* (Cambridge: MIT Press, 1992). I have also written many articles and two peer reviewed books devoted to consumer decisions pertaining to smoking, *Smoking: Making the Risky Decision* (Oxford University Press, 1992) and *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (University of Chicago Press, 2002).

7. In addition to my extensive work for the EPA, I have consulted for several other governmental entities on a variety of issues. I have also taught courses about risk, uncertainty, risk analysis, and hazard warnings to hundreds of FDA officials, congressional staff, and federal and state judges. I served as the Associate Reporter on The American Law Institute Study on Enterprise Responsibility for Personal Injury and co-wrote the chapter on Product Defects and Warnings. I have testified before Congress on nine occasions as an expert in economics and risk analysis. This testimony addressed such topics as, for example, alcoholic beverage warnings. Apart from my academic and governmental work, I have consulted on matters such as risk perception, hazard warnings design, and safety devices for large companies, including Bic, Dupont, Becton Dickinson, Bristol-Meyers Squibb, R. J. Reynolds, Anheuser-Busch, Black & Decker, and Medline Industries. My discussion below draws on my professional expertise and knowledge of the literature on risk and warnings.

EMPIRICAL EVIDENCE ON GRAPHIC WARNINGS AND SMOKING PREVALENCE

8. The most meaningful test of whether graphic warnings will have an effect on smoking behavior is to analyze the effect of these warnings on smoking prevalence in countries that have implemented these warnings. Before considering smoking prevalence trends in Hong Kong, I first present a graphical analysis of the performance of graphic warnings policies in Australia, Canada, and the United Kingdom. All three countries currently require that text and graphic warnings occupy a large proportion of the cigarette packaging, as described more fully below. Claims that graphic warnings have fostered quitting and other smoking related behaviors in Canada, Australia, and other

countries that have implemented these warnings, are unsupported by the data and can be rejected based on the statistics that I present and studies of the Canadian experience by the U.S. FDA.

9. Advocates of graphic warnings routinely cite studies in these countries that have shown that smokers claimed that the warnings would make them more likely to quit, and nonsmokers responded that they would be less likely to initiate smoking. However, despite the favorable evidence on stated smoking intentions and subjective assessments of the efficacy of graphic warnings, in fact these warnings have not influenced the pre-existing downward trend in smoking prevalence.

10. In Canada, cigarette packs have had on-product warnings since 1972. Large text only warnings, occupying 33% of the front and back of cigarette packets, were required from 1994 to 2000 and beginning from December 2000 to March 2012, cigarette packages were required to carry a warning on 50% of the front and 50% of the back of the packaging (one in English and the other in French). Beginning March 21, 2012, the required graphic warnings in Canada were increased to 75% on both the front and back of the cigarette package.

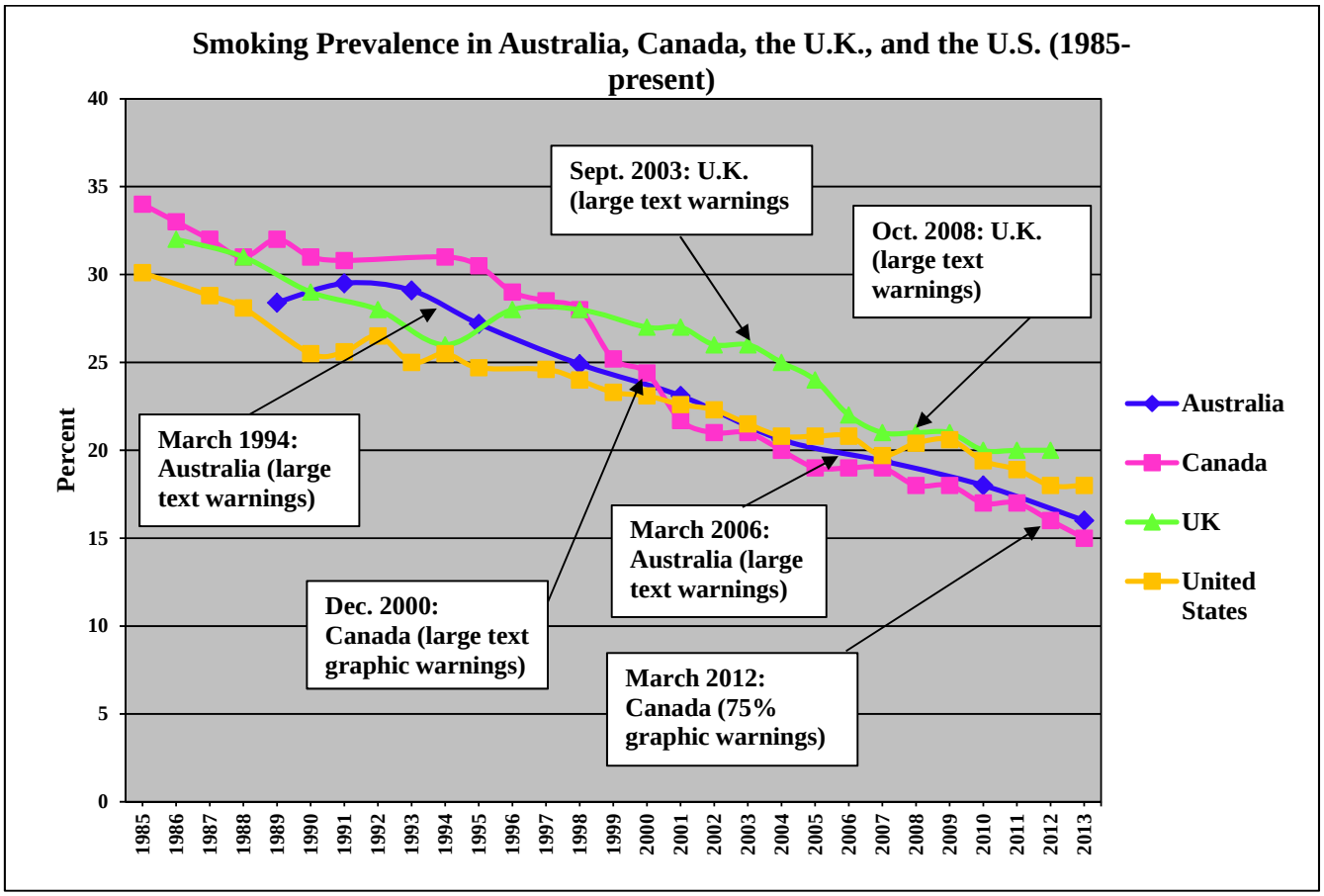
11. The United Kingdom previously employed large text warnings on cigarettes from September 2003 to October 2008. The warning on the front (30%) was one of the "general warnings" and the warning on the back of the pack (40%) was one of the "additional warnings." From October 2008, cigarettes in England were required to include graphic warnings on 40% of the rear of the pack and a text warning on 30% of the front of the pack.

12. Australia has employed similar warnings on cigarette packs since 1994. From March 1994 to March 2006, the Australian warnings were required to include large text (25% of the front of the pack, and 33% of the rear of the pack). Australia implemented large size graphic warnings beginning in March 2006. These graphic warnings were required to cover 30% of the front of the package and 90% of the back, so that overall 60% of the front and back panels of a pack was appropriated for warnings. The size of the graphic warning on the front of the pack was increased to 75% on Dec. 1, 2012.

13. Despite the presence of these large text warnings and/or large text and graphic warnings on cigarette packaging in Canada, the U.K., and Australia, there is no evidence that the presence of these warnings produced a reduction in smoking among adults or youth in those countries based on analysis of smoking prevalence in each country. Smoking prevalence has declined over time and will continue to decline for a variety of reasons unrelated to cigarette warnings such as higher product taxes. Thus, simply noting that the smoking rate has declined is not a valid test of the efficacy of warnings. The appropriate test for an effect of the new warnings is whether graphic warnings have produced an acceleration of the pre-existing downward trend in smoking prevalence.

14. Inspection of the smoking prevalence trends provides a test of whether there has been a shift in prevalence trends for any particular country, and also a test of whether there has been a shift relative to the prevalence rates in the U.S., where there are no graphic warnings in place. Figure 1 below demonstrates that there has been no such shift in prevalence rates after the introduction of graphic warnings either based on the within country trends or comparison to the U.S.

Figure 1. Smoking Prevalence in Australia, Canada, the U.K., and the U.S. by Year



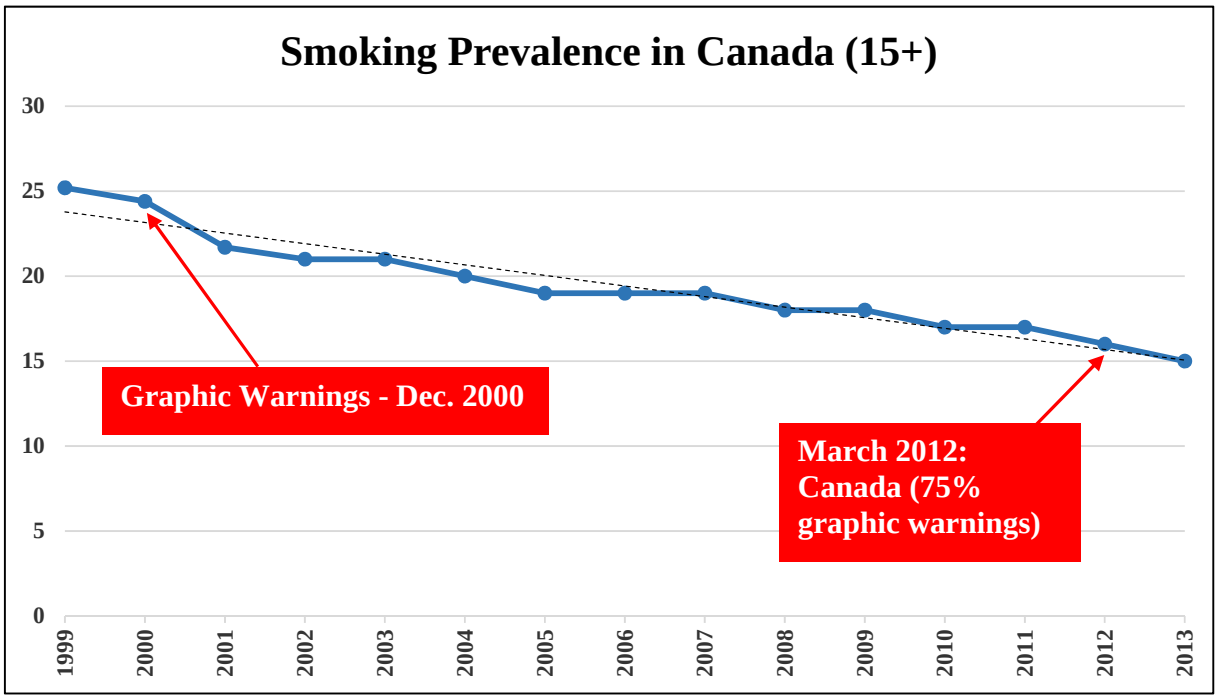
The smoking prevalence data for these countries were obtained from government sources. As indicated on the chart, these data include youth and adults.

15. In the case of Canada, which uses both large text, placed on the front and back of the pack, and graphic imagery regarding health effects of smoking, there is no apparent impact at all of the 50% graphic warnings or the increased size of these warnings to 75% on the pre-existing trend in smoking prevalence.

16. Figure 2 shows the smoking prevalence rates in Canada using a more consistent statistical series based on the 1999-2012 Canadian Tobacco Use Monitoring Survey (CTUMS) data and the Canadian Tobacco, Alcohol, and Drugs Survey, 2013 data. It

also indicates no evidence of an acceleration in the pre-existing smoking prevalence trend after the advent of the 50% graphic warning or the increased size of these warnings to 75%. The dashed trend line is based on a linear regression of the smoking prevalence rate against a time trend and a constant term.

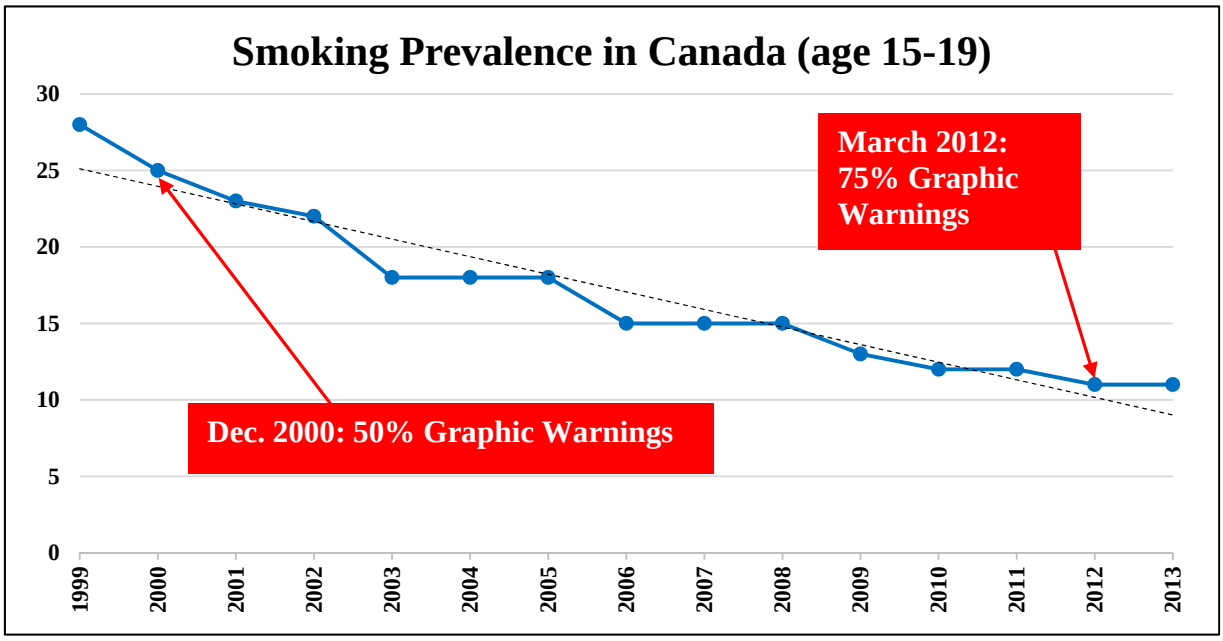
Figure 2. Smoking Prevalence in Canada (Ages 15+) by Year



17. The drop in smoking prevalence rates from 26% in 1999 to 16% in 2012 and 15% in 2013 reflects a steady downward trend. There is no apparent effect on smoking prevalence rates in Canada of either the 50% graphic health warnings or larger 75% graphic health warnings—despite having 14 years of data on smoking prevalence following the introduction of graphic health warnings.

18. A similar pattern is observed in Figure 3 for smoking prevalence rates since 1999 for the group that has exhibited a greater decline in smoking rates, those aged 15 to 19. Their smoking rate was 27.7% in 1999, which declined fairly steadily to 10.9% in 2012 and then to 10.7% in 2013. The 2013 smoking prevalence rate for those aged 15-19 reflects a continuation of past trends and is not even significantly different than the smoking prevalence rate before the advent of 75% graphic warnings. Figure 3 and the dashed trend line indicate this long run pattern.

Figure 3. Smoking Prevalence in Canada (Ages 15-19) by Year



19. The lack of any impact of these warnings in Canada—despite having 13 years of data on smoking prevalence following their introduction—vividly demonstrates simply assuming, on the basis of "common sense" or otherwise, that such warnings will reduce smoking, is unjustified based on real world experience.

20. The data from the U.K. and Australia shown in Figure 1 are consistent and again reflect that when large warnings were adopted there was no acceleration of the pre-existing downward trend in smoking prevalence. In fact, the U.K. data demonstrates a flattening out of the decline in smoking prevalence in the first year after the large text warnings were introduced in 2003 and again when graphic warnings were introduced in 2008. This pattern is telling, as one would expect based on the novelty of the modified warnings that the best evidence of impact would be in the short term immediately following their adoption. Thus, data from the three countries discussed above all reflect real world applications of graphic warnings, but there is no evidence that such warnings had any effect on smoking prevalence.

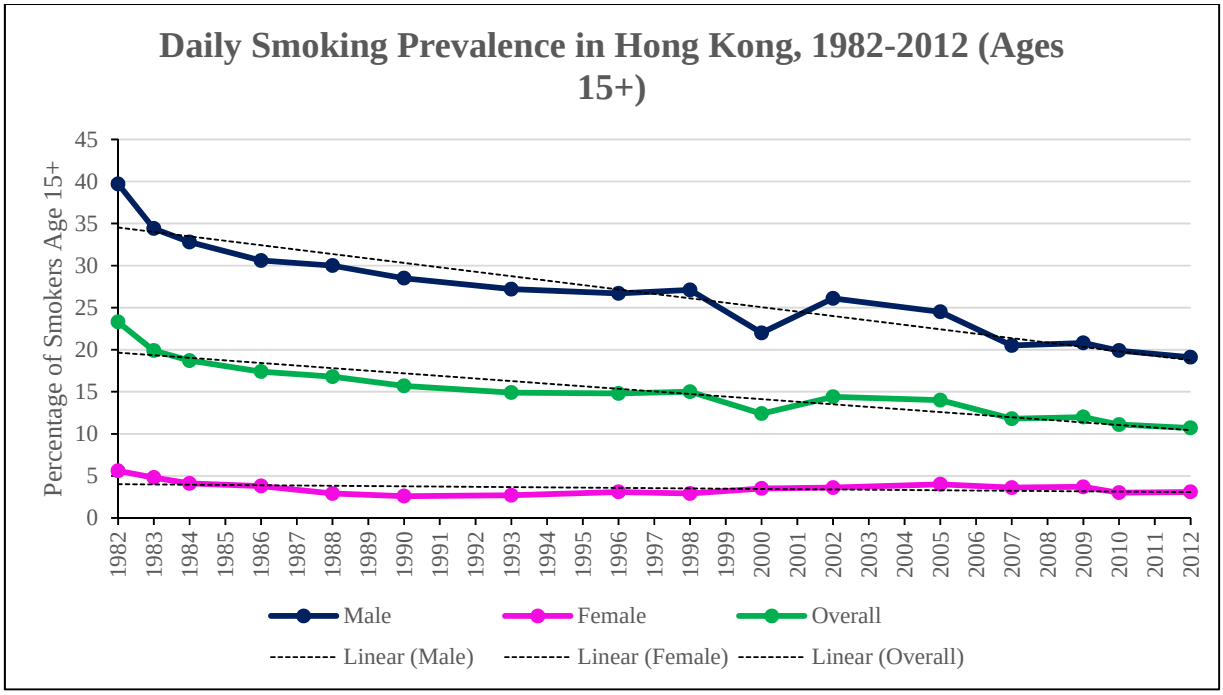
21. An earlier study by Gospodinov and Irvine (2004) used micro data from the Statistics Canada data set to assess warnings that they characterized as "gruesome" with large font vivid text messages plus images. Consistent with my analysis of the chart above, the authors concluded that the new warnings had no effect on smoking prevalence.

22. Likewise the Public Health Research Consortium (2010) for the U.K. Department of Health concluded that health warnings did not alter behavior even though they have been effective generally in reaching the public. Data for this study were based on a subsample for respondents to the Health Survey for England 2007/2008. Despite the visibility of the graphic warnings and evidence that the public had received the warnings, there was no fundamental change in risk beliefs or behavior after the advent of graphic warnings. More specifically, the report concluded: "The range and depth of knowledge about the health risks of smoking did not change after the pictures were introduced." The overall impact of the graphic warnings was limited. "There were very

few smoking-related behavior changes observed after the pictures were introduced." The warnings had a "negligible" impact on young people.

23. The introduction of 50% graphic warnings requirement in Hong Kong on October 27, 2007 similarly had no impact on reducing smoking prevalence. Figure 4 indicates trends in daily smoking prevalence for ages 15+ for males, females, and overall. In each case, the daily smoking prevalence rates follow the dashed linear trend line in a steady manner. There is no evidence of a break in the trend in 2008. For example, the overall daily smoking prevalence rate was 11.8 in 2007 and 12.0 in 2009.

Figure 4. Daily Smoking Prevalence in Hong Kong (Ages 15+) by Year

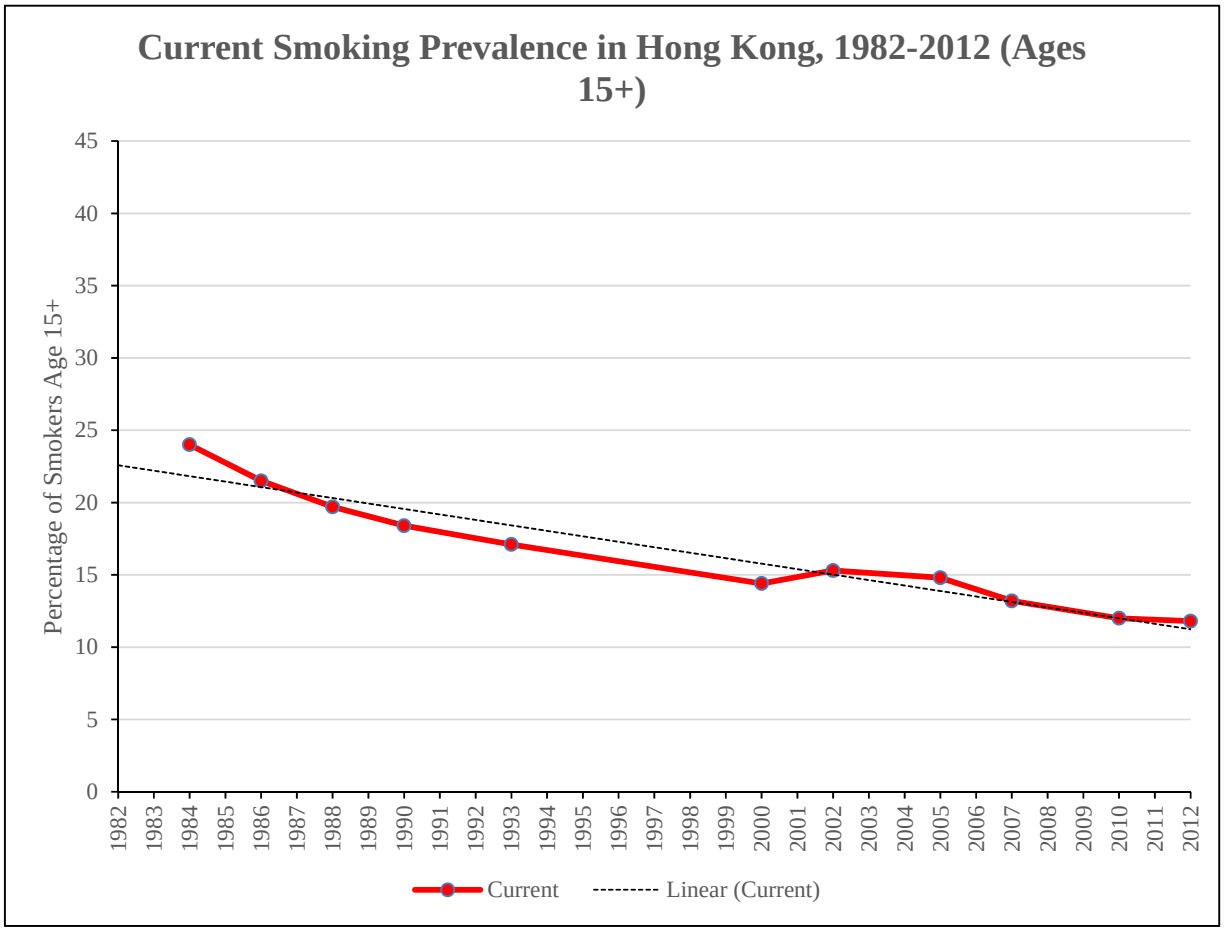


24. The lack of any effect that is apparent visually is also borne out in a formal statistical analysis. A regression of the smoking prevalence rate on a constant term, a time trend variable, and an indicator variable for the 2008-2012 post-graphic health warnings

period fails to show any statistically significant drop in daily smoking prevalence rates starting in 2008. Indeed, while the effect is not statistically significant, the results indicate a positive rather than a negative effect on daily smoking prevalence rates. These results continue to hold if the statistical analysis also accounts for changes in the level of cigarette duties. For all three daily smoking measures shown in Figure 4, there is no evidence that graphic health warnings have reduced smoking prevalence rates.

25. Figure 5 presents information on current smoking prevalence rates in Hong Kong, which is a more inclusive category than daily smoking prevalence. Current smoking prevalence rates include daily smoking and occasional smoking. The data series used to construct the current rates are drawn from different data eras. The patterns shown in Figure 5 indicate a steady downward trend throughout the 1982-2012 period, with no evident shift starting in 2008. Focusing on the consistent data series starting in 2000 also indicates a steady trend with no evident shift, as current smoking prevalence rates are 13.2% in 2007 and 12.0% in 2010, a difference that is consistent with the general downward trend. Formal statistical analysis using regression models indicates no statistically significant shift in smoking prevalence rates after accounting for the general trend. This absence of any impact also holds true after including the level of excise duties in the statistical analysis.

Figure 5. Current Smoking Prevalence in Hong Kong (Ages 15+) by Year



WHY GRAPHIC HEALTH WARNINGS DO NOT ALTER SMOKING PREVALENCE RATES

26. It is generally recognized that one of the most remarkable public health achievements of the last half century has been the communication of the risks of smoking to the public and the success of various cigarette warnings efforts in reducing smoking rates. In 1964, the US Surgeon General issued a report concluding that cigarette smoking was causally related to lung cancer in men. The report attracted widespread international attention, and was followed in subsequent years by numerous additional reports including reports by the US Surgeon General and the Royal College of Physicians in the United Kingdom

that considered the relationship between cigarette smoking and a myriad of specific illnesses and diseases, such as lung cancer, cardiovascular disease, and chronic obstructive lung disease. Similar information has been publicized in a variety of ways over the last several decades, including in schools and the news media, and by public health organizations.

27. The public, including youth are well informed about the risks of smoking. Statistics reflect the widespread exposure of the public to anti-smoking messages, and indicate universal awareness of the potential health consequences of smoking. Youth are often taught about the dangers of smoking in schools, and are targeted in media campaigns that warn of possible health risks.

28. Warnings on cigarette packets have reinforced the media coverage of smoking risks. Much of the effect of these warnings stemmed not from the wording or size of the warnings but from the fact that cigarettes were one of the first mass marketed consumer product to have safety warnings pertaining to inherent risks associated with the product. Once a warning has achieved noticeability, increasing the warning size or prominence does not have an influence on risk beliefs or smoking behaviors. Eventually there is diminishing marginal effectiveness of making any warning more prominent.

29. Awareness of the risks of smoking in Hong Kong is effectively universal. Mackay et al. (1986) notes that "[b]y the end of 1983, 95% of the population were not only aware of the government's publicity but also believed that smoking was harmful." Lam et al. (2002) also state "[t]he respondents' knowledge about the health risks associated with active and passive smoking and levels of experience of discomfort and symptoms from exposure to passive smoking was high. Ninety seven per cent agreed that smoking is

hazardous to health." The 2009 Global Youth Tobacco Survey (GYTS) data also establishes an overwhelming level of youth awareness that smoking is harmful, with 95.4 % of respondents answering 'Definitely Yes' (89.8% %) or 'Probably Yes' (5.6%) to the question 'Do you think cigarette smoking is harmful to your health?'.

30. Given that the public are aware of the risks of smoking, there is no beneficial informational role for increased warnings. In the absence of any effect of additional warnings on risk beliefs, one would not expect that warnings that reiterate what consumers already know would alter smoking behavior. It is well documented that reminder warnings do not alter consumer or worker behavior. Independent studies have also demonstrated that further attempts to modify consumer behavior are misguided if they are premised on the notion that people lack adequate information about smoking. The Surgeon General addressed this topic at some length in her 1994 report entitled "Preventing Tobacco Use Among Young People, A Report of the Surgeon General" ("1994 SGR"). There, the Surgeon General explained her conclusion as follows: "In the 1960s and early 1970s, strategies to prevent the onset of cigarette smoking were often based on the premise that adolescents who engaged in smoking behavior had failed to comprehend the Surgeon General's warnings on the hazards of smoking. The assumption was that these young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke." However, "[c]omprehensive reviews published at that time concluded that smoking-prevention programs based on the information deficit approach were not effective." Consequently, a wave of prevention programs developed in the late 1970s and throughout the 1980s

that fundamentally redefined the concept of adolescent smoking prevention. These smoking prevention programs "focus[ed] particularly on social influences, norms, and skills training." According to the Surgeon General, "[o]nly the social influence approaches have been scientifically demonstrated (through replicated research studies) to reduce or delay adolescent smoking." The 2012 Surgeon General report updates these assessments and reiterates this position.

31. Studies also demonstrate that applying different warning formats (e.g., use of warning colors, safety symbols, signal words, etc.) to information does not increase behavioral compliance. Bolder warnings do not convey unknown information and telling people something that they already know in **bold** letters or **LARGE TYPE FACE** or with graphics does not change that. There is no empirical evidence that "shouting" works in increasing behavioral compliance in this context.

32. A substantial literature also demonstrates that factors other than a lack of awareness of the risks of smoking are the main determinants of smoking initiation. The causes of youth smoking have been the subject of two reports by the U.S. Surgeon General as well as dozens of studies throughout the world. As the review below indicates, the key contributing factors to smoking initiation by youths are influences involving one's parents, siblings, friends, peers, access to cigarettes, personal characteristics, and cost.

33. The U.S. Surgeon General (1994) report listed factors driving initiation such as low socioeconomic status, peer and sibling use and approval of tobacco, lack of parental support, low levels of academic achievement, and low self-image. The more recent U.S. Surgeon General (2012) report reiterated these themes and added emphasis on the high accessibility and availability of tobacco products, such as obtaining tobacco products

from parents, siblings, or peers. More generally, parental support, social norms, use by friends, and religion are among the other causal factors cited.

STUDIES BY THE U.S. FOOD AND DRUG ADMINISTRATION

34. To test for the likely effect of graphic warnings, the U.S. FDA undertook two types of studies assessing the effect of graphic warnings. The first line of inquiry consisted of statistical analyses of the effect of graphic warnings on smoking prevalence rates in Canada. The other approach used was a large scale experimental study of the effect of different types of graphic warnings. Neither type of study indicated that there would be an effect of graphic warnings on smoking behavior. These studies provide no evidence to support a claim that merely increasing the size of existing graphic warnings from 50% to 85% would have a beneficial effect on smoking behaviors.

35. The first set of studies analyzed smoking prevalence trends as illustrated above and tested statistically whether the Canadian graphic warnings reduced smoking prevalence rates. The FDA undertook two such statistical studies, a 2010 study that ignored changes in cigarette tax rates and a 2011 study that incorporated recognition of the effect of cigarette taxes on smoking prevalence. Neither of these studies succeeded in demonstrating any effect of graphic warnings in Canada.

36. The 2010 study by the FDA used the U.S. smoking prevalence trends as a reference point for what trends in Canada would have been in the absence of graphic warnings. The FDA found in its preferred analysis that graphic warnings reduced smoking prevalence rates by 0.212 percentage points from 2001-2008 as compared to 1999-2000. If the trends in the U.S. are ignored, then the graphic warning level effect could be 1.648 percentage points, but the FDA did not consider this to be a valid statistical test and, as

in the case of the lower estimate, one could not reject the statistical hypothesis that there was zero effect of the graphic warnings. The FDA concluded that the "effectiveness estimates are in general not statistically distinguishable from zero."

37. Although the 2010 study took into account smoking trends, it ignored changes in the price of cigarettes, which may have been related to other changes in cigarette policies. Thus, even these studies indicating a zero effect of graphic warnings may have overstated the efficacy of graphic warnings. In 2011 the FDA updated its analysis to account for cigarette tax changes, finding an estimated effect of graphic warnings of 0.574 percentage points in a comparison of 2001-2009 to 1994-2000 if the analysis ignores the U.S. smoking trends. However, if both taxes and the U.S. experience are included as controls, which the FDA indicates is the FDA's "preferred estimation method," then the estimated effect of graphic warnings is 0.088 percentage points. The FDA is correct in preferring a statistical approach that accounts for cigarette tax changes and accounts for U.S. smoking trends so as to control for what Canadian trends would have been without the graphic warnings. After making these adjustments, the FDA estimates that the effect is less than one-tenth of a percentage point. Not surprisingly, the FDA concluded that their "effectiveness estimates are in general not distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule [requiring graphic warnings] will not change the U.S. smoking rate."

38. As a second level of analysis the FDA commissioned a survey to measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels (the **"FDA Study"**). The FDA Study included approximately 18,000 participants and is the largest survey of stated consumer responses

to cigarette graphic health warnings ever conducted. This study tested the relative efficacy of 50% graphic warnings relative to a control of a text warning statement only. The control group viewed a pack of cigarettes with just a text warning statement presented on the side of the packet in accordance with the current standard warning on cigarette packets in the US. The treatment groups (exposed to warning images) viewed a hypothetical pack of cigarettes that included the graphic warning label. The FDA Study failed to find a consistent pattern of significant effects on risk beliefs for a wide variety of possible graphic health warnings. Notably, the authors concede that *"[t]he graphic cigarette warning labels did not elicit strong responses in terms of intentions related to cessation or initiation."*

39. The study design is less informative than examination of smoking prevalence trends for a number of reasons. The study presented respondents with computer images of different graphic warnings and compared their smoking attitudes and stated smoking intention responses to those elicited without the use of graphic warnings. This design does not in fact measure actual behavior (e.g., quitting smoking) following exposure to these messages. Rather, it employs a proxy measure—stated intention to quit—that is known to be unreliable and inaccurate and that undoubtedly overestimates actual behavior. Many smokers who indicate an intention to quit make no effort to do so. This may be attributable to social-desirability bias associated with questions pertaining to this and similar subjects. Consequently, quit intentions such as this tend to significantly overestimate the number of smokers who actually intend to quit as a result of the proposed warning. There was no effort to account for this bias other than to acknowledge it.

40. The researchers did not take advantage of the opportunity to see if people actually changed their behavior after seeing the graphic warnings. Interestingly, even though respondents were re-contacted a week after as part of the study, those who indicated previously that they intended to quit were not asked if they had in fact taken any steps to do so.

41. Putting aside these methodological limitations, it is clear from the data that these warning labels were ineffective at increasing smokers' stated intentions to quit. The study considered nine different cigarette warnings for which the study examined an average of four different graphics approaches for each warning. The consistent result was that irrespective of the warning or the graphic illustration accompanying it there was no evident effect on quit intentions or other smoking-related behaviors for any of the sample groups.

42. Finally, this study also sought to assess the impact of the proposed graphic warning labels on discouraging smoking initiation among youth respondents. Even accepting the research design at face value, the FDA Report concluded that the data do not support the conclusion that exposure to the graphic warning labels will discourage smoking initiation. ("*For youth, we used a measure of how likely [they] felt they were to be smoking 1 year from now as a measure of the impact of viewing the warning images on potential initiation. We did not find much evidence for an impact of the warning labels on this outcome.*"). This study failed to find any demonstrable impact of graphic warnings over and above text warnings, on intentions related to smoking initiation or cessation. Given these outcomes, it cannot be expected that merely increasing the size

of existing graphic warnings from 50% to 85% would have any impact on smoking behaviors.

43. Notwithstanding that its own analysis and study did not find any support for the effectiveness of proposed graphic warnings, the U.S. FDA proceeded to introduce the warnings. However, the U.S. courts overturned this regulation in 2012, finding that the proposed graphic warnings were unconstitutional. The U.S. Court of Appeals for the D.C. Circuit concluded, as I did in my discussion above, that there is a consistent lack of evidence in support of the efficacy of graphic warnings based on the results of either FDA's major survey of different graphic warnings approaches or its statistical analysis of the Canadian graphic warnings experience. The Court stated:

> "FDA has not provided a shred of evidence—much less the ''substantial evidence'' required by the APA [Administrative Procedures Act]—showing that the graphic warnings will ''directly advance'' its interest in reducing the number of Americans who smoke. FDA makes much of the ''international consensus'' surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, Proposed Rule at 69,532, and FDA might be correct that intentions are a ''necessary precursor'' to behavior change, Final Rule at 36,642, it is mere speculation to suggest that respondents who report increased thoughts about quitting smoking will actually follow through on their intentions. And at no point did these studies attempt to evaluate whether the increased *thoughts* about smoking cessation led participants to actually quit. Another Australian study reported increased quit *attempts* by survey participants after that country enacted large graphic warnings, but found ''no association with short-term quit success.'' Proposed Rule at 69,532. Some Canadian and Australian studies indicated that large graphic warnings *might* induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent. *See id.* But again, the study did not purport to show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates.
>
> FDA's reliance on this questionable social science is unsurprising when we consider the raw data regarding smoking rates in countries that have enacted graphic warnings. FDA claims that Canadian national survey data suggest that

graphic warnings may reduce smoking rates. But the strength of the evidence is underwhelming, making FDA's claim somewhat misleading. In the year prior to the introduction of graphic warnings, the Canadian national survey showed that 24 percent of Canadians aged 15 or older smoked cigarettes. In 2001, the year the warnings were introduced, the national smoking rate dropped to 22 percent, and it further dropped to 21 percent in 2002. *Id*. at 69,532. But the raw numbers don't tell the whole tale. FDA concedes it cannot directly attribute *any* decrease in the Canadian smoking rate to the graphic warnings because the Canadian government implemented other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking, during the same period. *Id*. Although FDA maintains the data ''are suggestive'' that large graphic warnings ''may'' reduce smoking consumption, *id*., it cannot satisfy its First Amendment burden with ''mere speculation and conjecture.'' *Rubin*, 514 U.S. at 487, 115 S.Ct. 1585.

FDA's Regulatory Impact Analysis (''RIA'') essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates….In light of the number of foreign jurisdictions that have enacted large graphic warning labels, the dearth of data reflecting decreased smoking rates in these countries is somewhat surprising, and strongly implies that such warnings are *not* very effective at promoting cessation and discouraging initiation."

FINDINGS IN THE PUBLIC HEALTH LITERATURE

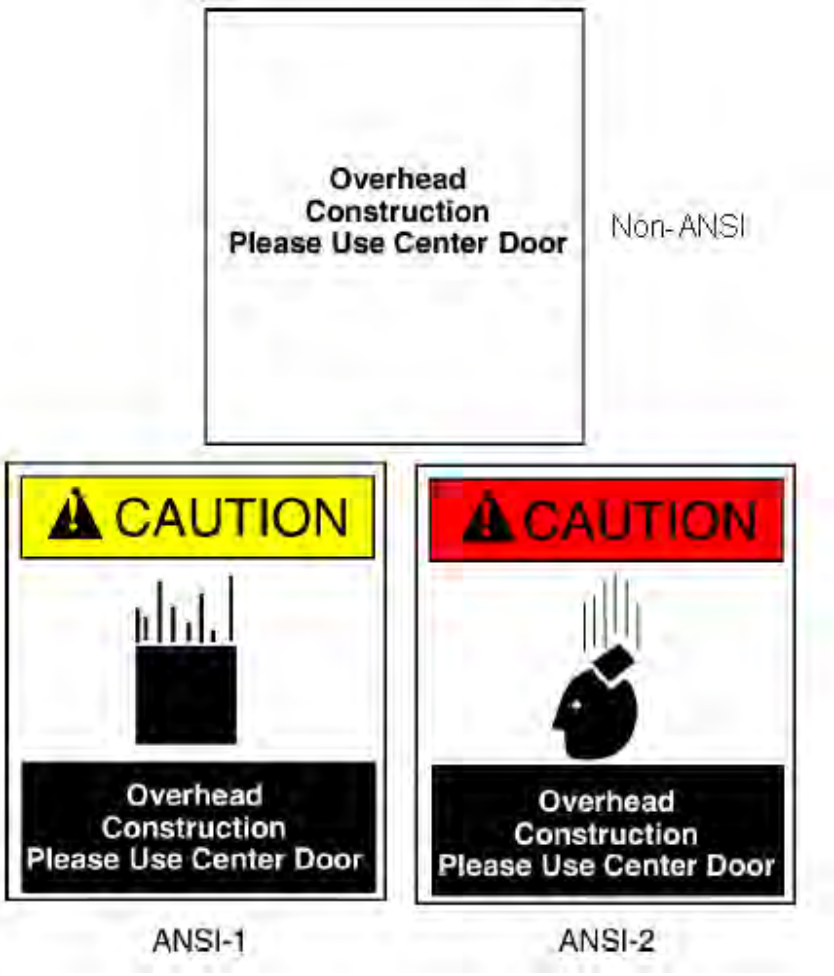
44. There have been numerous articles that have attempted to assess the effect of graphic warnings on smoking behavior and which have asserted, without sound empirical support, that graphic plus text warnings are significantly more effective than text only warnings in influencing consumer behavior.

45. The 2012 report by the U.S. Surgeon General provides an overview of the studies of what the report terms "pictorial health warnings" related to cigarettes. There are two principal questions with respect to assessing the efficacy of such warnings. First, do graphic warnings communicate the risks more effectively than text only warnings and alter risk beliefs? Doing so is presumably a prerequisite to altering behavior. Second,

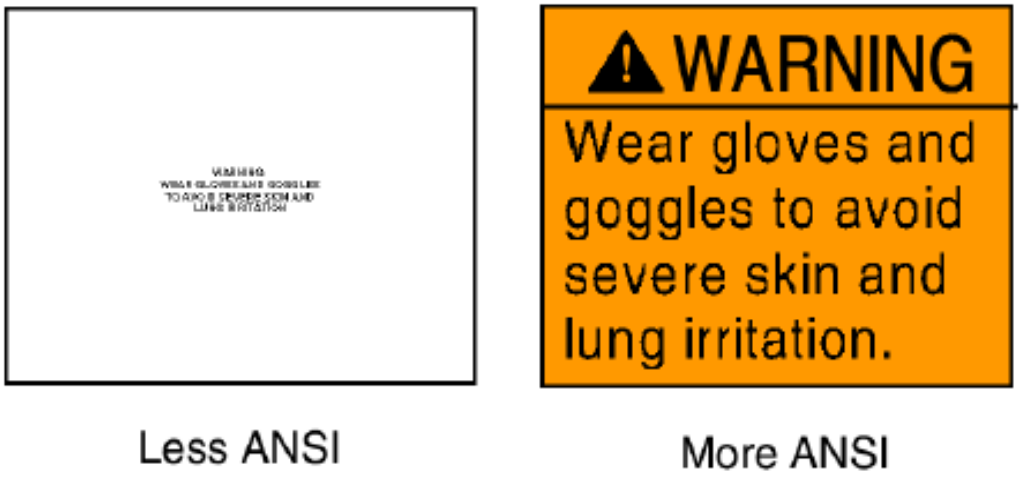
do graphic warnings lead to changes in smoking related behavior by fostering smoking cessation and decreasing smoking initiation?

46. The types of evidence in the literature that is reviewed by the U.S. Surgeon General do not address either of these questions in a meaningful way. With respect to risk beliefs, the U.S. Surgeon General relies on studies where respondents in focus groups and other survey contexts report that they thought that graphic warnings were more likely to be noticed, thought about and more likely to be recalled, and communicated the risks better. But none of these subjective responses indicates that graphic warnings actually altered risk beliefs with respect to cigarettes more than do warnings without pictorial information. Moreover, informal focus group and survey evidence of this type is subject to serious "demand effects," whereby the respondent gives the answer that he or she believes the survey administrator or the focus group leader wants to hear. Asking respondents if they thought graphic warnings would affect their beliefs is not a substitute for determining whether graphic warnings actually alter beliefs.

47. Further, studies demonstrate that survey respondents' predictions of the impact of warnings are unreliable and that people dramatically overstate the likelihood of compliance with warnings. For example, Frantz et al. (2005) examined the extent to which predicted responses to different warnings signs and labels correspond with actual responses. Participants were shown a pair of warnings for: (1) car sun visor labels for lap belts, (2) file cabinet tipping labels, (3) construction hazard signs, and (4) laboratory warning signs. For example the construction hazard signs shown to participants were:



And the two laboratory warning signs shown to participants were:



48. These signs had the same general message wording but were formatted very differently (with a text only sign that that was less consistent with ANSI (the American National Standards Institute) and ANSI-style signs with bolder larger text, color and symbols). Participants were asked to predict how many people, out of 100, would (a) notice the signs and (b) comply with the warnings. The results showed that most participants thought the ANSI-style signs would elicit significantly greater compliance than the 'Non ANSI' or 'Less ANSI' signs. However, results showed no difference between the signs regarding compliance rates. The authors concluded that: *"[t]he present study generally replicated the findings of Laughery et al. (2002) for participants' predictions of the extent to which people would notice and/or comply with warnings. Participants in the present study consistently and incorrectly reported that people would be more likely to notice and more willing to comply with warnings that had greater conformance to ANSI as opposed to less. The present study shows that these ratings have little or no utility in predicting people's actual behavior in response to the warnings.*"

49. The second and more fundamental issue pertaining to graphic warnings studies is whether they demonstrate that there will be concrete, demonstrable effects on smoking behavior. The studies reviewed by the U.S. Surgeon General do not consider any behavioral changes. Rather the studies report that respondents indicate that after being shown graphic warnings they "thought about quitting and forgoing cigarettes," stated that they had "increased motivation to quit smoking," or that an "intention to smoke was lower among those students who had talked about the warning labels and had forgone cigarettes." Unlike the FDA study, most of these studies do not compare the efficacy of graphic warnings to similar warnings without the pictorial information so that the

experiments are not designed to provide a proper test of the graphic warnings component. In addition, stated quit intentions in surveys and stated intentions to not start smoking are quite different matters than actual behavior, and none of the studies document any behavioral consequences of graphic warnings.

50. Other studies that deal with the effect of graphic warnings on smoking risk beliefs and behaviors have similar limitations to those reviewed by the U.S. Surgeon General. With respect to smoking risk beliefs, such studies rely on smokers' perceptions of the effectiveness of graphic warnings without documenting any change in risk beliefs induced by warnings or indicating the effect of graphic warnings relative to comparable text only warnings. Studies pertaining to smoking behavior adduce evidence consisting of subjective inferences and self-reports, which are no substitute for empirical evidence of whether graphic warnings have actually been effective in changing smoking behaviors. Some studies have offered evidence that calls to smoking toll-free helplines increased after contact information was included in the warnings as evidence of efficacy in altering cessation, but no studies have provided a link between these calls and cessation behavior.

51. A tobacco-related study that documents the role of informational saturation with respect to the size of cigarette warnings is the study by Bansal-Travers et al. (2011). Respondents addressed the question of which cigarette they would buy if they were trying to reduce the risk to their health. The percentage choosing cigarette packages with different warning labels was 34 percent for warnings comprising 30 percent of the label, 11 percent for warnings comprising 50 percent, and 53 percent for the warning comprising 100 percent of the label. This U-shaped pattern of concern for averting risk

and its relation to the percentage of warning on the pack implies that there is no consistent relationship at all between the amount of warning information and choices based on health risk. And once again, the study's focus avoids the more fundamental issue of whether increasing the warning label's percentage significantly affects whether the warning is read, understood, and leads people to have more accurate risk beliefs. And if there are such effects, will they be observed for regular smokers rather than in a one-time experiment?

52. A rationale often made for new warnings policies is that warnings policies are subject to a "wear-out effect." That is, over time, people read the warnings less frequently. In terms of the theory of hazard warnings that type of behavior is exactly what one expects, but it does not indicate a failure of the warnings policy. Once a person has read and acquired the information, it is not necessary to reread the information repeatedly in order to understand the information. Failing to reread the warning does not imply that the person does not know the information included in the warning. Moreover, if the objective is to only deal with such a "wear-out effect," that can be accomplished by a change in the warning message. Increasing the size of the warning from 50% to 85% is not needed and will not have any improved benefit in terms of reducing smoking rates.

53. It is also often claimed that that consumers do not have an adequate perception of specific health risks. However, such concerns can be met by changing the current warning content and do not require increasing the size of the warnings.

CONCLUSION

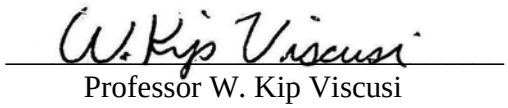
54. The available evidence on the efficacy of graphic warnings is substantial and provides a consistent basis for assessing the impact of graphic warnings. Overall, there is a

profound gap between the claims of efficacy of graphic warnings and evidence of actual impacts. Studies in the literature in support of graphic warnings have relied on subjective reports of assessments of the warnings, claims of likely effects on behavior, and study designs that generally fail to compare the graphic warnings to a text only counterpart. Moreover, even if the reported effects are taken at face value there is no way to translate this evidence into a predicted effect of graphic warnings.

55. The best evidence on the effect of graphic warnings should rely on actual policy impacts rather than hypothetical or experimental effects. Because graphic warnings policies have been in place in many countries, undertaking such an assessment is feasible. Examination of the effect of graphic warnings in Canada, Australia, and the U.K. indicates that there has been no effect on the trend in smoking prevalence rates. Additionally, a statistical analysis of the Canadian data by the U.S. FDA found that any effects of graphic warnings cannot be distinguished statistically from a zero effect. The introduction of graphic warnings in Hong Kong in 2007 has similarly had no impact on reducing smoking prevalence. The continued downward trend in smoking prevalence rates in Hong Kong is similar to that in the U.S., which has no graphic health warnings and only smaller text warnings. Graphic health warnings and larger warnings do not enhance the efficacy of warnings in influencing smoking prevalence rates.

56. However, if there are concerns regarding the current warnings being worn out and lower levels of awareness of specific illnesses, these can be met by changing the current warning content. Increasing the size of the warnings is not needed and will not have any improved benefit in terms of reducing smoking rates.

57. The U.S. courts concluded that there is not "a shred of evidence" indicating that larger graphic cigarette warnings will be effective in reducing smoking prevalence. There is no sound basis in experimental data, survey data, or data on smoking behavior to conclude that larger graphic warnings are more effective in increasing risk awareness or reducing smoking behavior. It cannot be expected that merely increasing the size of existing graphic warnings from 50% to 85% would have any impact on smoking behaviors.



Professor W. Kip Viscusi

Expert Report of Professor Philip Zerrillo, Ph.D.

Hong Kong

June 18, 2015

TABLE OF CONTENTS

Expert Report of Philip Zerrillo, Ph.D.

I. Introduction

A. Qualifications

1. My name is Philip Zerrillo. I am a Full Professor in the Marketing department at Singapore Management University. In addition, I have several other responsibilities at the university. I am the Dean of Post Graduate Professional Programmes, in which I develop, administer and govern graduate degree programmes in the areas of Business, Economics, Law, Accounting, Social Sciences and Information Systems. Additionally, I am the Executive Director of the Center for Practice Management, the Academic Director of the PhD in General Management, and the Executive Director and founder of the university's case writing initiative. I am also the Vice Dean of the Lee Kong Chiang School of Business.

2. I am also Executive Chairman of the Board for the Masters in Marketing (MIM) programme at Thammasat University in Thailand. I have taught graduate level courses in marketing channels and marketing strategy for 17 years in this programme. I also teach a doctoral level seminar on teaching effectiveness at Thammasat University, and am a member of the board of directors for the School of Accountancy and Commerce.

3. I am the Dr. Bienvenido Tontocco, Distinguished Chaired Professor in Retailing, at Jose Rizal University (Philippines).

4. Previously, I was a Visiting Professor at the J.L. Kellogg Graduate School of Management of Northwestern University, where I taught courses on marketing management, distribution channel management and marketing strategy. Before that, I served as the Associate Dean and Director of Executive Education at the McCombs School of Business and the Graduate Dean and Director of Graduate Studies at the college. In addition, I have taught at numerous other universities, internationally in Asia, Europe, the Middle East and the United States.

5. My field of expertise is marketing and in particular managerial marketing as it is applied in the field. I have taught graduate school courses in many management and marketing subjects, including branding and brand management. In these courses I have covered topics such as brand value, creation of new brands, brand competition, pricing, and strategy.

6. I hold a Ph.D. in Marketing from Northwestern University's J.L. Kellogg Graduate School of Management, and an undergraduate degree from The University of Texas (BBA). After my undergraduate studies I spent seven years in the finance industry, before entering the Ph.D. program. This background has given me practical insights into the financial performance of the marketing and branding functions of firms. True to this

background, much of my post graduate professional work has focused on market actions and their impact on the financial performance of firms.

7. I am a member of the Board of Directors of Sharps Compliance (NASDAQ: SMED) and have been since 1998. In my role as a board member I am currently chairman of the audit and governance committees.

8. I have consulted with numerous firms in areas such as hi-tech, oil and gas, consumer electronics, internet, metal fabrication, health and fitness, tobacco, alcohol and consumer packaged goods. I have conducted, supervised, evaluated or reviewed a great number of marketing research studies in my various roles as thesis supervisor, Ph.D. advisor, ad hoc reviewer for The Journal of Marketing and The Journal of Marketing Research and as a consultant to industries.

9. Further information about my academic and professional qualifications is provided by my curriculum vitae in Appendix A.

B. Scope of Assignment

10. I have been asked by British American Tobacco Company (Hong Kong) Limited ("**BAT (HK)**") to submit this report describing the importance of trademarks and the brands that they represent, and how they affect consumers, manufacturers, competition in the marketplace, and international trade. I have been asked in particular to opine upon the ramifications to trademarks and brands that will result from the proposed regulation to increase the size of the graphic health warnings (hereinafter "GHWs") on cigarette packages in Hong Kong to cover 85% of the package surface area, and the resulting impact on consumers, manufacturers and the marketplace. In particular, I have been asked to examine these issues in the context of Hong Kong where brand communication is highly restricted, including an extensive ban on tobacco advertising and sponsorship, and GHWs already occupy 50% of the cigarette package surface area.

11. To write this report, I have relied upon my own expertise in marketing and branding (described above). I also have reviewed and considered a wide range of authoritative writings on marketing and branding by experts in the field. Appendix B lists the materials that I considered in the course of my investigation. This report contains my findings and opinions as of the submittal date.

C. Summary of Opinions

12. It is my expert opinion that:

a) Trademarks (such as words, logos, images, designs or combination of these elements) and packaging are vital to brands.

b) Trademarks perform valuable functions for both consumers and the firms that own them. A trademark identifies the brand and differentiates the product performing important navigation and reassurance functions for consumers. It signals the source or origin of the product and, as such, aids the consumer's navigation among competing products. Trademarks also symbolize a product's quality and features, and guarantee that the goods or services measure up to expectation. The existence of trademarks, and the brands they represent, is particularly important for effective market competition, as they enable firms to uniquely identify and differentiate their products other than on the basis of price alone. For manufacturers, the protection of the intellectual property rights afforded to trademark owners means that the firm can invest in the trademark and the associated brand with confidence. In addition to the firm's ability to obtain the benefits of its valuable asset sustained over time, it provides an incentive for the firm to create greater value for all stakeholders including consumers.

c) Increasing the size of GHWs to cover 85% of the cigarette packages will make it impossible for manufacturers to use some trademarks as registered (including logos and labels) and for them to use other trademarked elements effectively. Trademarks will not be able to adequately serve their essential functions of differentiating products and uniquely identifying their origin and quality.

d) In Hong Kong, the extensive ban on advertising and sponsorship of cigarettes means that the limited space available on cigarette packs for trademarks is the only tool manufacturers have to identify and differentiate their products from other competitive offerings. A further reduction in this already limited space will minimize or even eliminate any meaningful use of trademarks and, in doing so, destroy their value. As a result, decades of investment in brands and their related trademarks, along with their inherent goodwill, will be lost.

e) Brands including trademarks play an important role in the cigarette market, and their erosion or elimination changes the nature of the market. In general, markets without brands become price-driven commodity markets.

f) Commodity markets produce lower prices that encourage more consumption. Commodity markets also make the market inhospitable to firms trying to enter the market and for existing brands, particularly small brands, to compete for a greater market share. Commoditization of the cigarette market in Hong Kong and a shift to pure price driven competition could also lead to an increase in illicit trade because without the added value of brands, legitimate products will be less clearly differentiated from illicit products.

g) Ultimately, in a commoditized cigarette market in which consumers are price sensitive and the ability to identify the products of a firm is severely limited, the incentives to invest in better quality or better service will be reduced.

h) Moreover, firms that do not have a well-known brand would be incentivized to compete only on price and reduce the quality of their goods, ultimately affecting the consumer. The relationship between consumers and their brands is a very important means to incentivize manufacturers to honor that relationship and not behave in a purely transactional manner.

II. The Context of Packaging Regulation in Hong Kong

13. I have been given to understand that almost all forms of tobacco adverting are banned in Hong Kong under the Smoking (Public Health) Ordinance (Cap. 371) (the "**Ordinance**"). This ban covers a broad range of advertising channels including print, radio, television, the Internet, and promotional activities such as free samples or gifts. Additionally, it is my understanding that under the Smoking (Public Health) (Notices) Order (Cap. 371B) (the "**Order**"), all cigarette packages and retail containers must bear a health warning and tar and nicotine yields. This warning is required to cover at least 50% of the two largest surfaces.

14. In light of these prohibitions and the restrictions under the Ordinance and the Order, it is clear that the law in Hong Kong already severely restricts the ability of manufacturers to use their trademarks in order to differentiate their brands and communicate with consumers. In fact, one of the only forms of communication available to manufacturers under the present law, though limited, is the display of their trademarks on the tobacco package itself.

III. British American Tobacco Trademarks

15. I am advised that BAT (HK) is the proprietor or licensee in Hong Kong of the trademarks associated with the CAPRI, CASTAN, DUNHILL, HILTON, WINFIELD, VICEROY, PALL MALL, KENT, SHUANGXI, STATE EXPRESS 555 and LUCKY STRIKE cigarette brands as visible on the cigarette package or cartons of cigarettes sold in Hong Kong. These trademarks include words, stylized labels, and full pack marks, including words, signatures, crests, logos colors and designs. I have been advised that the following are examples of some label and full pack trademarks for BAT (HK) products sold in Hong Kong.

Figure 1: Label and Full Pack Registered Trademarks of BAT (HK) Products Sold in Hong Kong

IV. Introduction to Brands and Trademarks

A. The Function of Trademarks and Brands

16. Trademarks are a type of intellectual property. A trademark is a legally protected "sign," such as a name, word, phrase, graphic, logo, image, design or combination of these elements, that acts to exclusively identify to consumers the source of the product and differentiate it from the competition.[1] It may consist of words, designs, letters, numerals or the shape of goods or their packaging.[2] The owner of the trademark has the exclusive right to affix the trademark to units of the product and to use the trademark in its communications. As such, trademarks are essential components of brands because they are the outward representation of the brand to consumers.[3]

17. In fact, some definitions of "brand" are almost indistinguishable from the definition of "trademark." For example, the American Marketing Association defines a brand as a "name, term, sign, symbol, or design, or a combination of them, intended to identify the goods and services of one seller or group of sellers and to differentiate them from those of competition."[4] Trademarks are really not exactly the same thing, but rather

---

1 Helmers, Christian and Mark Rogers (2010), "Trademarks and performance in UK firms," in da Silva Lopes, Theresa and Paul Duguid (editors), *Trademarks, Brands and Competitiveness*, Routledge, page 56.

2 Fogg, Janet (1998), "Brands as intellectual property," in Hart, Susannah and John Murphy, *Brands: The New Wealth Creators.* New York: New York University Press, page 72.

3 Aaker, D. A., (1991), *Managing Brand Equity*, New York, NY: The Free Press, page 21.

4 http://www.marketingpower.com/_layouts/dictionary.aspx?dLetter=B

trademarks are a crucial component of brands.[5] Many brands are based on a combination of several trademarked elements[6] that identify and differentiate one owner's product(s) from a similar offering by competitors.[7]

18. Therefore, brands and the trademarks associated with them play important roles in the marketplace. They help consumers navigate through the available choices in a product category and can provide a measure of reassurance about product quality, contents, origin and relative price. In sum, trademarks, as signals of the brand, have three important functions that combine to provide the consumer with a level of assurance:

    - "To distinguish the goods or services of one business from those of another
    - To indicate the source or origin of the goods or services
    - To serve as an indication of consistent quality…."[8]

19. Because visual identity is so important to brands, trademarks and other forms of intellectual property, such as patents and unique package design, are among a company's most valuable assets.[9] Accordingly, the protection of trademarks and other intellectual property is vital to maintaining the value of the brand[10] and protecting investment and business goodwill.

20. A strong visual identity can act as a type of shorthand expression of the brand and its features. Strong visual identity is apparent in the trademarked logos presented in Figure 2. These trademarked images combine the company's name (or, in some cases, initials which have come to stand in for the name) with a distinctive colored logo that are recognized globally.

21. Moreover in the case of fast moving consumer goods such as cigarettes, the package and trademark serve as the only point of purchase assurance to the customer that the product inside is reputable, and that the producer of that product is identifiable and potentially honorable.

---

5 Aaker, D. A., (1991), *Managing Brand Equity*, New York, NY: The Free Press, page 21.

6 Lindemann, Jan. (2010), *The Economy of Brands*, Palgrave MacMillan: 2010, page 7.

7 Murphy, J.M. (1990), *Brand Strategy*, Cambridge: Director Books, page 2.

8 Fogg, Janet (1998), "Brands as intellectual property," in Hart, Susannah and John Murphy, *Brands: The New Wealth Creators.* New York: New York University Press, page 72.

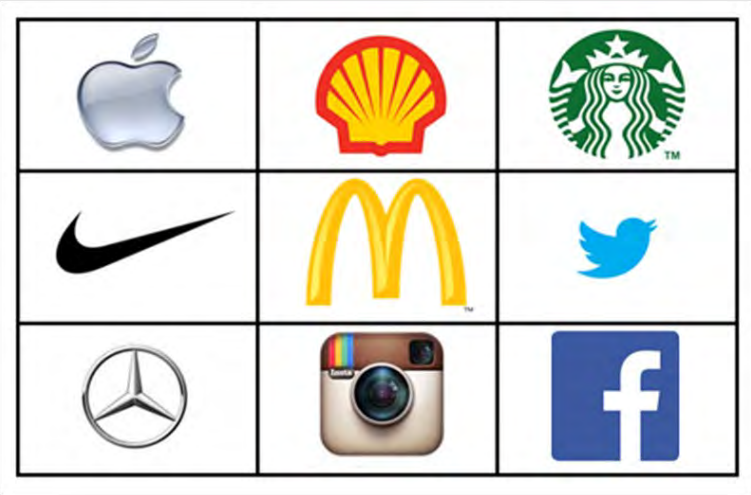
9 H.M. Meyers and M.J. Lubliner, The Marketer's Guide to Successful Package Design, Chicago: American Marketing Association/NTC Business Books, 1998, p. 191.

10 Fogg, Janet (1998), "Brands as intellectual property," in Hart, Susannah and John Murphy, *Brands: The New Wealth Creators.* New York: New York University Press, page 81.

Figure 2: Logos Combine the Company Name with a Distinctive Graphic to Represent the Brand

22. In some cases, the logos are so widely recognized that the brand name is not even necessary. For example, both Twitter and Starbucks have recently dropped the brand name from their iconic logos. Figure 3 shows examples of global brands whose trademarked pictures are so ubiquitous that they communicate the brand's identity without words.

Figure 3: Graphic Logos Can Evoke the Brand in the Customer's Mind without the Use of Words



23. Other brands use trademarked "wordmarks" (also known as "logotype") to give their brands strong visual identity across media. Figure 4 presents some highly-recognizable wordmarks.

Figure 4: Wordmarks or Logotype Designs are Stylized Versions of Brand or Company Names at a Glance

24. Figure 5 below shows some examples of Hong Kong brands that are recognized widely, even outside of Hong Kong.

Figure 5: Iconic Hong Kong Trademarks that are Widely Recognized

B. Effective Packages are Critical to Brand Awareness and Differentiation

25. Well-designed packaging with distinctive trademarked features plays an important role in brand identification and differentiation particularly in a market such as in Hong Kong where packaging is the last means of communication. The design of a product package is critical to the creation and maintenance of brand awareness and differentiation. An important characteristic of effective packaging design is that it is "holistic." In other words, when it comes to effective packaging the overall effect of the package comes not

from any individual element but rather from the combination of all elements working together as a holistic design. This means that the combination trademarks that are used to create the packaging, including words, colors, images, and typefaces, cannot be easily divided without diminishing the overall effect and power of the trademark and brand. The whole is greater than the sum of the parts, and particularly greater than any one part (such as the written name only). Indeed as discussed above, some brands only use trademarked logos with no wordmarks and in other cases the trademark comprises both words and graphics, which are integrated and essential to identifying and distinguishing the brand.

26. Effective packaging also requires consistency over time. Because consumers spend just a few seconds looking at a package,[11] a key to effective package design and immediate consumer recognition is the maintenance of "consistency" that "identifies the product unequivocally and provides reassurance to the consumer faced with bewildering choice."[12] Consistency in package design is also important because it takes "long and repeated exposure to develop 'visual equity.'" [13]

27. Figure 6 shows some examples of iconic packages for brands with a strong visual identity.

---

[11] Young, Scott and Vincenzo Ciummo (2009), "Package Viewing Patterns: Insights and Implications for Global Design," *Package Design Magazine*, July 2009, pages 26-30. Accessed at http://www.prsresearch.com/fileUploads/Package_Viewing_Patterns.pdf

[12] Murphy, John M. Brand Strategy. Prentice Hall: 1990, page 89.

[13] Murphy, John M. Brand Strategy. Prentice Hall: 1990, page 84.

Figure 6: The Visual Identity of these Iconic Packages is Widely Recognized

28. Figure 7 shows examples of Hong Kong products with iconic packaging.

Figure 7: Hong Kong Products with Iconic Packaging

V. Brands and their Trademarked Symbols Serve Important Functions in the Market

A. Benefits to Consumers

29. Particularly in a market such as in Hong Kong, in which packaging is the last means of communication, the trademarked symbols and packaging associated with brands perform essential navigation and reassurance functions for consumers. In many categories, there is a dizzying number of product choices, and the buying process can be time-consuming and even stressful. Brands, as identified by the associated trademarked elements, can help customers navigate through the huge quantity of information available. Specifically, it is the brand's trademarked elements that identify and differentiate the product and, as such, aid the consumer's navigation among competing products. Brands help consumers organize and remember a large quantity of information. They can simplify a complicated purchase decision by reducing the need to evaluate the offerings in an entire product category across multiple dimensions.

30. The presence of a strong brand can also reduce the risk involved in making a purchase decision because the consumer has confidence in the quality of the product because of its popularity and/or longevity in the market. For example, a customer interested in buying tires might be bombarded with product choices (both branded and unbranded). Instead of doing time-consuming research on the characteristics of each offering, the buyer might

just simply choose Michelin tires, confident either through past experience or reputation that he or she would be satisfied with the purchase.

31. In particular, the trademarked symbols of the brand provide reassurance that the brand's customers are getting the quality product they expect. Consumers often choose to purchase a branded rather than a non-branded product, as they believe that someone stands behind these products. The use of one's name reduces the anonymity of the supplier and hence subjects them to the evaluation and scrutiny of the consumer. As consumers repeatedly purchase and consume the product, they determine if the brand meets or fails to meet their expectations on an ongoing basis. The prominent use of trademarks identifies the owner of the brand and implicitly guarantees an assurance of quality from the brand owner to the purchaser. When consumers pay a premium price for a branded product, they are paying for an implicit guarantee of superior quality.[14] Branded batteries such as Energizer provide a good example of a branded product providing both perceived and actual high quality over many of their unbranded counterparts.

B. Benefits to the Firm

32. For manufacturers, the protection of the intellectual property rights afforded to trademark owners means that the firm can invest with confidence in the trademark and the associated brand and obtain the benefits of its value and associated business goodwill sustained over time. In many cases, the brand's trademarked name (together with its associated trademarked logo or other brand markers) is the only means of communication that a competitor cannot copy. For example, one marketing reference explains it this way: "An orange ... is an orange ... is an orange. Unless, of course, that orange happens to be Sunkist, a name that 80% of consumers know and trust."[15]

33. A strong brand can also make it easier for a firm to enter new geographic markets. In today's world of global media and travel, it is quite likely that a foreign brand entering a new market would find that some consumers in the new market would be familiar with its brand before it even entered. Some of these consumers would likely have even tried the product while traveling or living abroad and be in a position to share their knowledge of the brand through word-of-mouth.

---

[14] Png, I. P. L., & Reitman, D. (1995). "Why are some products branded and others not?" *Journal of Law and Economics*, *38*(1), 207-224.

[15] Davis, Scott M., *Brand Asset Management: Driving Profitable Growth Through Your Brands*. John Wiley & Sons, Inc.: 2002, page 203, quoting Russell Hanlin, CEO, Sunkist Growers.

C. Importance of Brands to the Efficient Functioning of the Market

34. In addition to bringing many benefits to the manufacturer and consumer, brands are important because they contribute to the efficient functioning of the market in a number of important ways.

35. **Competition:** In a sense, the brand encapsulates all of the non-price dimensions of competition. Therefore, differentiation through branding offers manufacturers an alternative to price competition. Competing on price alone is not good for the functioning of the market in the long run because price competition naturally drives out all but the lowest cost producers and leads to excessive concentration in the industry. This effect is particularly important in industries with high economies of scale, like cigarette production. In categories such as cigarettes, where the products themselves can be seen as broadly similar, trademarks and other brand elements are key sources of differentiation.

36. **Competitive Advantage in a Mature Market:** In order to understand the role of brands in markets, it is important first to examine the nature of demand in mature markets. Economists speak of two types of demand: primary demand and secondary demand. Primary demand refers to the total demand that exists in the market. The total demand for soft drinks is an example of primary demand. Secondary demand refers to the demand for a specific brand within the market; for example, the demand for Diet Coke. In mature markets, primary demand is relatively stable, and firms' efforts to increase sales are centered on efforts to increase secondary demand by stealing market share away from their competitors. In fact, "for many businesses active in mature markets, brand support and marketing can be the biggest single item of overhead cost.[16]

37. The tobacco market is an example of such a mature market, where consumers are well aware of the product features and benefits. In this type of market, firms' efforts are focused on stealing market share from one another not on increasing overall market demand.

38. Brands that consumers can identify by their trademarked components, are a particularly important element of the competition for secondary demand in industries like tobacco where the products are similar. Without branding in such markets, "Customers readily purchase entirely on the basis of comparative pricing … [which] leads to cut-throat competition for consumers," as described above.[17] In developing his concept of generic strategies, Professor Michael Porter has pointed out that there really are only two possible

---

[16] Blackett, Tom, "What is a brand?" in Rita Clifton (editor) *Brands and Branding*, 2nd edition. London: The Economist in association with Profile Books, 2009, page 24.

[17] Pope, Joe; David Cullwick and Jo Kennelly (1998), "Commodity Branding" in Hart, Susannah and Murphy, John, editors, *Brands: The New Wealth Creators*, MacMillan Business: 1988, page 161.

sources of sustained competitive advantage, cost advantage or differentiation.[18] "You win either by being cheaper or by being different, that is, being perceived by the customer as being better or more relevant."[19] Therefore, firms that are unable to differentiate their product are left with no alternative but to compete on cost.

39. **New Entrants and International Competition:** One of the benefits of brands to market structure is that they can make it possible for new competitors to enter the marketplace and differentiate themselves from their competitors. In an unbranded commodity market, new entrants to the marketplace have a very difficult time encouraging consumers to try their product except on the basis of price. Given that they cannot effectively differentiate their products through communication about the brand, the only way to encourage trial is to compete on price. However, in a market like cigarettes where incumbents have significant scale advantages, competing on price is not likely to be an attractive option for new entrants. In contrast, in a market with brands, it is possible for a new brand to establish itself in consumers' minds as something different from existing brands and, therefore, as something worthy of switching to. One of the keys to ensuring that a market functions efficiently is ensuring that incumbents feel a continuous threat that new entrants may enter the market and therefore continue to try to improve the quality of their products and brand reputation. In essence it ensures a "best behavior" practice on the part of market participants.

40. A further impact of the reduced power of brands is a reduction in international trade and competition in the market. For a foreign international competitor to succeed in the market, it is essential that the competitor is able to maintain some price premium over local competition in order to compensate for the added costs of doing business internationally.[20] It is all but impossible for a foreign competitor to maintain these margins as an incumbent, or to establish them as a new entrant, if the international foreign competitor is not able to build and maintain a strong brand.

41. **Quality, Innovation and Niche Products:** In the cigarette market, in which product configuration, method of consumption and visual characteristics are similar to one another, brands are also important because they serve as one of the few areas of competition available. The long term value generated by a firm's efforts to deliver quality products is captured in the value of its brands. In a market where brands cannot be utilized for product differentiation, the long term value of investments in quality and innovation is greatly diminished.

---

[18] Porter, Michael E. *Competitive Advantage*, The Free Press: 1995, page 11.

[19] Lindemann, Jan. *The Economy of Brands*, Palgrave MacMillan: 2010, page 12.

[20] These added costs faced by foreign firms are a well-established principle of international business. They are often referred to as "the liability of foreignness." See, for example, Srilata Zaheer, "Overcoming the Liability of Foreignness," *Academy of Management Journal*, 1995, Vol. 38, No. 2. 341-363.

42. Reducing the value of brands in the market also has the effect of making it difficult for niche players to survive. Normally, niche players are able to survive in markets by building brands that appeal to a small segment of consumers. Without the benefit of the brand, these niche players would disappear as part of the process of industry consolidation and monopolization described above.

43. Moreover, in markets with limited differentiation and limited incentive for investment, business models that differentiate on better quality or better service are discouraged.

VI. Impact of Increased Sized Graphic Health Warnings

44. The requirement to display 50% graphic health warning on Hong Kong cigarette packages already severely limits the use of trademarks and prevents firms from designing cigarette packages holistically. However, by increasing the size of the warning to 85%, trademarks will not be able to adequately serve their essential functions.

45. Enlarging the GHWs on cigarette packages to 85% of the packages will also result in a reduction in the “visual equity” of the brands involved through a loss of consistency in the affected packages. As discussed below, reducing further and thus eliminating the impact of the trademarks on cigarette packaging will have negative implications for consumers, firms and the market in general.

46. Figure 9 below shows cigarette packs of brands sold in Hong Kong with the proposed health warning covering 85% of the packages on the right. The images clearly illustrate that the effect of GHWs covering 85% of the packages would destroy the "visual equity" of the brands involved.

Figure 9: The Proposed Health Warnings Destroy the "Visual Equity" of the Related Brands

47. Increasing the size of GHWs to cover 85% of the cigarette packages will make it impossible for manufacturers to use some of their trademarks as registered (including logos and labels) and for them to use other trademarked elements effectively.

48. With GHWs covering 85% of the package it would be impossible to effectively include all the desired information on the package. Increasing the size of the GHWs to 85% will prevent consumers' from being able to perceive the brand on cigarette packages. Without distinctive packaging to make the trademark elements stand out, a brand becomes undifferentiated from competing brands. Trademarks will not be able to effectively differentiate, and identify the origin and quality of products, which are essential functions of trademarks. The consequence of this is that the trademarks and their related brands are practically destroyed and the goodwill inherent in the trademarks and their related brands will be lost, along with the decades of significant investment it took to generate such goodwill.

49. In the case of similar products, where trademarked symbols and packaging are key sources of differentiation, the function of these brand elements as a navigational tool to consumers is critical. With less than 15% of the packaging space available for trademarks, customer confusion is a significant concern. Increased opportunity for customer confusion reduces the value of brands for the manufacturers and consumers and reduces consumer welfare.

50. Additionally, the consumer's confidence in evaluating the authenticity of the brand is diminished by the lack of trademarked packaging. That is, the package is in essence a guarantee of what is inside. The holistic representation of the package serves as a large, multi-faceted signal to the consumer of the maker and the probability that the maker is authentic. Further reducing the available space for trademarks, reduces the ability of consumers to judge with confidence whether the product within the package was actually produced by the manufacturer. Thus, in the absence of holistic and complete packaging, the opportunity for counterfeiters and other fraudulent actors to take advantage of the consumer is increased.

51. Finally, a market with differentiated products through strong brands provides more choice for the consumer, which is a vehicle towards increased consumer power in the market, driving efficiency and other improvements.

52. Manufacturers will also receive less benefit from an impaired trademark and brand. The most obvious detriment will be in the reduced ability of firms to maintain their premium brands on the basis that they will look the same as lower quality brands and will not look and feel like premium quality products. Furthermore, any measure which diminishes brand equity will reduce the ability of new tobacco firms to introduce their brands into new geographic markets and compete with the existing brands.

53. This is especially so when the markets being entered place severe restrictions on the ability of firms to utilize their trademarks and realize the value in their brands. Thus, increasing the size of GHWs on Hong Kong cigarette packages to 85% will decrease both

the ability of foreign firms to enter the Hong Kong market and the ability of Hong Kong firms to expand abroad. Foreign firms will not be able to communicate to Hong Kong consumers about their brands, and Hong Kong firms will not have strong domestic brands to use as a base to launch their efforts in new markets. The effect of these two factors will be to reduce both the likelihood of new entrants and the basis for non-price competition in the market.[21]

54. The elimination or minimization of cigarette brands will also impact the market structure and market dynamics. First, competition will shift from brand competition to price competition. In the short term, a lack of competitive dimensions could lead to market rigidity, with little switching by consumers among brands. This market rigidity will further discourage innovation and investment and will hasten competition on price alone. It will also give an advantage to domestic brands that are likely to be able to compete more effectively on price.

55. The impact of the loss of brand differentiation in the Hong Kong tobacco market will differ among firms depending upon the extent to which they have already established their market position and depending upon the nature of their business model. Firms for which the business model depends upon the use of diversity so as to appeal to the niche tastes and firms that are currently seeking to enhance their market position by winning market share from the leading firms stand to suffer more than firms relying on one dominant brand – indeed, the latter may gain in the short run (in terms of market share) because they will still benefit from being known as a market leader and will be subject to less competitive pressure from other firms. Nonetheless, even as their market share increases, margins on these brands will decrease and eventually be eroded more or less completely, as the market evolves to pure price competition.

56. As cigarettes become commodity products resulting in competition on price alone, price conscious smokers will likely navigate toward low value, non-premium brands. The focus on commodity pricing likely will result in lower prices to consumers, a result which could also lead to increased purchases and consumption.

57. Commoditization of the market and a shift to pure price driven competition could also lead to an increase in illicit trade, since without the added value of brands, legitimate products will be less clearly differentiated from cheaper illicit products both in terms of appearance and perceived quality and value.

58. In sum, it is my opinion that increasing the size of GHWs to 85% will preclude any effective or meaningful use of trademarks, thereby preventing them from performing their essential brand functions. Further, it is my opinion that the elimination of trademarks as a platform for brand communication has a number of important negative

---

[21] See, for example, Srilata Zaheer, "Overcoming the Liability of Foreignness," *Academy of Management Journal*, 1995, Vol. 38, No. 2. 341-363.

repercussions for consumers, manufacturers, and the market in general, including some unintended consequences that are at cross-purposes with the stated health goals of the initiatives.

Dated: June 18, 2015

Philip Zerrillo, Ph.D.

Appendix A: CV of Philip Zerrillo

PHILIP C. ZERRILLO PH.D.

EDUCATION

Ph.D. Northwestern University, J.L. Kellogg Graduate School of Management (Marketing)

B.B.A. The University of Texas (Austin) Marketing

HONORS

2013
The Dr. Benvinido Tantocco Distinguished Chair in Retailing, Jose Rizal University (Philippines)

2007
Journal of Business to Business Marketing (Best paper Award)

1993
Institute for the Study of Business Markets NCR AT&T Doctoral Award Competition "Most Outstanding Doctoral Dissertation Submission", Grand Prize Award

1990-1992
Northwestern University, J.L. Kellogg Graduate School of Management," Steel Resource Foundation" Doctoral Fellowship

1989-1993
Northwestern University, J.L. Kellogg Graduate School of Management, Doctoral Fellowship

1982
The University of Texas, "The Most Outstanding Scholar Award

ACADEMIC EXPERIENCE

2010- Present	Full Professor (Practice) Singapore Management University. -Dean Post Graduate Professional Programmes (Law, Business, Information Sciences, Economics, Social Sciences, Accounting) -Executive Director Case Writing Initiative -Executive Director Center for Management Practice - Academic Head Ph.D. in Business (General Management)
2010- Present	Executive Chairman of the Board -Thammasat University MIM (Thailand)
2008-2010	Visiting Professor – Northwestern University, Kellogg Graduate School of Management
2005-Present	Lecturer- Goizueta School of Business, Research fellow Zyman Institute for Brand Science (ZIBS), Emory University

1999-2004	Associate Dean and Executive Director, Executive Education, University of Texas at Austin
2000-2002	Graduate Business Dean, The University of Texas at Austin
1997-2001	Director of Dallas Based Executive MBA Program (Focusing on Technology)
1993-1998	Assistant Professor- The University of Texas Graduate School of Business (Marketing Core, Channels and Distribution Policy, Pricing, Marketing Strategy Global Studies)
1997-1998	Visiting Professor-Northwestern University, J.L. Kellogg Graduate School of Management (Channels and Distribution Policy, International Distribution)
1991-1993	Lecturer- Northwestern University, J.L. Kellogg Graduate School of Management (Distribution Channels)

YEARLY VISITING POSITIONS

2010-Present	Washington University St. Louis (Shanghai Campus)
1997-Present	Visiting Professor-Thammasat University, Bangkok, Thailand
1997-Present	Visiting Lecturer-Hebrew University, Jerusalem, Israel
2009-Present	Lecturer Owen School of Management- Vanderbilt University
2008-Present	Smith School of Business- University of Maryland (Shanghai)
2002-2006	Visiting Professor IMADEC University, Vienna, Austria
2004-2006	Visiting Professor Helsinki School of Economics- Singapore
2000-2003	Visiting Professor Aoyama Gakuin University, Tokyo, Japan
2002-2003	Sun Yat Sen University, Guangzhou, China

RECENT INDUSTRY EXPERIENCE

2007- Present	Monitor Consulting
2005	Principal, Business Asia 101- focusing on business event planning and networking

1996-2001	CEO, Farig Consulting,- Key Corporate Clients 3M, PPG, Motorola, Accenture, E-Partners solutions, Input /Output KUHF Radio, On-air investment and business show host Rauscher Pierce Refsnes, Registered representative

BOARDS AND ADVISORY BOARDS

2010- Present	Thammasat University- Executive Chairman of the Board MIM programme
1998-Present	Sharps Compliance, Lead Director, Audit Committee Chairman Member (NASDAQ), Medical waste disposal
2002-2005	Tholos International, European based video conferencing company
1999-2001	GKS Services, (Founder- acquired by Applied Materials), Data mining applications for semiconductor fabrication applications
1996-2000	Garden.Com (NASDAQ), Internet based distribution of garden products
1997-2000	Exterprise Incorporated, (acquired by Commerce One) Business-to-business exchange software

TEACHING HONORS AND ACTIVITIES

2011	Outstanding Professor Address- SMU MBA commencement
2008	Northwestern University, Faculty Honor Roll
2008	Chosen to Deliver "Goizueta MBA Final lecture" Student recognition of the outstanding professor asked to deliver their farewell lecture"
2005-2007	Emory University. "Special Faculty Recognition for Outstanding MBA Teaching"
2000-2005	University of Texas Teaching Honor Roll - During every teaching semester
2001-2005	Doctoral Teaching Seminar for Doctoral Candidates, Thammasat University
2002	MBA Class of 1997 Alumni Award "The Professor with the Greatest Impact"
2002	MBA Class of 2002, "Outstanding Contributor to Student Life"
1994-1998	The University of Texas, Finalist, "The Joseph Beasley Award for Teaching Excellence"
1997-1999	Member of "Northwestern University, J.L. Kellogg Graduate School of Management Teaching Honor Roll" for teaching excellence

1993-1996 The University of Texas, Graduate Business Council, "Outstanding Marketing Core Instructor"

1995 Guest Lecturer, University of Texas, Graduate School of Business course on "Teaching Effectiveness"

1992-1993 Member of "Northwestern University, J.L. Kellogg Graduate School of Management Teaching Honor Roll" for teaching excellence and outstanding representation of the student honor code

RECENTLY PUBLISHED RESEARCH

James C Anderson, Philip Zerrillo and Lihua Wang, "Inter Organizational Properties and Inter-organizational Perceptual Agreement: A Model and Empirical Test in Marketing Channel Relations" December 2007, (Winner of Best Paper Award)

Frenzen, Jonathan, Paul Hirsch and Philip C. Zerrillo, "Consumption Preferences and Changing Lifestyles," Neil Smelzer and Richard Swedberg (eds.), The Handbook of Economic Sociology, Russell Sage, Princeton NJ. (1994)

Iacobucci, Dawn and Philip C. Zerrillo, "Multiple Levels of Relational Phenomenon," Dawn Iacobucci (ed.) Relationships in Marketing, Russell Sage, Princeton NJ. (1996)

Iacobucci, Dawn and Philip C. Zerrillo, "The Relationship Life Cycle: I) A Network-Dyad-Network Dynamic Conceptualization, and II) The Application of Some Classic Psychological Theories to its Management," Jagdish Sheth and Charles Frame (eds.) Review of Marketing, JAI Press, Greenwich, (Forthcoming, 1996)

Peterson Robert, Karen Smith and Philip Zerrillo, "Trademark Dilution and the Practice of Marketing" Journal of the Academy of Marketing Science, Vol 27, No. 2 pp 255-268 (1999)

Shervani, Tasadduq and Philip Zerrillo, "The Albatross on New Product Innovations," Business Horizons, Vol 40 No.1, (Jan 1997) pp.57-62 (Also republished Engineering Management Review Winter 1997, Vol 4 Pg 26-32) Also Republished JPIM On-line Hot Topic, review Dec 2000) (Also republished Euskotek, Revist de la Red ParquesTecnologicosNumero 6 Ano1999,)

Zerrillo, Philip C., Jon M. Flemming and Angela McKee, "Vertical Territory and Customer Resale Restrictions a New Rule of Reason Approach," Iowa Law Review: Journal of Corporation Law, (May 1997)

Zerrillo, Philip and Dawn Iacobucci, "Trade Promotions a Call For a More Rational Approach," Business Horizons, Vol 38 No.4, (July-August) (1995) pp. 69-76

Zerrillo, Philip and Angela McKee, "Vertical Restraints and Consumer Welfare, Clear Distinctions for Restraints: Via a Modified Rule of Reason Approach" Contemporary Knowledge of Relationship Marketing, Emory University Center for Relationship Marketing June 1996,

Zerrillo, Philip and Ravi Raina, "A Vertical View of Marketing Networks: A New Entrants Approach" Dawn Iacobucci (ed.) Relationships in Marketing, Russell Sage, Princeton NJ. (1996)

Philip C Zerrillo and Greg M. Thomas, "Developing Brands in Emerging Markets, a Framework for Growth," Journal of Place Branding Fall 2007.

PUBLISHED CASES

2011 Memaska Steel (Singapore Management University case Series, European Case Clearing House)

2011 With Kevin Sproule, Hammerlick Brewing (Singapore Management University case Series, European Case Clearing House)

2012 With Havovi Joshi and S.N. Venkat Tata Salt- What to do When a a Challenger Brand Grows Up? Case A

2012 With Havovi Joshi and Sn Venkat Tata Salt Case B. (Singapore Management University case Series, European Case Clearing House)

2012 Minh Long Porcelain (Singapore Management University case Series, European Case Clearing House)

2013 Minh Long Porcelain Case B. (Singapore Management University case Series, European Case Clearing House)

2013 Tata Starbuck, Brewing a Perfect Blend (Singapore Management University case series. European Case Clearing House)

EXPERT TESTIMONY

Latin America Courier, and Pegaso Express V. Airborne Express Inc., Airborne Express Inc., Airborne Freight Corporation, George Trevino DHL Holdings (USA) Inc, DHL Danzas Air and Ocean North America, DHL Worldwide Express Inc., and DHL International De Mexico S.A. Friedman V. 24hr Fitness

JK Enterprises LLC., DBA Jeremy Franklin Suzuki, Et.al, v. American vs. American Suzuki Motor Corporation, et.al.

Stripes LLC, vs. Carlson Worldwide Inc., TGI Friday's, Inc, and TGI Friday's, of Minnesota Inc.

EXECUTIVE EDUCATION/CONSULTING

Developed and delivered executive training for consulting firms, (Accenture, Monitor Consulting, Deloitte consulting) universities (Thammasat (Thailand), Northwestern University Kellogg Graduate School of Management, University of Maryland, The

University of Texas, Help Institute of Malaysia, Songang (Korea), Tech de Monterrey (Mexico)), and private clients including Genentech, Cargill, Imperial Tobacco (UK), 3M, LG, CP Food (Thailand), Baxter, Scott& White Hospitals, Texas Instruments, Freescale, Motorola, General Electric etc.

Recent consulting engagements: Motorola, Input/Output, 3M, 24Hr Fitness, Foley Lardner, Batesville Casket, LG Electronics, Imperial Tobacco, Suffolk Group, Orrick Hamilton, Countrywide Financial, CP Food.

CONTACT INFORMATION

Philip C. Zerrillo Ph.D.
Singapore Management University
Dean
Executive Director
Full Professor

Phone: (65) 6828 0260
Cell: (65) 9452 3746
Email: zerrillop007@hotmail.com

September 2012

Appendix B: Documents Considered

Books

Aaker, David A. *Managing Brand Equity*. New York, NY: The Free Press, 1991.

Davis, Scott M. *Brand Asset Management: Driving Profitable Growth Through Your Brands*. John Wiley & Sons, 2002.

Hart, Susannah and John Murphy, Brands: The New Wealth Creators. New York: New York University Press, 1998.

Lindemann, Jan. *The Economy of Brands*. Palgrave MacMillan, 2010.

Meyers, H.M. and M.J. Lubliner. *The Marketer's Guide to Successful Package Design*. Chicago: American Marketing Association/NTC Business Books, 1998.

Murphy, John. M. *Brand Strategy*. Prentice Hall, 1990.

Porter, Michael E. *Competitive Advantage*. New York, NY: The Free Press, 1985

Articles and Reports

Blackett, Tom. "What is a brand?" in *Brands and Branding*, 2nd edition, edited by Rita Clifton. London: The Economist in association with Profile Books, 2009.

Helmers, Christian and Mark Rogers (2010), "Trademarks and performance in UK firms," in da Silva Lopes, Theresa and Paul Duguid (editors), Trademarks, Brands and Competitiveness, Routledge, page 56.

Fogg, Janet (1998), "Brands as intellectual property," in Hart, Susannah and John Murphy, Brands: The New Wealth Creators. New York: New York University Press, page 72.

Png, I. P. L., & Reitman, D. (1995). "Why are some products branded and others not?" Journal of Law and Economics, 38(1), 207-224.

Pope, Joe; David Cullwick and Jo Kennelly (1998), "Commodity Branding" in Hart, Susannah and Murphy, John, editors, Brands: The New Wealth Creators, MacMillan Business: 1988, page 161.

Young, Scott and Vincenzo Ciummo (2009), "Package Viewing Patterns: Insights and Implications for Global Design," Package Design Magazine, July 2009, pages 26-30. Accessed at http://www.prsresearch.com/fileUploads/Package_Viewing_Patterns.pdf

Zaheer, Srilata. “Overcoming the Liability of Foreignness.” *Academy of Management Journal* 38 (1995).

Online Resources

American Marketing Association Dictionary. Available at: https://www.ama.org/resources/Pages/Dictionary.aspx?dLetter=B&dLetter=B.

Statement of John Hector on the likely impact on illicit trade of increasing the size of graphic health warnings on tobacco product packages in Hong Kong to 85%.

19 JUNE 2015

Statement of John Hector on the likely impact on illicit trade of increasing the size of graphic health warnings on tobacco product packages in Hong Kong to 85%.

1. My name is John Hector. I retired from the U.K. Her Majesty's Revenue and Customs ("**HMRC**") in July 2011 following 45 years in the Department. I joined Her Majesty's Customs and Excise (later renamed HMRC) in 1965, and worked as an investigator from 1977 until my retirement. I developed specialist expertise in Asia, holding posts in Thailand from 1998 to 2003 and Beijing from 2006 to 2011.

2. During my time in Beijing, I held the role of Fiscal Crime Liaison Officer at the UK Embassy. My role was to combat the flow of illicit trade in tobacco products to the UK and Europe in conjunction with the Chinese law enforcement agencies. I worked closely with the Police and Customs authorities in both China and Hong Kong. My work focused on the gathering and exchange of intelligence to identify and intercept illicit trade. Hong Kong was a major point of interest because of its location on the Pearl River which was used as a route to smuggle cigarettes from China. I was also responsible for liaising with law enforcement bodies to combat the illicit trade of tobacco products in the neighbouring countries of Vietnam, Thailand, South Korea and Japan.

3. Since leaving HMRC I have worked as a consultant to various industries in relation to cross border smuggling, mainly in the Far East. I am still in regular contact with colleagues in China and Hong Kong Customs, and recently visited Hong Kong and China while working on behalf of the Mauritius Government. I am well aware of illicit trafficking in Hong Kong.

4. I have been requested by British American Tobacco Company (Hong Kong) Limited to provide my observations on the illicit trade of tobacco products in Hong Kong and the likely impact on illicit trade of increasing the size of graphic health warnings on tobacco product packages in Hong Kong from 50% to 85% of their surface area, based on my many years of experience in tackling the illicit tobacco market.

Nature of Illicit Market in Hong Kong

5. While I do not think it is possible to definitively state the size of the illicit market given its very nature, the 2013 International Tax and Investment Center and Oxford Economics in a report on the illicit tobacco trade in 14 selected Asian markets (the "ITIC Report"), estimated that 33.6% of tobacco consumption in Hong Kong is illicit.[1] Of the 14 Asian countries surveyed, Hong Kong had the third largest percentage of illicit consumption in the region. It was estimated that illicit trade in tobacco would cost the Hong Kong government HK$3.2 billion in lost tax revenues in the fiscal year 2013/2014.

6. During my time with HMRC in Beijing, we tended to work on an estimate of about 18% to 20% of total tobacco consumption in Hong Kong being illicit. However, I would not be surprised if illicit consumption has increased, particularly given further increases in the cost of cigarettes in Hong Kong. However, on any view, it is clear the sale and consumption of illicit tobacco in Hong Kong is significant, and poses a large problem for public health and law enforcement.

7. The illicit market in Hong Kong is primarily comprised of contraband cigarettes, and to a lesser extent, counterfeit cigarettes. Contraband cigarettes are cigarettes taxed in one country, where taxes are lower and smuggled into another country to be illegally re-sold. Counterfeit cigarettes are fake copies of well-known branded cigarettes smuggled into a country for sale without payment of tax.

[1] Asia-14: Illicit Tobacco Indicator 2013, at p. 63, available at http://www.oxfordeconomics.com/asia14

8. Hong Kong is particularly vulnerable to the illicit trade in contraband cigarettes because of the high price of cigarettes in Hong Kong compared to neighbouring countries. For example a pack of cigarettes costs US$ 0.80 or US$ 1.1 in Vietnam and China respectively, compared with US$ 6.4 in Hong Kong.[2] The largest share of contraband tobacco which is smuggled into Hong Kong comes from mainland China in breach of personal duty free allowances. Contraband products also come from Vietnam, Macau and Indonesia.[3] Many of the contraband brands are devoid of graphic health warnings. The price and familiarity of contraband brands make them attractive to consumers of illicit tobacco once smuggled into Hong Kong.

9. Counterfeit cigarettes are also present in the illicit Hong Kong marketplace. Again Hong Kong is particularly vulnerable to the illicit trade in counterfeit given its border with mainland China (where a large percentage of the world's counterfeit tobacco products are manufactured) and Hong Kong's position as a regional port. Chinese counterfeiters are mainly based in the provinces of Guangdong and Fujian, and their products are smuggled out of China to Hong Kong and the world.

10. The international illicit trade in tobacco is perpetrated in Hong Kong through organized crime and smuggling syndicates. These groups smuggle illicit products out of China, often via barges on the Pearl River network. Smugglers will then load containers carrying illicit products onto ocean-going ships while within Hong Kong's waters. Fleets of transport vehicles also move quantities of illicit products either mixed in with a cover load or concealed within the frame of the vehicle over the China/Hong Kong border or through Hong Kong's ports. Much of this illicit product is destined for overseas markets, including Australia and Europe.

11. The illicit trade of products intended to be re-sold in Hong Kong is primarily conducted by smuggling syndicates and individuals who import duty free cigarettes in excess of permitted limits. Those entering Hong Kong are permitted to bring with them only 19 cigarettes or less without incurring duties. Many may bring small quantities of additional cigarettes with them, which they then sell to local merchants, shop owners and casual vendors. While the illegal importer receives a higher price than they themselves paid in purchasing the product outside Hong Kong, the seller will then recoup that cost and more once the pack is sold to the end customer in the Hong Kong marketplace. Given the vast number of people arriving at Hong Kong's border daily, including the hundreds of thousands that commute to work from homes in mainland China, it is very difficult to detect and combat illegal import conducted en masse in small quantities.

12. Illicit products can be easily purchased by consumers in Hong Kong. In my experience, illicit non-duty paid cigarettes are widely available for purchase in shops of all manner which exist everywhere, as well from street peddlers. It has also been reported that illicit cigarettes are available for purchase through telephone schemes run by smuggling syndicates, whereby orders for illicit products are placed by customers and delivered clandestinely, and that criminal syndicates sell illicit tobacco in schools and on public housing estates.[4] Smuggled cigarettes may also be mixed with duty paid products and inserted into the legitimate supply chain. [5]

[2] Ibid at p. 60
[3] Ibid at p. 16
[4] http://www.stopit.hk/wp-content/uploads/2015/02/HKUAIT-Budget-Consultation-2015-EN-FINAL.pdf
[5] Ibid

13. Illicit trade is tackled in Hong Kong by the Customs and Excise Department ("**C&ED**"). The C&ED is tasked with preventing and detecting smuggling activities under the Import and Export Ordinance. As set out on its website, the C&ED has taken significant steps to combat illicit trade in tobacco, such as conducting raids on storage, transport and distribution networks, and conducting undercover operations to target peddling. It has also increased random checks on individuals at border crossings to enforce duty free limits. However, the scale of the task faced by C&ED is vast. C&ED report that in 2013 on average 281,000 people crossed the land border between mainland China and Hong Kong each day (many of whom commute to jobs in Hong Kong). A total of 12.3 million passengers also arrived in Hong Kong from the Mainland and Macau by sea and by helicopters. In addition, the throughput of air passengers in Hong Kong was 59.9 million and the throughput of air cargoes was about 4.13 million tonnes. Hong Kong is also one of the busiest container ports in the world. It handled 22.4 million TEUs (20-foot equivalent units) in 2013 and in 2013, 29, 915 ocean-going vessels and 157, 625 river-trade vessels arrived in Hong Kong.[6] The illicit trade in tobacco continues to present significant enforcement problems and remains well in excess of Hong Kong's neighbours.

14. Euromonitor International in its 2015 report 'Tobacco in Hong Kong, China' states:

    "*Cigarette smuggling across borders remained active and serious in Hong Kong, although the authorities had already made a great deal of effort to prevent this. The large price difference between taxed and untaxed cigarettes made the illicit tobacco trade in Hong Kong highly profitable yet a low risk activity for criminal syndicates. The total volume seized by the Hong Kong Customs and Excise Department rose significantly in 2013. As more restrictive measures are anticipated for the future, further tax increments might fuel the illicit tobacco trade*."[7]

15. A survey conducted by research agency IPSOS in December 2014, also reported that 90% of respondents agreed that Hong Kong had a problem with black market cigarettes, with 70% agreeing that it was easy for children under 18 to access illegal tobacco products and 81% believing that it is easy for adults to access illegal tobacco products.[8]

Impact of increased graphic health warnings on illicit trade

16. The impact of further regulation on the illicit trade must be carefully considered given the existence in Hong Kong of a well-established and accessible illicit market. Consumers can easily find and purchase illicit products if they want to. Given the high price of legal cigarettes in Hong Kong compared to neighbouring countries there is already a greater incentive for illicit trade in Hong Kong. This situation will only be made worse by the introduction of further measures that incentivise the illicit market, such as making legal products less recognisable or increasing the product range that the illicit market can provide consumers. Cigarette smugglers can readily provide whatever type of packaging that smokers of any age want.

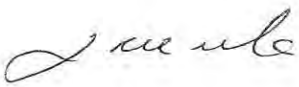
17. In my view, increasing the size of graphic health warnings from 50% to 85% will only make the significant illicit problem in Hong Kong worse by incentivising consumers' willingness to purchase the cheapest products available rather than pay the increasingly higher price for legal products which no longer look and feel like premium products. It will provide the illicit

[6] http://www.gov.hk/en/about/abouthk/factsheets/docs/customs.pdf
[7] http://www.euromonitor.com/tobacco-in-hong-kong-china/report
[8] Available at http://www.stopit.hk/wp-content/uploads/2015/02/Hong_Kong_IT_Survey_2015_EN-FINAL.pdf

tobacco trader with an additional advantage in that they can provide packaging without large graphic health warnings if that is what consumers want.

18. As outlined above, the illicit trade in Hong Kong is well established. Consumers can easily find and purchase illicit product if they want to.

19. In addition to the public health and criminal impacts of the illicit trade, the impact of increased illicit trade will also deprive the Government of Hong Kong of duties and taxes associated with the licit, legitimate trade of tobacco.



John Hector 19 June 2015

HERBERT
SMITH
FREEHILLS

Privileged and Confidential

The Chairman
Panel on Health Services
Legislative Council
Legislative Council Complex 1
Legislative Council Road Central
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
DX 009028

www.herbertsmithfreehills.com

Our ref
6461/30975151
Your ref

Date
20 July 2015

By email: panel_hs@legco.gov.hk and by post

Dear Sirs,

Special Meeting on 6 July 2015 – Legislative proposals to strengthen tabacco control

We write on behalf of our client, British American Tobacco (Hong Kong) Ltd, and further to the special meeting of the Panel on Health Services of the Legislative Council (the "**Panel**") on 6th July 2015 (the "**Meeting**"), at which the Government's proposal to increase the size of the graphic health warnings ("**GHWs**") for packets and retail containers of cigarettes to 85% (the "**Proposal**") was discussed.

Our client thanks the Panel again for the opportunity to make written and oral submissions on the Proposal, and appreciates the opportunity that was given to them to express their views and concerns.

Following the Meeting, our client believes that there would be a particular benefit in further discussing with the Government and the Panel, in light of submissions that were made and questions raised at the Meeting, the impact that the Proposal will have on intellectual property rights and the market and the experience of other countries that have introduced larger GHWs on tobacco product packaging.

Our client's trademarks and other intellectual property will not be capable of meaningful or economically viable use if the size of the GHW is increased to 85%, as they will no longer be able to display their trademarks and branding as registered on their packaging. As already expressed, since intellectual property rights are protected under the Basic Law, the Proposal would therefore be unconstitutional.

Our client also believes that the Proposal is manifestly disproportionate. The impact on our client and other manufacturers will be very substantial. By devaluing their intellectual property, the Proposal would also distort competition, drive down prices leading to increased consumption, and incentivise illicit trade, so it would actually undermine the Government's public health objective.

Furthermore, the Proposal would constitute a violation of Hong Kong's international obligations under the WTO Agreements and International Investment Treaties, damaging Hong Kong's international reputation and exposing the Government to the risk of litigation and legal decisions requiring it to repeal the subsidiary legislation and/or pay substantial sums in compensation. Our client believes that further discussion of these issues is essential in order to ensure that the Panel is fully informed of the potential impact of the Proposal.

At the Panel Meeting, it was specifically asked whether there is evidence linking larger health warnings with a reduction in smoking prevalence to which the Undersecretary for Food and Health provided certain statistics from the Canadian, Australian and Thai experience in support. Our client disagrees with the Government's interpretation of this data and submits that a proper analysis actually confirms that there was no correlation between the reduction in smoking prevalence and the increased size of the GHW.

Our client believes it is important for the Panel to consider this evidence and an analysis of data from these three countries is set out in the Annexure to this letter.

In closing, we would again like to thank you and the other Panel members for the time given at the special meeting and the fair remarks made on the need for further and comprehensive consultation by the Government. In particular, our client appreciates the Chairman's remark that the Government has a responsibility to consult and communicate with stakeholders in respect of the Proposal, including members of the tobacco industry, so as to facilitate and best ensure proportionate policy-making that properly takes into account the wider range of interests.

Yours faithfully

Herbert Smith Freehills

Herbert Smith Freehills

cc. The Vice-Chairman and other Panel members

cc: Secretary for Food and Health
18/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue,
Tamar,
Hong Kong

Annexure – Evidence Demonstrating the Lack of Effectiveness of Larger Warnings in Australia, Canada and Thailand.

At the Meeting at which the Government's proposal to increase the size of the GHWs for packets and retail containers of cigarettes to 85% was discussed, the Undersecretary made reference to smoking statistics from Canada, Australia and Thailand as evidence supporting the efficacy of larger GHWs. However, set out below is an analysis of data from these jurisdictions which demonstrates that the introduction of larger GHWs in these countries has not been effective in reducing smoking prevalence.

1. AUSTRALIA

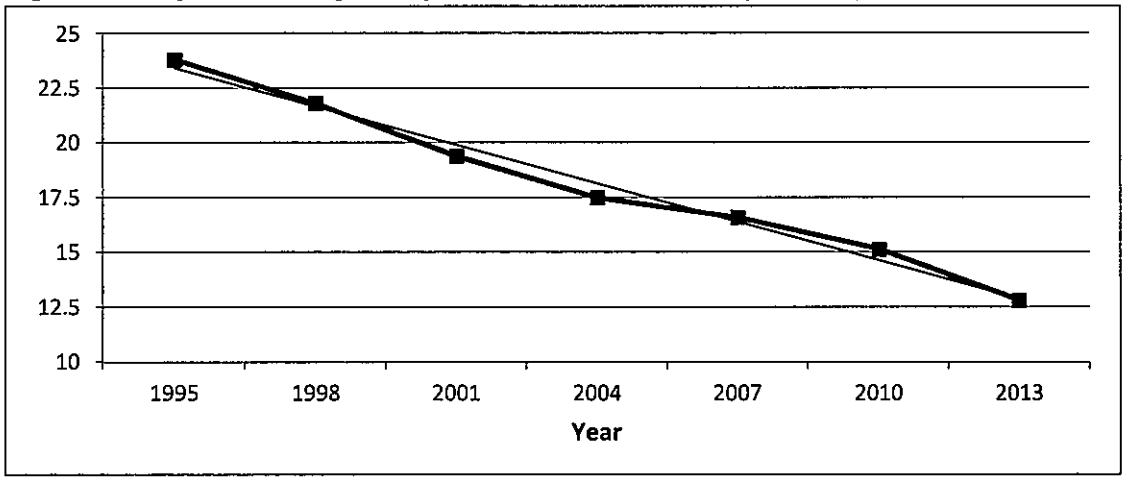
Australia increased the size of the warnings on the front of cigarette packets from 30% to 75% (in addition to existing 90% warnings on the back of cigarette packets), along with introducing plain packaging in December 2012. At the Meeting, the Undersecretary quoted figures for Australia that the percentage of smokers had decreased from 15.1% in 2010 to 12.8% in 2013. However, simply noting a decline in smoking prevalence without factoring in the existing long term declining trend is inaccurate and inappropriate, and cannot be taken as proof of increased GHWs leading to reduced smoking prevalence.

In fact, as shown below, analysis of the data quoted by the Undersecretary shows that the increased GHWs have not had any impact on the pre-existing declining trend in smoking prevalence in Australia and the larger GHWs have not been more effective in changing behaviours. For completeness, there were also a number of other measures in force at the time which may also have contributed to the declining trend (including a bi-annual 25% tax increase on tobacco and other regulatory measures).

The statistics quoted by the Undersecretary are derived from the Australian National Drug Strategy Household Survey ('**ANDSHS**'), which is conducted by the Australian Government every 3 years. The most recent survey was carried out in 2013 after the introduction of larger graphic health warnings and plain packaging in December 2012.

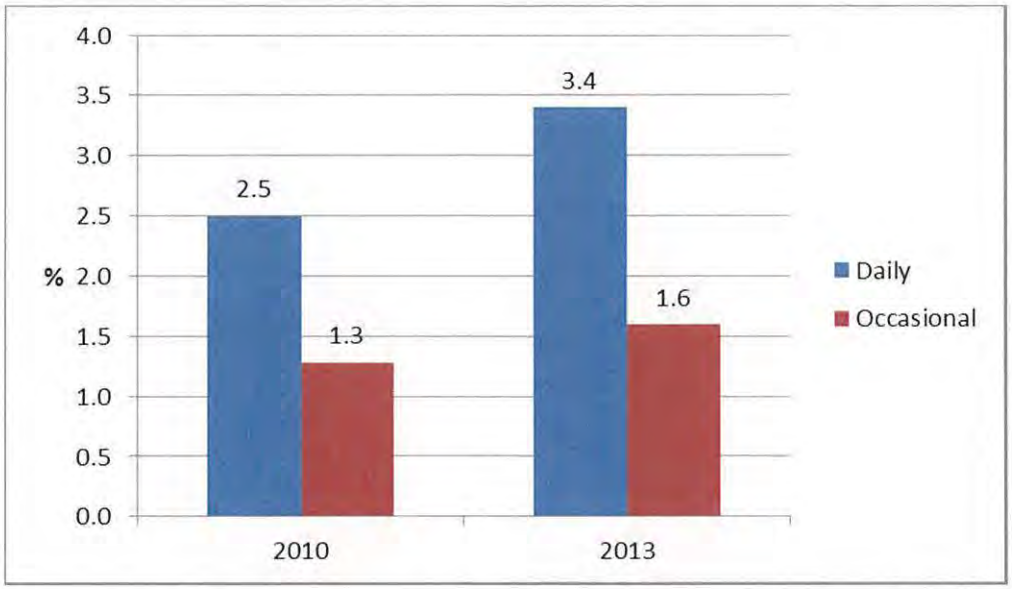
Figure 1 below shows the data for daily smokers aged 14 and over from the ANDSHS for the years 1995 to 2013, together with a linear best-fit trendline. As shown, the proportion of daily smokers has been declining steadily in Australia for a number of years and the proportion in 2013 is almost exactly on the trendline.

Figure 1: Daily smokers aged 14 years or older 1995-2013 (per cent)



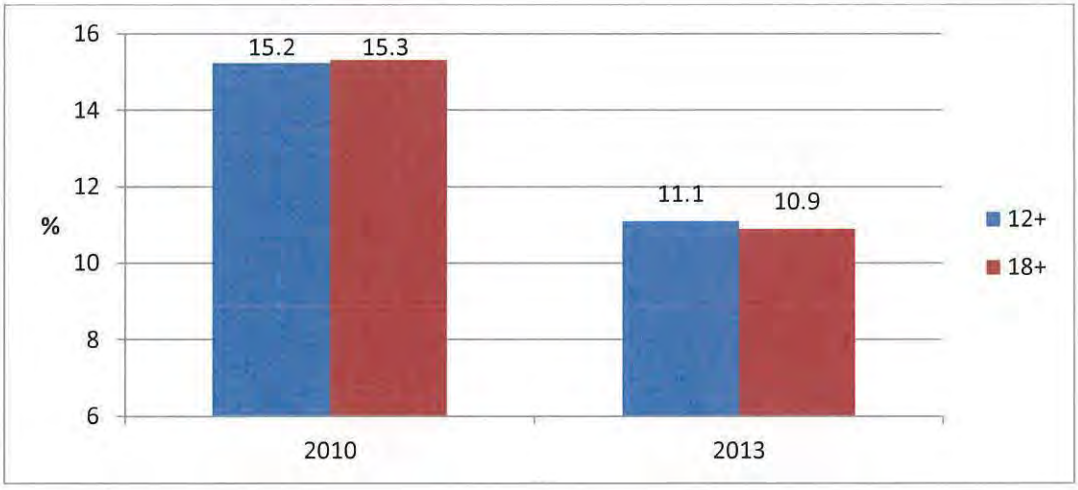
The ANDSHS also shows that the percentage of 12-17 year olds who smoked on a daily basis increased from 2.5% to 3.4% between 2010 and 2013 (the highest rate since the ANDSHS in 2004), and the percentage of occasional smokers aged 12-17 also increased from 1.3% to 1.6% over this period (Figure 2). While not statistically significant, this data is not supportive of either larger GHWs or plain packaging leading to fewer adolescents taking up smoking.

Figure 2: Daily and occasional smokers[1] aged 12-17 years (per cent)



The ANDSHS also examines the main reasons that smokers attempted to quit or change their smoking behaviour in 2013 compared to 2010. As shown in Figure 3, the percentage of smokers *nominating health warnings on tobacco packets as the reason* for trying to quit smoking reduced from 15.2% in 2010 to 11.1% in 2013 for all respondents (aged over 12) and from 15.3% to 10.9% for respondents aged over 18.[2] In other words, the percentage of smokers citing health warnings as the cause of their smoking cessation efforts actually reduced significantly in the period following the introduction of the plain packaging. Therefore, contrary to supporting the proposal for introduction of larger GHWs, this suggests that larger GHWs are less effective in inducing smokers to quit.

Figure 3: Proportion of respondents nominating health warnings on tobacco packs as the reason for trying to quit smoking



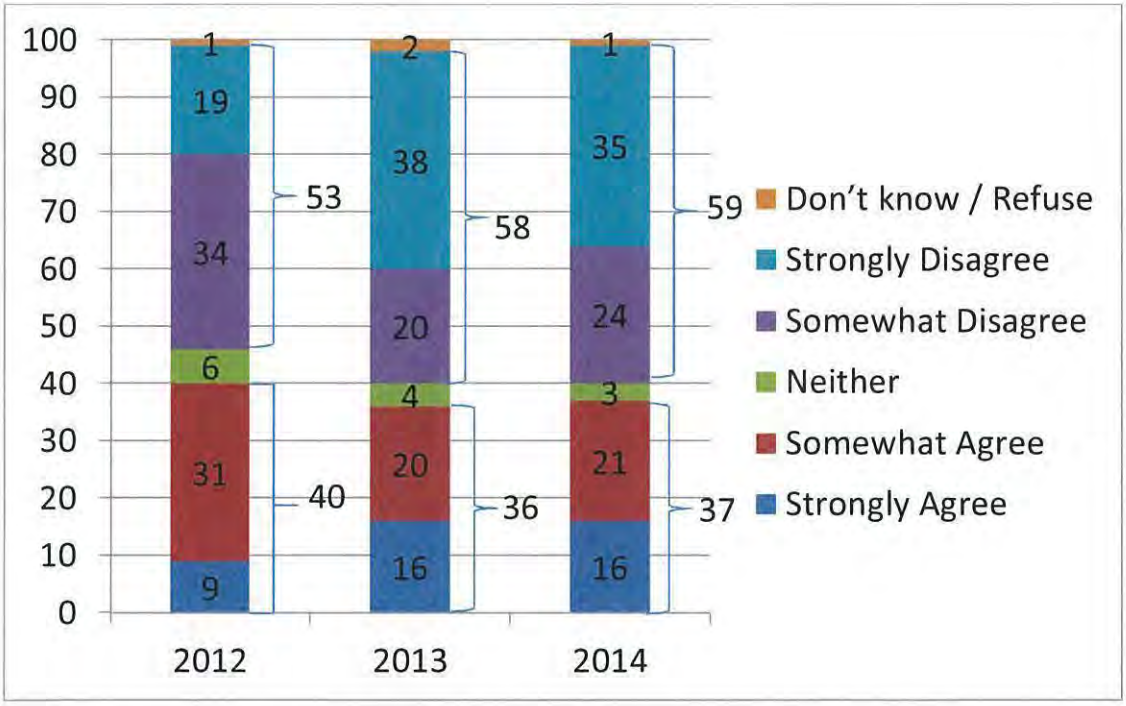
[1] Occasional smokers includes people who reported smoking weekly or less than weekly.

[2] *National Drug Strategy Household Survey detailed report: 2013*, Drug statistics series no. 28, Australian Institute of Health and Welfare, Nov 2014 http://www.aihw.gov.au/publication-detail/?id=60129549469, at Table 3.16.

Other evidence also shows that the larger GHWs in Australia, along with plain packaging, have not been effective in increasing the effectiveness of warnings. This evidence includes the Cancer Institute NSW (New South Wales) Tobacco Tracking Survey ('**CITTS**') which is a serial cross-sectional survey of adult smokers and recent quitters that includes questions pertaining to smoking-related cognitions and behaviours. The CITTS sample obtained provides data from January 2009 to December 2014.

Figure 4 shows that when asked whether graphic warnings encouraged smokers to quit, the number of respondents strongly agreeing or somewhat agreeing reduced from 40% in 2012 to 36% in 2013 (after the introduction of larger GHWs and plain packaging in Australia in December 2012) and remained at 37% in 2014. The number of respondents somewhat or strongly disagreeing increased from 53% to 58% between 2012 and 2013 and increased further to 59% in 2014 (whilst the number of respondents strongly disagreeing doubled from 19% to 38% between 2012 and 2013).[3] This suggests that GHWs were less effective at encouraging smokers and recent quitters to stop smoking after they were made larger, even with the introduction of plain packaging.

Figure 4: Do you agree with the following statement? The graphic warnings encourage/d me to stop smoking



In terms of the wider impact of GHWs, the CITTS data also strongly challenge the assumption that an increase in size improves the effectiveness of GHWs as shown in Table 1 below. They show that since the larger GHWs and plain packaging were introduced in Australia:

- The proportion of smokers ignoring the health warning has increased;
- The proportion of smokers thinking that health warnings are exaggerated has increased;
- The proportion of smokers thinking that health warnings help them quit has decreased; and
- The proportion of smokers seeking to hide their cigarettes from others due to the health warnings has not changed.

[3] This question was asked to respondents who noticed graphic health warnings in 2012 and to all respondents in 2013 and 2014. (2012 n=2314, 2013 n=1085, 2014 n=1986).

Table 1: Awareness of graphic warnings before and after increased GHWs and plain packaging[4]

	2012	2013	2014
I don't look at warnings each time I get a cigarette	3.7%	3.8%	3.8%
The graphic health warnings are exaggerated	2.7%	3.2%	3.1%
The graphic warnings encouraged me to stop smoking	2.8%	2.6%	2.6%
They make me feel that I should hide my packet from the view of others	2.5%	2.6%	2.5%

2. CANADA

Canada increased the size of the warnings on cigarette packets from 50% to 75% in March 2012. However, similar to the trend observed from the Australian data, the data from Canada following the introduction of larger GHWs does not show any acceleration in the trend of long term decline in smoking prevalence in Canada. Therefore, the Undersecretary's reliance on this data as evidence of the success of larger GHWs is similarly misplaced.

Indeed it is notable that official Canadian smoking prevalence data for 2013[5], which the Undersecretary quoted as evidence in support of the effectiveness of larger GHWs, specifically notes that there was no change in the overall smoking prevalence from 2012 (when the larger GHWs were introduced in Canada) to 2013.

Figure 5 shows the smoking prevalence rates in Canada from 1999 to 2013 using Canadian Government data.[6] It indicates no evidence of any acceleration in the pre-existing smoking prevalence trend after the introduction of the 50% graphic warning or after the size of these warnings was increased to 75%. The dashed trend line is based on the best-fitting straight line for the smoking prevalence rate data.[7]

It also should be noted that there was a dramatic 82% increase in cigarette excise tax rates from 2000 to 2002. Consequently, the introduction of graphic health warnings in the middle of that time period was accompanied by a stark increase in cigarette taxes. Given the negative effect of taxes on cigarette consumption – as taxes increase, consumption decreases – any assessment of the effect of graphic health warnings based on overall trends in smoking prevalence rates will be confounded by the influence of the higher tax rates.

---

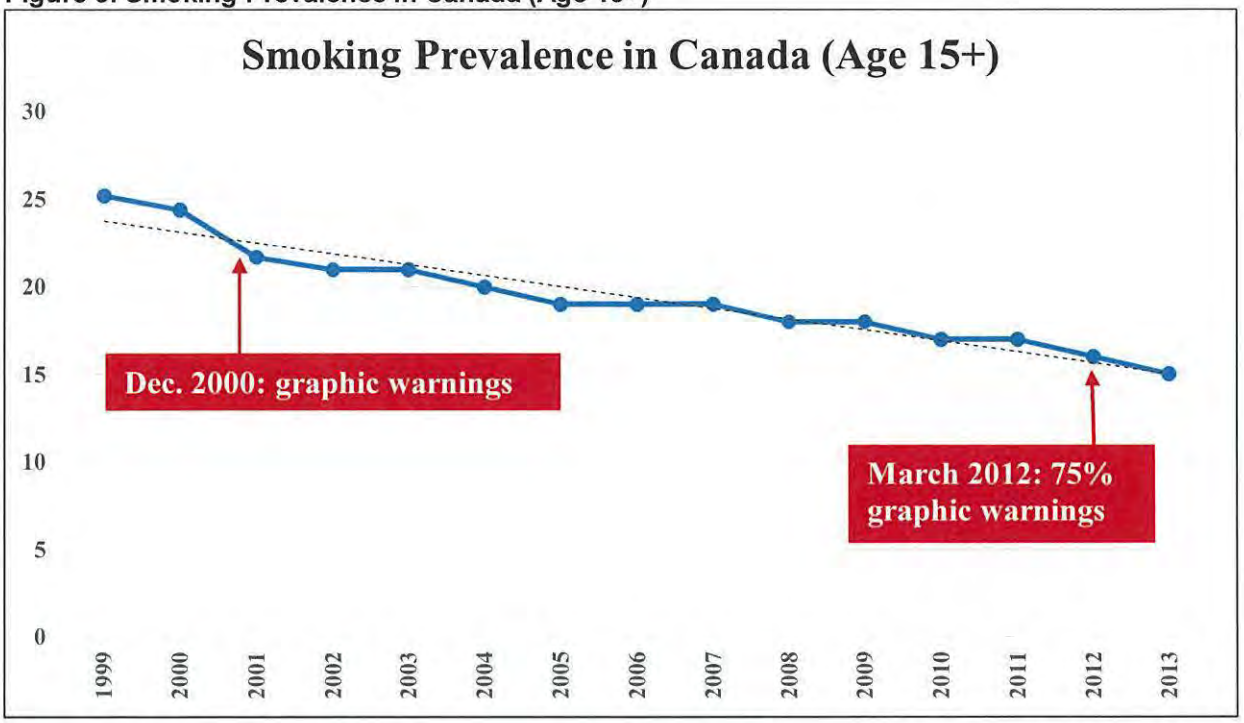
4 The analysis in Table 1 is an average response score using a scale of 1 to 5 for each response, where 1 = "strongly disagree" and 5 = "strongly agree". "Don't know" and "refuse" responses were removed before calculating the average.

5 Summary of Results for 2013 available at http://healthycanadians.gc.ca/science-research-sciences-recherches/data-donnees/ctads-ectad/summary-sommaire-2013-eng.php

6 The data is derived from that Canadian Government Canadian Tobacco Use Monitoring Surveys (CTUMS) data for 1999-2012, and Canadian Tobacco, Alcohol, and Drug Survey (CTADS) data for 2013.

7 More specifically, the trend line is based on a linear regression of the smoking prevalence rate on a constant term and a time trend.

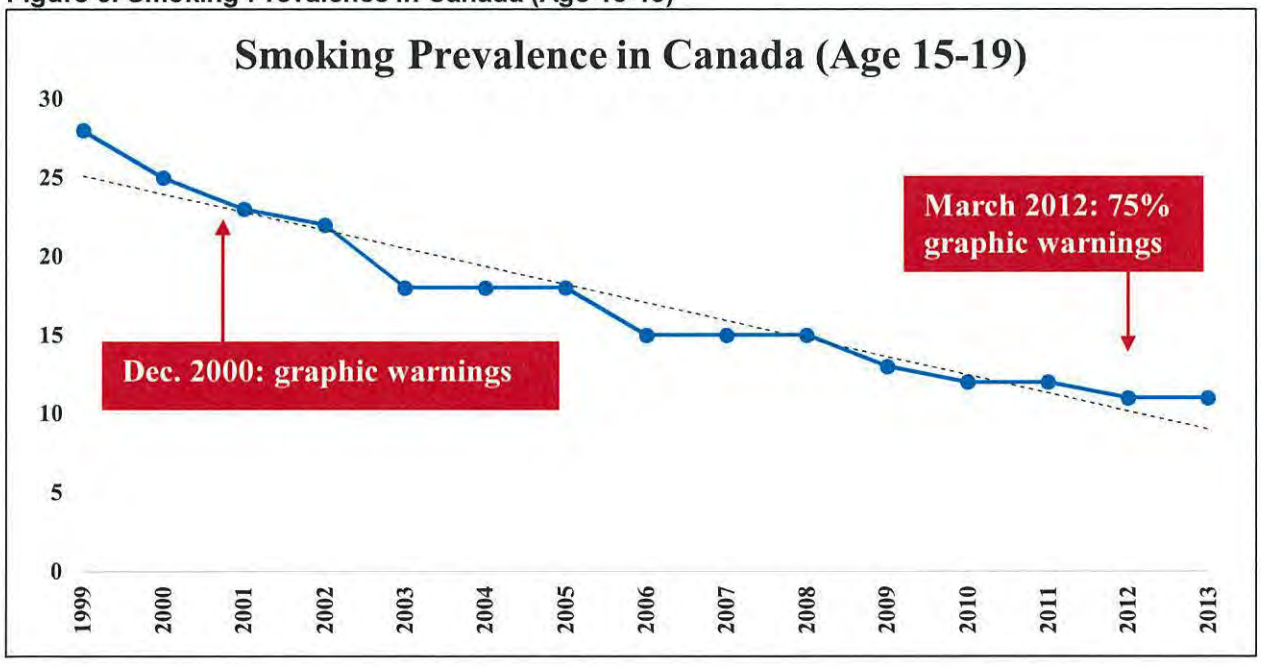
Figure 5: Smoking Prevalence in Canada (Age 15+)



This result demonstrates that simply assuming, on the basis of "common sense" or otherwise, that larger warnings will reduce smoking, is unjustified based on real world experience.

A similar pattern is observed in Figure 6 for smoking prevalence rates since 1999 for youth, aged 15 to 19. The 2013 smoking prevalence rate for those aged 15 to 19 reflects a continuation of past trends and is not even significantly different than the smoking prevalence rate before the advent of 75% graphic warnings. Figure 6 and the dashed trend line indicate this long-run pattern.

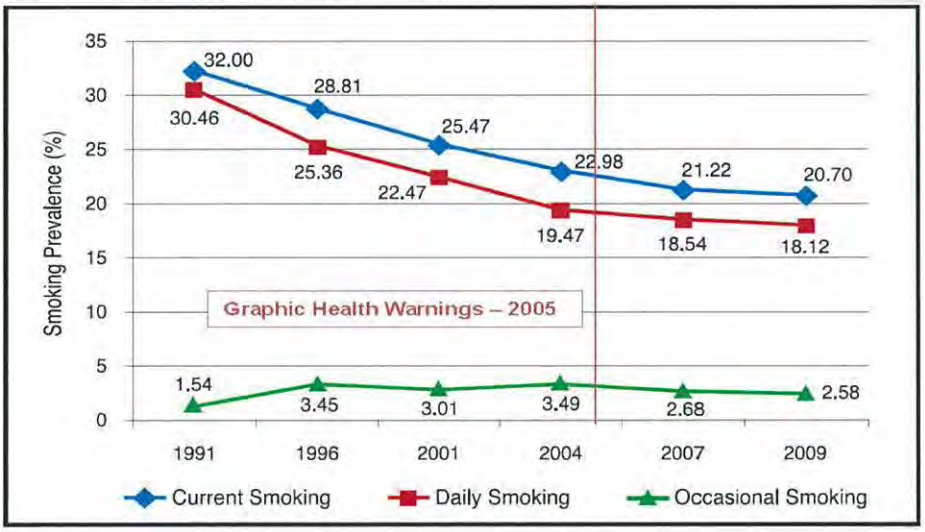
Figure 6: Smoking Prevalence in Canada (Age 15-19)



3. THAILAND

At the meeting before the Panel, the Undersecretary also claimed that evidence from Thailand demonstrated that larger GHWs are more effective. However, the introduction of graphic warnings in Thailand in 2005 has similarly had no impact on reducing smoking prevalence. The chart below demonstrates that the rate of decline in smoking prevalence rates in Thailand actually diminished after the introduction of graphic warnings in 2005.[8] This failure to accelerate the decline in smoking rates is especially noteworthy since cigarette taxes and cigarette prices rose during the post-2005 period.[9]

Figure 1: Trends of Smoking Prevalence (1991-2009)



Consistent with the lack of impact of graphic warnings in Thailand on smoking prevalence, the Thailand Ministry of Information and Communication Technology, National Statistical Office, Smoking and Drinking Behaviour Surveys show that smoking prevalence slightly increased in Thailand from 21.2% in 2007 to 21.4% in 2011.[10] The Global Adult Tobacco Survey (GATS) Thailand 2011 also found that *"[t]he prevalence of current tobacco smoking did not show a statistically significant change between 2009 and 2011 among men (45.6% vs 46.6%, respectively), women (3.1% vs 2.6%, respectively), and overall (23.7% vs 24.0%, respectively)."* This survey also found that 94.6 percent of current smokers in Thailand noticed the health warning on cigarettes packages when they covered 55% of the packaging[11] (which is only 5% larger than the current warnings in Hong Kong), so the lack of impact of the warnings is not because they are not seen by smokers. It follows that these survey results do not provide any evidence that increasing the size of the graphic warnings would make them more effective. The data from Thailand is therefore not supportive of a conclusion that larger GHWs lead to a decrease in smoking prevalence.

---

8 Chart sourced from Southeast Asia Initiative on Tobacco Tax, Thailand Tobacco Tax Report Card, October 2010.

9 Id, Figure 4 for taxes and Figure 7 for prices.

10 Ministry of Information and Communication Technology, National Statistical Office, Smoking and Drinking Behaviour Survey, 2007 & 2011, Table 1.

11 GATS Report, (2011) Thailand Country Report, Page xxiii & Table 8.2.

HERBERT
SMITH
FREEHILLS

Dr. KO Wing-Man, BBS, JP
Secretary for Food and Health
Food and Health Bureau,
18/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong

23rd Floor Gloucester Tower
15 Queen's Road Central
Hong Kong
T +852 2845 6639
F +852 2845 9099
D +852 2101 4629
DX 009028
E dominic.geiser@hsf.com
www.herbertsmithfreehills.com

Our ref
6461/17503/30975151
Your ref
FH CR 3/3231/15
Date
30 July 2016

By registered post

Dear Sirs,

Re: Government's proposal to change the Health Warnings on Tobacco Products Packets and Retail Containers

We refer to our letter of 29 July 2016. For the Government's ease of reference and consideration, we enclose copies of (1) the US FDA Study and (2) the Final Results Report by Nonnemaker J et al dated December 2010 referred to in footnotes 44 and 46, respectively of the Written Submission of British American Tobacco Company (Hong Kong) Limited.

Please do not hesitate to contact us should you have any queries.

Yours faithfully,

Herbert Smith Freehills

Encl.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2010–N–0568]

RIN 0910–AG41

Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to add a new requirement for the display of health warnings on cigarette packages and in cigarette advertisements. This rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics, depicting the negative health consequences of smoking, to accompany the nine new textual warning statements required under the Tobacco Control Act. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) to require each cigarette package and advertisement to bear one of nine new textual warning statements. This final rule specifies the color graphic images that must accompany each of the nine new textual warning statements.

DATES: This rule is effective September 22, 2012. See section VIII of this document, *Implementation Date,* for additional information. The incorporation by reference of a certain publication listed in the rule is approved by the Director of the Federal Register as of September 22, 2012.

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Kristin Davis, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *gerie.voss@fda.hhs.gov* or *kristin.davis@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. Purpose and Overview

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FCLAA, and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat.

1776). Section 201 of the Tobacco Control Act modifies section 4 of FCLAA (15 U.S.C. 1333) to require that the following nine new health warning statements appear on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive
- WARNING: Tobacco smoke can harm your children
- WARNING: Cigarettes cause fatal lung disease
- WARNING: Cigarettes cause cancer
- WARNING: Cigarettes cause strokes and heart disease
- WARNING: Smoking during pregnancy can harm your baby
- WARNING: Smoking can kill you
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Section 201 of the Tobacco Control Act also states that ''the Secretary [of Health and Human Services] shall issue regulations that require color graphics depicting the negative health consequences of smoking'' to accompany the nine new health warning statements.

As discussed in the preamble to the proposed rule (75 FR 69524 at 69525, November 12, 2010), cigarette smoking kills an estimated 443,000 Americans each year, most of whom began smoking when they were under the age of 18 (Ref. 1). Tobacco use is the foremost preventable cause of premature death in the United States, and has been shown to cause cancer, heart disease, lung disease, and other serious adverse health effects (Ref. 2). The U.S. Government has a substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use (section 2(31) of the Tobacco Control Act).

Although FCLAA has required the inclusion of textual health warnings on cigarette packages and in cigarette advertisements for many years, there is considerable evidence, which was presented in the preamble to the proposed rule (75 FR 69524 at 69529 through 69531) and is discussed in section II.B of this document, that the existing cigarette health warnings are given little attention or consideration by viewers. A 2007 report from the Institute of Medicine (IOM) described the warnings as ''invisible'' (Ref. 3), and found that they fail to communicate relevant information in an effective way. The warnings currently in use in the United States also fail to include any graphic component, despite the evidence in the scientific literature that larger, graphic health warnings promote greater understanding of the health risks of smoking and would help to reduce consumption (*see* 75 FR 69524 at 69531 through 69533). In proposing this regulation and preparing this final rule, we found substantial evidence indicating that larger cigarette health warnings including a graphic component, like those being required in this rule, would offer significant health benefits over the existing warnings. Consistent with Executive Order 13563, this regulation is ''based on the best available evidence'' and has allowed ''for public participation and an open exchange of ideas.''

B. Background

On November 12, 2010, as directed by section 201 of the Tobacco Control Act and in the interest of public health, we issued a proposed rule seeking to modify the warnings that appear on cigarette packages and in cigarette advertisements to include color graphic images depicting the negative health consequences of smoking; these images were proposed to accompany the nine new textual warning statements set forth in section 201 of the Tobacco Control Act (*see* 75 FR 69524). The Agency received more than 1,700 comments to the docket for the November 12, 2010, notice of proposed rulemaking (NPRM) on required warnings for cigarette packages and advertisements. Comments were received from cigarette manufacturers, retailers and distributors, industry associations, health professionals, public health or other advocacy groups, academics, State and local public health agencies, medical organizations, individual consumers, and other submitters. These comments are summarized and responded to in the relevant section(s) of this document. Similar comments are grouped together by the topics discussed or the particular portions of the NPRM or codified language to which they refer.

To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parenthesis, appears before the comment's description, and the word ''Response,'' in parenthesis, appears before FDA's response. Each comment is numbered to help distinguish among different comments. Similar comments are grouped together under the same comment number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received.

II. Need for the Rule and Responses to Comments

A. Cigarette Use in the United States and the Resulting Health Consequences

1. Smoking Prevalence and Initiation in the United States

In explaining the need for the proposed rule, we provided information in the NPRM on smoking prevalence and initiation rates among adults and children in the United States. As stated in the NPRM (75 FR 69524 at 69526), approximately 46.6 million U.S. adults (or 20.6 percent of the adult population) are cigarette smokers (Ref. 4). Moreover, almost half (46.3 percent) of youth in grades 9 through 12 in the United States have tried cigarette smoking, and 19.5 percent of youth in grades 9 through 12 are current cigarette smokers (Ref. 5 at p. 10). Smoking rates among U.S. adults have shown virtually no change during the 5-year period from 2005 to 2009 (Ref. 4), and smoking rates among U.S. youth have not decreased from 2006 to 2009 (Ref. 6).

Furthermore, each year millions of U.S. adults and children become new smokers. Data from the 2008 National Survey on Drug Use and Health indicate that 2.4 million persons aged 12 or older in the United States smoked cigarettes for the first time in the past 12 months (Ref. 7 at p. 59). In addition, these data indicate that almost 1 million Americans aged 12 or older started smoking cigarettes daily within the past 12 months (Ref. 7 at p. 60).

In other words, approximately 6,600 people aged 12 or older in the United States become new cigarette smokers every day, and more than 2,500 individuals become new daily cigarette smokers every day (Ref. 7 at pp. 59–60). Moreover, nearly 4,000 of the people who become new cigarette smokers every day and nearly 1,000 of the individuals who become new daily cigarette smokers every day are children under the age of 18 (Ref. 7 at pp. 59–60). These statistics for youth smokers are particularly concerning, as studies suggest that the age people start smoking can greatly influence how much they smoke per day and how long they smoke, which in turn influences their risk of tobacco-related disease and death (Refs. 8, 9, and 10).

FDA received many comments that were strongly supportive of the proposed rule, some of which provided data and information consistent with that in the NPRM regarding cigarette use prevalence and initiation in the United States (75 FR 69524 at 69526 through 69527). Many of these comments also stated that smokers would be more

likely to quit smoking and that nonsmokers would be less likely to start smoking if cigarette advertisements and packages display, visually and graphically, the health effects of cigarettes. Most of these comments expressed a belief that the required warnings would help reduce the existing and future use of cigarettes. Some comments that were supportive of the proposed rule discussed the smoking prevalence and initiation rates in the United States in particular populations. These comments, and FDA's responses, are summarized in the following paragraphs.

(Comment 1) Multiple comments indicated that people with less education and lower incomes have higher smoking prevalence rates in general. One comment from a health care association indicated that women of low educational background have higher smoking prevalence rates and that many of these women still are not aware of cigarettes' impact on life expectancy, heart disease, and pregnancy.

(Response) We agree that adults with low education levels have higher than average smoking prevalence rates. For example, as discussed in the NPRM (75 FR 69524 at 69526), 49.1 percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree (Ref. 4). We also agree that graphic health warnings may be particularly important communication tools for these smokers, as there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels (Ref. 11 at p. 18 and Ref. 3 at p. 295).

(Comment 2) Multiple comments noted that smoking rates vary by race and ethnicity, with American Indians/Alaska Natives having the highest rates. One comment also noted that the health and economic costs of smoking vary by race and ethnicity. For example, the comment stated that African-American smokers suffer disproportionately from smoking-related diseases, including lung cancer, heart disease, and strokes (*citing* Ref. 12), and called for measures to address these disparities.

One comment from a State public health agency indicated that racial minority populations and economically disadvantaged populations have smoking prevalence rates that are two to three times higher than the general population.

(Response) We agree that smoking rates vary by race and ethnicity and socioeconomic status. For example, prevalence data from 2009 for current U.S. adult cigarette smokers indicate that, among racial/ethnic groups, adults reporting multiple races had the highest smoking prevalence (29.5 percent), followed by American Indians/Alaska Natives (23.2 percent) (Ref. 4). We also agree that economically disadvantaged populations have higher smoking prevalence rates. For example, data from 2009 indicate that the prevalence of current smoking was higher among U.S. adults living below the Federal poverty level (31.1 percent) than among those at or above this level (19.4 percent) (*Id.*). We have selected required warnings that will help effectively convey the negative health consequences of smoking to a wide range of population groups, including different racial and ethnic groups and different socioeconomic groups, and that can help both to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting. For additional information regarding our selection of required warnings to reach a broad range of population groups, see section III of this document regarding our selection of the final images.

(Comment 3) Multiple comments stated that tobacco use disparities exist among lesbian, gay, bisexual, and transgender individuals. One comment from a community organization stated that lesbian, gay, bisexual, and transgender individuals smoke at rates almost 50 percent to 200 percent higher than the rest of the population and strongly supported the proposed rule.

(Response) We agree that evidence suggests that gay, lesbian, bisexual, and transgender populations have higher smoking rates than their heterosexual counterparts (Ref. 13). The required warnings will help convey information about various health risks of smoking to individuals from a wide range of demographic groups and will help encourage smoking cessation and discourage smoking initiation.

(Comment 4) One comment from a nonprofit research organization indicated that members of the U.S. military have rates of smoking that are unacceptably high, particularly among younger members. The comment detailed the negative outcomes of smoking to military personnel, including lower physical performance, an increased risk of injury during physical tasks, a greater number of days sick and unable to report for duty, poorer job performance, and a higher likelihood of premature discharge from active duty, and stated that smoking and its negative effects among active duty personnel costs the military an estimated $1 billion annually in health care and lost productivity (Ref. 14). The comment also referred to evidence suggesting the tobacco industry has targeted military members and fought efforts to reduce tobacco product consumption by military personnel, and indicated that the proposed rule is an important step in protecting military members from the health harms of cigarette use and will likely decrease cigarette use among military personnel.

(Response) We agree that members of the U.S. military have higher smoking prevalence rates than the general population; approximately 20.6 percent of the U.S. adult population smoke cigarettes, while data from 2008 indicate that 31 percent of active duty military personnel smoke cigarettes (Ref. 15). We agree that the required warnings will help convey information about various health risks of smoking to a wide range of individuals, including members of the U.S. military and veterans who began smoking while in military service, and that the required warnings will encourage smoking cessation and discourage smoking initiation in these individuals.

2. Health Consequences of Smoking

Smoking is responsible for at least 443,000 premature deaths per year in the United States, and each year cigarettes are responsible for approximately 5.1 million years of potential life lost (Ref. 1). Annual direct health care expenses due to smoking total approximately $96 billion, and annual productivity losses due to premature deaths alone from cigarette smoking total approximately $96.8 billion (*Id.*).

The Agency received many comments that were supportive of the proposed rule, some of which reiterated the health risks of smoking described in the NPRM (75 FR 69524 at 69527 through 69529) and stressed the need for measures, such as graphic health warnings, to curb smoking in the United States in order to improve health and to reduce the massive health care costs attributable to tobacco-related illnesses. Some of these comments cited data demonstrating that smoking is the leading cause or most powerful risk factor for particular diseases, such as chronic obstructive pulmonary disease (COPD), bladder cancer, and atherosclerosis.

However, FDA also received multiple comments disputing the health risks of smoking. These comments and FDA's responses are summarized in the following paragraphs.

(Comment 5) One comment from an individual expressed a belief that addiction to nicotine is 99 percent

psychological and only 1 percent pharmacological, and that nicotine is no more addictive than caffeine.

(Response) We disagree with the assertion that nicotine addiction does not have a substantial physiologic component. While we acknowledge that behavioral processes play a role in initiation and maintenance of nicotine addiction, nicotine is a powerful pharmacologic agent that acts in a variety of ways at different sites in the body. As stated in the NPRM, nicotine causes physical dependence characterized by withdrawal symptoms that usually accompany nicotine abstinence (75 FR 69524 at 69528). Regarding the relative addictiveness of nicotine and caffeine, caffeine is distinct from nicotine in its abuse liability, which includes a consideration of multiple factors, including the dependence potential of a substance and the degree to which it produces adverse effects (*see* Ref. 16 at p. 304). Caffeine produces only minimal disruptive physiological effects and, unlike nicotine from tobacco products, caffeine is generally not used in ways that are considered to be of significant adverse health effect (*see Id.* at pp. 285 and 304).

(Comment 6) One comment stated that nicotine withdrawal is the only medical condition that is irrefutably caused by cigarettes.

(Response) We disagree with this comment. While nicotine addiction is one negative health effect of cigarette smoking, it is not the only medical condition irrefutably caused by cigarettes. As detailed in the 2004 report of the Surgeon General, ''The Health Consequences of Smoking,'' which summarizes thousands of peer-reviewed scientific studies and was itself peer-reviewed, cigarettes have been shown to cause an ever-expanding number of diseases and conditions, including lung cancer, laryngeal cancer, oral cavity and pharyngeal cancers, esophageal cancer, bladder cancer, pancreatic cancer, kidney cancer, stomach cancer, cervical cancer, acute myeloid leukemia, all the major clinical cardiovascular diseases, COPD, and a range of acute respiratory illnesses (Ref. 2).

Maternal smoking during pregnancy causes a reduction in lung function in infants, and women who smoke during pregnancy are more likely to experience premature rupture of the membranes, placenta previa, and placental abruption (*Id.* at pp. 508 and 576). Smoking also increases rates of preterm delivery and shortened gestation, and women who smoke are twice as likely as nonsmokers to have low birth weight infants; smoking also increases the risk of sudden infant death syndrome (SIDS) (*Id.* at pp. 569, 576, 587 and 601).

Children who smoke experience impaired lung growth and an early onset of lung function decline (*Id.* at pp. 508–509, 2004 SG). Smoking during adulthood also leads to a premature onset of accelerated age-related decline in lung function (*Id.* at p. 509). Smoking also results in poor asthma control and causes a range of respiratory symptoms in children, adolescents, and adults, including coughing, phlegm, wheezing, and shortness of breath (*Id.*).

Furthermore, cigarette smokers have poorer overall health status compared to nonsmokers, and an increased risk of adverse surgical outcomes related to wound healing and respiratory complications compared to nonsmokers. Smokers are also at an increased risk for hip fractures, and smoking increases the risk for periodontitis, cataract, and the occurrence of peptic ulcer disease in persons who are *Heliobacter pylori* positive (*Id.* at pp. 717–719, 736, 777, 780, and 813).

In addition, exposure to secondhand smoke has been shown to cause a variety of negative health effects in nonsmokers, including lung cancer, cardiovascular disease, and respiratory symptoms (*see* Ref. 17).

(Comment 7) Some comments were submitted by individuals disputing the negative health consequences of smoking that are described in the graphic warnings. These comments generally indicated that the individuals submitting the comments were smokers, and that they and/or their family members (who were exposed to secondhand smoke) had not experienced negative health effects from smoking.

(Response) We disagree with these comments. Cigarette smoking has been shown to cause a wide range of negative health consequences, as detailed in the previous response. Furthermore, it can be years before some of the negative health consequences of smoking clinically manifest. Thus, the personal health status of the individuals submitting these comments could change in the future. A scientific determination that a product causes a particular negative health consequence is based on data from large groups of individuals, and the fact that an individual product user has not experienced (or has not yet experienced) a particular negative health consequence does not mean the product does not cause that harm.

Moreover, to the extent these comments indicate that many smokers do not fully understand the serious health risks of cigarettes or do not believe that these risks apply to them, they illustrate the need for health warnings that effectively communicate the negative health consequences of smoking to consumers. For additional information regarding consumers' lack of knowledge of smoking risks, see section II.C of this document.

(Comment 8) One comment stated that cigarettes are a minor public health concern compared to obesity and alcohol, and that cigarette use results in less health care costs than medical treatment for the obese.

(Response) As discussed in the NPRM, cigarette smoking is the leading cause of preventable death and disease in the United States (Ref. 4). Furthermore, cigarettes are responsible for health care expenditures and productivity losses resulting in a combined economic burden of approximately $193 billion per year (Ref. 1). The total costs of smoking to society are much higher, as the estimate for productivity losses does not include costs associated with smoking-related disability, employee absenteeism, or costs associated with secondhand-smoke attributable disease morbidity and mortality (*Id.*).

We disagree that cigarettes are a minor public health concern, even as compared to other public health issues, and also disagree with the implication that the public health issue of smoking should not be addressed because other public health issues exist. The required warnings will have a significant, positive impact on public health (75 FR 69524 at 69526), and as a result will help mitigate the single largest cause of preventable death and disease in the United States.

B. Inadequacy of Existing Warnings

In the preamble to the proposed rule, FDA explained how cigarette packages and advertisements can be effective channels for communication of important health information, particularly given that pack-a-day smokers are potentially exposed to warnings more than 7,000 times per year (75 FR 69524 at 69529). However, the existing warnings have suffered from three crucial problems: (1) They have not changed in more than 25 years, (2) they often go unnoticed, and (3) they fail to convey relevant information in an effective manner. FDA also explained that larger, graphic warnings communicate the health risks of smoking more effectively. The preamble to the proposed rule presented extensive evidence from other countries' experiences with graphic warnings as well as information from the 2007 IOM Report (75 FR 69524 at 69531). On the

basis of the available scientific evidence, the IOM concluded that larger, graphic warnings would promote greater public knowledge of the health risks of using tobacco and would help reduce consumption (Ref. 3).

We received numerous comments regarding the adequacy of the existing warnings that appear on cigarette packages and advertisements. The large majority of these comments supported our analysis of the existing warnings, but a few comments disagreed with this analysis. These comments, and our responses, are summarized in the following paragraphs.

(Comment 9) A substantial number of comments, including those from health institutions, nonprofit organizations, academics, and consumers, agreed with FDA's conclusion that the existing warnings that appear on cigarette packages and advertisements are ineffective at conveying the health risks of smoking (75 FR 69524 at 69529 through 69531).

However, one comment stated that the current warnings were ''fine.'' Two comments expressed the belief that the existing warnings have worked successfully in the current information environment.

(Response) We disagree with the comments stating that the existing warnings that appear on cigarette packages and advertisements are effective. As several other comments noted, the Surgeon General has long recognized that the cigarette warnings are deficient. For example, in its 1994 report the Surgeon General noted that the warnings had become ineffective due to their size, shape, and familiarity (Ref. 18). That same year, the IOM concluded that the warnings were ''inadequate * * * and woefully deficient when evaluated in terms of proper public health criteria'' (Ref. 19 at p. 237). Yet those same warnings are still in use more than 16 years after the Surgeon General's report and 26 years after their inception. Accordingly, we conclude that the existing warnings for cigarettes do not adequately communicate the health risks of smoking.

C. Consumers' Lack of Knowledge of the Health Risks

In the preamble to the proposed rule, FDA described how the existing warnings that currently appear on cigarette packages and advertisements have largely gone unnoticed by both smokers and nonsmokers (75 FR 69524 at 69530). FDA also provided clear evidence that the warnings have failed to convey appropriately crucial information such as the nature and extent of the health risks associated with smoking cigarettes (75 FR 69524 at 69530 through 69531).

FDA received many comments regarding the level of consumers' knowledge regarding the health risks of smoking. Several comments stated that consumers are adequately informed about the risks of smoking or even overestimate the risks of smoking, while many other comments explained that consumers lack knowledge about a wide variety of smoking risks. A summary of these comments, and our responses, is included in the following paragraphs.

(Comment 10) Several comments, including comments from tobacco product manufacturers and individual consumers, objected to the new required warnings, in part because they claimed that consumers already know the health risks associated with smoking. The submitters expressed the belief that the new warnings are unnecessary, because the new warnings provide information that the public has been aware of for many years.

(Response) We disagree. Many comments provided significant evidence to support the notion that consumers, including those in communities with low literacy rates and military personnel, actually lack knowledge or underestimate the risks associated with smoking. As discussed in this document, this lack of knowledge may involve either an incomplete understanding of the statistical risks or a failure to understand the personal (as opposed to the statistical) risks (*see also* section XI.B.2 of this document). There is also a possibility that the risks are not considered at the time of purchase, even if they are understood—a special problem for those who are deciding whether to start to smoke. The requirements adopted here should help to counteract all of these problems.

While most smokers understand that smoking poses certain statistical risks to their health, many fail to appreciate the severity and magnitude of those risks (Refs. 20 and 21), and there is evidence that even when smokers appreciate the statistical risk, they underestimate the personal risk that they face (Ref. 22). A 2007 survey found that two in three smokers underestimate the chance of a smoker developing lung cancer compared to a nonsmoker (Ref. 23). The survey also found that up to a third of smokers erroneously believe that certain activities, such as exercise and taking vitamins, could ''undo'' most of the effects of smoking (*Id.*).

Other research also highlights how smokers underestimate the health effects of smoking. For example, in a 2008 survey, more than one-quarter of current smokers did not agree that smoking increases a person's chances of getting cancer ''a lot'' (Ref. 24). Furthermore, one study, involving smokers' perception of their personal risk, found that only 40 percent of current smokers believed they had a higher-than-average risk of cancer and only 29 percent believed they had a higher-than-average risk of heart disease (Ref. 25). Even among heavy smokers (those who smoke at least 40 cigarettes per day), less than half believed they were at increased risk for these diseases (*Id.*). In another demonstration of underestimation of personal risk, a study found that adolescent smokers underestimated their personal risk, even if they had an accurate sense of the statistical risk (Ref. 22).

A 2005 study of smokers in the United States and three other countries found that there were significant gaps in smokers' knowledge about the risks of smoking and that smokers living in countries where health warnings referred to specific disease consequences of smoking were much more likely to be aware of those consequences (Ref. 26). The study concluded that smokers are not fully informed about the risks of smoking, and that warnings that are graphic, larger, and more comprehensive in content are more effective in communicating the health risks of smoking (*Id.*).

Thus, even if consumers are aware of certain negative health consequences of smoking, such as lung cancer and emphysema, and even if they are aware of certain statistical risks, many smokers underestimate their personal risks, and many Americans are under-informed about other health risks associated with smoking. For example, while nearly all daily smokers in one study correctly identified that smoking caused lung cancer (99 percent) and emphysema (97 percent), a lower percentage of respondents correctly identified smoking as causing low birth weight babies (88 percent), worsened asthma (85 percent), miscarriages (76 percent), other cancers (69 percent), head and neck cancers (68 percent), cervical cancer (48 percent), stomach ulcers (46 percent), reproductive difficulties (44 percent), osteoporosis (41 percent), and SIDS (40 percent) (Ref. 27). In fact, research indicates that most people know only one or two of the many diseases causes by smoking. One survey found that while a majority of people knew that smoking caused life-threatening illnesses, more than half of the respondents were unable to name a smoking-related illness other than lung cancer (Ref. 28). Similarly, researchers

found that when asked about health risks of smoking, 39 percent of respondents either answered incorrectly or said they did not know (Ref. 29).

Americans also lack adequate understanding of the addictive nature of cigarettes. Although one comment provided local surveys showing that adults already know that cigarettes are addictive, there is also evidence that many adolescents do not appreciate the addictive nature of cigarettes. The 2007 IOM Report explained that ''adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior'' (Ref. 3 at p. 93). In addition, one survey found that fewer than 5 percent of daily smokers in high school think that they still will be smoking at all in 5 years, yet more than 60 percent of high school smokers are regular daily smokers 7 to 9 years later (Ref. 30). Another survey found that only 7.4 percent of adult smokers and 4.8 percent of young smokers expected to smoke longer than 5 years when they started, but 87 percent of these adults and 76 percent of these youth reported that they had been smoking for more than 5 years (Ref. 31).

There is also evidence that certain demographic groups are even less aware of the negative health consequences of smoking, which is particularly concerning in light of the evidence that these groups also have some of the highest smoking prevalence rates (*see* section II.A.1 of this document). For example, research shows that knowledge of smoking risks is lower among people with lower incomes and fewer years of education (Refs. 32 33 and 24). Smokers in the military also underestimate the actual risk of serious disease and substantially underestimate their own risks (a point that fits well with the evidence of underestimation of personal risks) (Refs. 34 35 and 36).

In addition to underestimating the risks smoking poses to their own health, Americans underestimate the health effects of secondhand smoke on others. In the 2010 Report, ''How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease,'' the Surgeon General concluded that ''many of the effects from active smoking can be observed in persons involuntarily exposed to cigarette smoke'' (Ref. 37). In addition, individual studies have shown that secondhand smoke triggers childhood asthma and is associated with both heart disease and cancer (Ref. 17). Yet, most parents believe that smoke exposure has little or no negative impact on children's asthma (Ref. 38), and a 2009 study found that nearly one-fifth of Americans do not believe that secondhand smoke is dangerous to nonsmokers (Ref. 39).

There is a final point. Even if many people do have an accurate understanding of the statistical risk, and even if, in the abstract, many smokers also have an accurate understanding of their personal risk, that understanding may be too abstract to be thought of at the time of purchase, especially (but not only) for those who are starting to smoke. Efforts to make the relevant risks salient are justified and indeed required under the Tobacco Control Act.

(Comment 11) A few comments claimed that adults actually overestimate the risks of smoking-related disease, and stated that this further underscores the lack of a need for graphic health warnings. In particular, one comment referred to a Montana survey in which adults believed that smoking caused colon cancer.

(Response) We disagree with these comments. While the Montana survey referred to in one of the comments indicates that some consumers are not aware of the precise relationship between smoking and certain diseases (for example, the 2004 Surgeon General's report notes that the evidence is suggestive but not sufficient to infer a causal relationship between smoking and colorectal cancer (Ref. 2 at p. 26)), we are aware of significant research indicating that many consumers are not sufficiently aware of the risks associated with smoking, as discussed in the previous response. We find that the weight of evidence clearly demonstrates that many consumers lack adequate knowledge about the health risks of smoking—especially the personal risks. In addition, the comments claiming that adults overestimate smoking's risks fail to take into account consumers' lack of knowledge of other health risks due to smoking, like the dangers of secondhand smoke, reproductive difficulties, and miscarriages, as described in the previous response.

D. Larger, Graphic Warnings Communicate More Effectively

Since Canada first introduced graphic health warnings for cigarettes in 2001, an extensive evidence base has been developed to examine the effects of graphic health warnings in Canada and in the more than 30 other countries that have adopted similar requirements for graphic health warnings on cigarettes. As FDA extensively discussed in the NPRM (75 FR 69524 at 69531 through 69533), the research literature indicates that large graphic health warnings, such as those being required in this rule, are more likely than text-only warnings to (1) get consumers' attention, (2) influence consumers' awareness of cigarette-related health risks, and (3) affect smoking intentions and behaviors. FDA received many comments on the efficacy of large, graphic warnings, as well as comments regarding the potential for any rebound effect from the use of graphic warnings. Those comments, and FDA's responses, are summarized in the following paragraphs.

(Comment 12) A wide variety of comments, including those from health institutions, nonprofit organizations, and academics, agreed with FDA's findings in the NPRM that larger, graphic warnings are effective.

However, several comments stated that the changes in the format and placement of the warnings being proposed, including the use of graphic images, will not result in reductions in cigarette use given the experiences in other countries. For example, one comment noted that Health Canada's own data found, among other things, that there was no statistically significant decline in smoking incidence consumption for adolescents or adults after the introduction of graphic warnings. This comment expressed the belief that Canada's warnings have been ineffective and that FDA's graphic health warnings will be similarly ineffective.

(Response) For the reasons stated in the NPRM, we conclude that larger, graphic warnings are effective in conveying the health risks of smoking, influencing consumer awareness of these risks, and affecting smoking intentions. We disagree with comments stating that the change in format and placement of the warnings will not be effective. The set of required warnings we have selected will satisfy our primary goal, which is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements, and this effective communication can help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.

The research literature clearly indicates that larger, graphic warnings are effective at communicating the health risks associated with smoking, encouraging users to quit smoking, and discouraging nonsmokers from beginning to smoke. We already included significant research to

substantiate this conclusion in the preamble to the proposed rule, and the comments did not specifically dispute this analysis (*see* 75 FR 69524 at 69531 through 69532). In addition, as we noted in the NPRM, the available evidence demonstrates that graphic health warnings are (1) more likely to be noticed than text-only warnings, (2) more effective for educating smokers about the health risks of smoking and for increasing the time smokers spend thinking about the health risks, and (3) associated with increased motivation to quit smoking (*Id.*). As several comments noted, evidence from countries with graphic health warnings also indicates that such warnings are an important information source for younger smokers, and that pictures are effective in conveying messages to children (Ref. 40 at pp. 3, 20, and 24–26). These important effects of graphic warnings are sustained longer than any impact from text-only warnings (Ref. 41).

Further, the data from Health Canada does not indicate that the warnings have been ineffective at conveying the health risks of smoking and impacting smoking intentions. We cited several studies in the preamble (including data from Health Canada) that illustrated the effectiveness of the Canadian graphic health warnings, which have been found effective at providing youth and adult smokers with health information, making consumers think about the health effects of smoking, and increasing smokers' motivations to quit smoking, among other things (*see* 75 FR 69524 at 69532). For example, national surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information (Ref. 3 at p. 294).

(Comment 13) One comment suggested that the new required warnings will have a greater impact on nonsmokers who inadvertently view cigarette packages than on smokers and, therefore, will not be effective in achieving FDA's goals.

(Response) We are not aware of any evidence to substantiate this comment. Further, our required warnings are intended to have an impact on *both* smokers and nonsmokers. As stated in the preamble to the proposed rule, ''the new required warnings are designed to clearly and effectively convey the negative health consequences of smoking on cigarette packages and in cigarette advertisements, which would help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health'' (75 FR 69524 at 69526). Therefore, the warnings are intended to have an impact on nonsmokers as well as smokers, and the required warnings will effectively communicate the negative health consequences of smoking to both of these important audiences.

(Comment 14) Several comments, including comments from cigarette manufacturers and individual consumers, expressed concerns that the new required warnings on cigarette packages and advertisements would cause people not to look at packages or cause them to hold their cigarettes in decorative cases. The comments also indicated that some of the proposed images would induce youth to purchase cigarettes rather than deter them from smoking, because the new images would be striking to youth. These comments stated that this ''rebound effect'' would undermine the intent of the warnings and decrease their effectiveness.

(Response) We disagree. Comments expressing concerns about a potential rebound effect did not provide persuasive scientific evidence to demonstrate such an effect is likely to occur (or that it would have sufficient magnitude to be a significant concern). The comments referenced older studies that did not specifically address graphic warnings on cigarette packages and advertisements, and also referred to a qualitative study conducted on the European Union's graphic warnings, in which some focus group participants commented that some warnings were humorous or that they were not persuasive in educating consumers about dental diseases associated with smoking (Ref. 42). When weighing this qualitative information against the quantitative research available, including evidence from countries with graphic health warning requirements, as well as the findings of the expert panel of the IOM in its 2007 report (*see* Ref. 3), the information referenced in the comments is not persuasive. (While focus groups can provide useful information, it is well known that they are not as reliable as real-world evidence for drawing conclusions about causal relationships and generalizing results to the population as a whole (Ref. 43).)

Furthermore, we note that in the European Union qualitative study referenced in the comments, the researchers concluded that pictures have the potential to add a powerful element to health warning messages and that the old text-only messages were not working (Ref. 42 at p. 43). They also noted that some of the warning messages the comments referred to, including the referenced dental disease image, provoked a highly emotional response in all the countries surveyed despite the comments from certain focus group participants (*Id.* at p. 35). The research literature suggests that images that evoke emotional responses can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 44).

While one comment said that the failure of fear-inducing messages based on health effects is ''well-known in areas outside of smoking prevention,'' the comment did not provide sufficient evidence of such failure in the area of smoking prevention. In fact, as some comments discussed, there is scientific evidence relating to cigarette graphic health warnings illustrating the success of fear-inducing messages (*see, e.g.,* Ref. 44). For example, one comment referred to research that found that smokers exposed to Canada's graphic health warnings generally did not try to avoid the fear-inducing messages, and that any avoidance engaged in by smokers does not appear to undermine quitting intentions or attempts (*citing* Ref. 45). Similarly, researchers analyzing data related to graphic warnings found that:

> [T]here is no evidence that pictorial warnings lead to boomerang effects. An analysis of data from the ITC Four Country Survey found that the Australian pictorial warnings, introduced in 2005, led to greater avoidant behaviours (*e.g.* covering up the pack, keeping it out of sight, or avoiding particular labels), compared to Canada, the United Kingdom, and the USA. Importantly, those smokers who engaged in avoidant behaviours were no less likely to intend to quit or to attempt to quit replicating the findings of a study of the Canadian warnings. Thus, although pictorial warnings can lead to avoidance and defensive reactions, such reactions are actually indicators of positive impact.

(Ref. 46, *citing* Refs. 20 and 44). To the extent that smokers engage in any defensive avoidance with respect to the new required warnings, we are adding a reference to a cessation resource to give smokers an immediate way to act upon this impulse and access cessation assistance. The research literature suggests that such a reference is effective in diminishing potential avoidance effects in response to messages that arouse fear (*see* Ref. 40 at pp. 39–41). See section V.B.6 of this document for additional information regarding our rationale and authority for including a reference to a cessation resource in the required warnings.

(Comment 15) Several comments expressed concern about the potential

effectiveness of the new required warnings, particularly those that are fear-based, with certain portions of the population. These comments expressed the following concerns: (1) Many youths and young adults are rebellious and will be attracted to what they perceive as the ''forbidden fruit;'' (2) fear-based warnings fail with groups that have low self-esteem; (3) fear-based warnings fail with adolescents, because they tend not to be influenced by health-based deterrents; and (4) the new required warnings are ''high fear messages'' that may actually inhibit reductions in smoking, because they decrease a person's perceived ability to quit smoking. These comments expressed the belief that the new required warnings would be ineffective.

(Response) While acknowledging the concerns, we disagree. It is true that messages that induce fear, pointing to a risk, may not be effective when people are unaware of how to reduce the risk, but in this case, the best way to reduce the risk is clear. We have chosen a balanced set of images, including those that may arouse fear and those that may generate other emotional responses in certain individuals in order to reach a diverse population of smokers and nonsmokers, as well as youth, young adults, and adults. Furthermore, as is explained in more detail in section III.B of this document, we conducted a research study to quantitatively evaluate the relative efficacy of the proposed required warnings in communicating the health harms of smoking to adults (aged 25 or older), young adults (aged 18 to 24), and youth (aged 13 to 17). The nine selected required warnings showed positive effects on important study measures in all study populations, including youth, relative to the text-only control. In particular, as is discussed in more detail in section III of this document, the selected required warnings showed strong impacts on the salience measures in our research study, including emotional and cognitive measures.

The research literature suggests that these measures are likely to be related to behavior change. For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers can confer negative feelings about smoking and undermine the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38). In addition, research has shown that younger adolescents are more likely to notice and think about health warnings that include graphic images (Ref. 47).

The required warnings will effectively communicate the negative health consequences of smoking, and we do not agree that they will have unintended negative effects among younger population groups.

(Comment 16) One comment expressed concern that the new graphic images on cigarette packages and advertisements would actually make cigarette smokers sicker, as the images would increase smokers' anxiety and damage their self-esteem.

(Response) We disagree. We are not aware of any scientific evidence to support this claim. In fact, as discussed in the preamble to the proposed rule, the available evidence suggests that graphic health warnings can benefit the public health by increasing smokers' intentions to quit and reducing the likelihood of initiation by nonsmokers (75 FR 69524 at 69532).

(Comment 17) A few comments stated that fear-based warnings fail to work when the message being conveyed is already clearly understood and does not provide new information. These comments expressed the view that, because consumers already understand the risks associated with smoking, the new required warnings would not be effective in achieving FDA's goals.

(Response) We disagree. As explained in section II.C of this document, there is substantial evidence demonstrating that the premise of these comments is not correct and that many consumers do not adequately understand the personal risks associated with smoking.

E. Need To Refresh Required Warnings

As amended by the Tobacco Control Act, FCLAA includes provisions that can help prevent or delay the wear out of the new required warnings. For example, section 4(c)(1) of FCLAA (15 U.S.C. 1333(c)(1)) indicates that the required warnings on cigarette packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product, and be randomly distributed throughout the United States, in accordance with a warning plan approved by FDA. Section 4(c)(2) of FCLAA requires the warnings to be rotated quarterly in cigarette advertisements, also in accordance with a warning plan approved by FDA.

Nevertheless, as stated in the NPRM, we intend to monitor the effects of the new required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. As stated in the NPRM, we will use the results of our monitoring and such research to help determine whether any of the textual warning statements or accompanying graphic images should be revised in a future rulemaking (75 FR 69524 at 69534). This commitment to continued empirical testing is consistent with Executive Order 13563, section 1, which states that our regulatory system ''must measure, and seek to improve, the actual results of regulatory requirements.''

FDA received numerous comments regarding the need periodically to refresh the warnings to minimize wear out, which we have summarized and responded to in the following paragraphs.

(Comment 18) Many comments, including comments from health institutions, nonprofit organizations, and academics, suggested that FDA should refresh the graphic warnings on a regular basis because consumers can become habituated to and ignore warnings. The comments referred to scientific research on the effectiveness of graphic warnings for cigarette packages and advertisements, which strongly recommends that warnings be periodically refreshed to maintain their effectiveness and impact on consumers (Refs. 18, 42, 44, and 26). The comments suggested a wide range of timeframes as to when FDA should refresh the graphic warnings. One comment suggested that FDA track the effectiveness of the required warnings on a quarterly basis and that the results of any testing be made publicly available. One comment suggested that FDA establish a conclusion that new graphic warnings for cigarette packages and advertisements will be required at no more than a 2-year interval. A few comments also suggested that FDA establish a target schedule for reconsideration and revision of the warnings, which would include ongoing consumer research and re-examination of the effectiveness of the required warnings.

(Response) We agree that refreshing the required warnings on a periodic basis can help maintain their effectiveness. Researchers have found that graphic images and text messages are likely to have greater impact at the time they are introduced and that

meaningful impact of the warnings may decline with repeated exposure (Ref. 41). Rotating a variety of cigarette warnings and updating the warnings periodically is likely to minimize the negative effects of overexposure (Ref. 3).

However, we are not aware of any research that warrants the selection of a particular timeframe for future iterations of required warnings. As stated by several comments, there is no definitive rate at which the warnings will wear out, as it depends on many factors including the variety of message executions, exposure level, and the appeal of the message.

We recognize the value of conducting ongoing evaluation of the effects of the required warnings after they enter the marketplace. We also intend to monitor and evaluate the effects of the required warnings, and to monitor the warnings for potential wear out. In addition, we will keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. As noted, this monitoring is consistent with Executive Order 13563, which recognizes the importance of measuring ''actual results'' and of analyzing significant rules after they are in effect to determine whether they should be ''modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.''

When we determine that changes to the required warnings are appropriate (including changes to the textual warning statements and/or the color graphic images) because they would promote greater public understanding of the risks associated with smoking, we can exercise our authority to initiate a new rulemaking to modify the required warnings under section 202(b) of the Tobacco Control Act (adding subsection (d) to section 4 of FCLAA).[1]

III. FDA's Selection of Color Graphic Images

A. Methodology for Selecting Images

When we issued the NPRM, we proposed color graphic images to accompany the nine textual warning statements required by Congress in section 201 of the Tobacco Control Act. In all, we proposed 36 potential required warnings, consisting of the color graphic images FDA developed and the nine textual warning statements from the Tobacco Control Act. These 36 proposed required warnings were made available as electronic files in portable document format (.pdf) and displayed in the document entitled ''Proposed Required Warning Images,'' which was included in the docket for the proposed rule. The proposed required warnings were also made available on FDA's Web site. Consistent with section 4 of FCLAA, 2 versions of each of the 36 proposed required warnings were developed; one with the textual warning statement in black font on a white background, and one with the textual warning statement in white font on a black background.

As explained in the preamble to the proposed rule (75 FR 69524 at 69534 through 69535), in considering and developing appropriate color graphic images to accompany the nine textual warning statements set forth in section 201 of the Tobacco Control Act, FDA assessed the graphic warnings that other countries have required, and worked with various experts in the fields of health communications, marketing research, graphic design, and advertising to develop 36 proposed required warnings. Each of the proposed color graphic images depicted the negative health consequences of smoking, and the themes and subjects depicted in each image illustrated the message conveyed by the accompanying textual warning statement.

The NPRM explained that we planned to select 9 final required warnings from among the 36 proposed required warnings. We sought comments on what color graphic images to require in this final rule, including comments on the 36 proposed color graphic images included with the NPRM.

In addition, as is described in more detail in section III.B of this document, we conducted research on the 36 proposed required warnings to evaluate the relative effectiveness of the proposed color graphic images and their accompanying textual warning statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation.

In order to determine which color graphic images to require in the final rule, we considered a number of factors. First, we considered the relative effectiveness of the proposed required warnings based on the strength of effect the different color graphic images had on the various endpoints and across the populations included in our study (see section III.B of this document for a more detailed description of the research study).

In addition, we considered the substantive public comments received in the docket related to the 36 proposed required warnings (see section III.C of this document for more information on the comments received; the comments relating to each image are summarized and responded to in sections III.D and III.E of this document). We also considered the comments received in the docket that suggested that we use other images in the required warnings, including images that have been used in other countries' graphic health warnings. However, as discussed in more detail in the following comment summaries and in section III.B of this document, we selected images for the nine required warnings from among the images we developed and proposed. Our research study, among other information, indicated these required warnings will effectively communicate the negative health consequences of smoking to a wide range of population groups. As explained in the comment responses throughout this section III, the comments submitted to the docket did not persuade us that other images, including images used in other countries' graphic health warnings, were more appropriate for use in the required warnings than the images we selected.

Furthermore, we considered the relevant scientific literature in the docket, and in particular the extent to which the literature supported or refuted aspects of the images and the extent to which the literature helped determine the appropriate weight to give to other information (including the appropriate weight to give to the various endpoints considered in our research study).

We also considered the variety and diversity reflected in the images in making selection decisions in order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, including audiences that have been targeted by tobacco industry marketing efforts. We took into account the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.,* photographic versus illustrative), themes, and human images (*e.g.,* race, gender, age). This is consistent with the evidence base for graphic health warnings from countries that have already implemented such warnings, which indicates that variety is important in enhancing the noticeability and salience of warnings and broadening their relevance for target groups (Ref. 40 at p. 46 and Ref. 48 at

[1] Section 202(b) of the Tobacco Control Act amends section 4 of FCLAA (15 U.S.C. 1333) to add a new subsection (d), ''Change in Required Statements.'' However, section 201 of the Tobacco Control Act also amends section 4 of FCLAA to add a new subsection (d), ''Graphic Label Statements.''

p. 9), and which suggests that warnings that include pictures of people should broadly represent the ethnic/racial profile of the relevant country (Ref. 11).

We also considered whether to have one image accompany each of the textual warning statements set forth in section 201 of the Tobacco Control Act.

We received multiple comments regarding our proposal to select 9 final required warnings and our proposal to select them from among the 36 proposed color graphic images that were made available with the NPRM. We have summarized and responded to these comments in the following paragraphs (we also received a number of comments on the proposed color graphic images themselves; these comments are summarized in sections III.D and III.E of this document. In addition, we received a number of comments regarding our research study, which assessed the relative effectiveness of the 36 proposed color graphic images; these comments are summarized in section III.C of this document).

(Comment 19) Several comments suggested that FDA select more than one graphic image for each new textual warning statement. The comments reasoned that by limiting the warnings to one graphic image per textual statement, the health warnings would effectively communicate to fewer segments of the smoking and nonsmoking populations. Some comments also suggested that selecting more than one image per warning statement would counteract wear out of the required warnings. One comment suggested that FDA develop multiple series of images and require that each series be used one at a time to delay wear out.

(Response) We decline to select more than one image for each warning statement as suggested in these comments. We believe that the set of nine required warnings we selected will be sufficient at this time to achieve our goal of effectively communicating the negative health consequences of smoking and to prevent wear out of the required warnings for several years. Furthermore, the nine selected required warnings will appeal to a diverse range of audiences, and, as discussed in section III.D of this document, the images selected showed significant effects on important measures in our research study across the three study populations (adults, young adults, and youth).

We intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. Given the significant changes being made to the text, format, and placement of the existing warnings by this rule, it will be valuable to obtain relevant data on the effects of the complete set of required warnings as soon as possible. If we were to expand the number of required warnings, it could delay an assessment of efficacy of the warnings under conditions of real-world use. We intend to use the results of our monitoring and of research conducted on the required warnings once they are in public use to determine whether changes should be made to the required warnings in a future rulemaking, including changes to add new images or to modify the existing required warnings. Accordingly, at this time we decline to select more than nine images.

(Comment 20) Multiple comments suggested that FDA use graphic warning images that have been tested or used in other countries instead of or in addition to one or more of the images that FDA proposed. Some of these comments indicated that images that are in use in other countries would be more effective and educational than some or all of FDA's proposed images.

(Response) We decline to follow this suggestion. FDA's research study evaluated the 36 proposed required warnings. The results from this research study suggest that the nine selected required warnings will effectively communicate negative health consequences of smoking to a diverse range of audiences. Moreover, if we were to select images that were not evaluated in our study, it would be difficult to objectively assess the relative efficacy of such images compared to the 36 proposed images. Compared to the information provided by our research study, the supporting information in the comments did not convince us that the images suggested by those comments would more effectively communicate the negative health consequences of smoking than the images we have selected in this final rule.

(Comment 21) A number of comments suggested that FDA use other images than those published with the proposed rule. For example, some comments recommended that FDA use images that depict real people with real diseases and not models. A few recommended that FDA include images that show negative cosmetic effects of smoking, such as stained fingers and bad breath, in order to impact adolescents concerned about body image. One comment suggested that FDA portray a picture of an obituary, while another recommended the use of an image depicting the amount of money smokers spend to purchase cigarettes every year.

(Response) We decline to select the images suggested in these comments. Each of the required warnings selected by FDA was quantitatively tested to assess its relative effectiveness in communicating the negative health consequences of smoking. In selecting the set of nine required warnings, we considered the results of our research study and a number of other factors and have concluded that the nine selected required warnings effectively communicate the negative health consequences of smoking. In addition, we are adopting the nine textual warning statements mandated by Congress in section 4(a)(1) of FCLAA. The images selected were designed to correlate with those warning statements; the available evidence base highlights the value of the text and images in graphic health warnings relating to one another in a meaningful way (*see* Ref. 40 at p. 41). Including images inconsistent with the textual warning statements could confuse consumers and detract from the effectiveness of the warnings. Furthermore, some of our selected images do show the negative cosmetic effects that can occur as a result of the health consequences of smoking. Moreover, some of the images proposed for use in the comments, such as an image showing the amount of money smokers spend to purchase cigarettes, would not be consistent with the statutory requirement that the required warnings depict the negative health consequences of smoking.

B. FDA's Research Study

As explained in the NPRM (75 FR 69524 at 69535), we conducted research on the 36 proposed required warnings. Specifically, we conducted an Internet-based consumer research study with over 18,000 participants that quantitatively examined the relative efficacy of the 36 proposed color graphic images in communicating the harms of smoking to 3 target groups: Adult smokers (age 25 or older), young adult smokers (aged 18 to 24), and youth (aged 13 to 17) who currently smoke or who are susceptible to smoking.

The purpose of the study was to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed color graphic images and their accompanying textual statements; (2) determine whether consumer responses to the proposed color graphic images and their accompanying textual statements differed across various groups based on age, smoking status, or

other demographic variables; and (3) evaluate the relative effectiveness of the proposed color graphic images and their accompanying textual warnings statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation.

We placed a report (Ref. 49; *see also* Ref. 50 [2]) that described the research study and presented the results of the analyses from the research study in the docket for the proposed rule and announced the report's availability by a notice in the **Federal Register** on December 7, 2010 (*see* 75 FR 75936 at 75936 through 75937) so that the public had an opportunity to comment on the results.

This section briefly describes the design of FDA's research study and key endpoints examined in the research study; a full description of the study and the several hundred pages of data and data analyses are contained in the study report and accompanying appendices (Ref. 49) that was placed in the docket for the proposed rule. This section also describes how the results from this research study informed the selection of the final required warnings.

FDA received numerous comments in the docket related to the research study; this section also includes a summary of the substantive comments received about the research study and FDA's responses to these comments.

1. Study Design

FDA's research study evaluated the required warnings proposed for each of the nine warning statements against a text-only control (which contained the warning statement without any accompanying color graphic image). Study participants were randomly assigned to be exposed to either one of the 36 proposed required warnings (treatment groups) or one of the 9 textual warning statements (control groups). Treatment groups for each target population (adults, young adults, and youth) viewed a hypothetical pack of cigarettes that included one of the proposed required warnings, which appeared on the upper 50 percent of the pack, while the control group viewed a hypothetical pack of cigarettes with a warning statement (but no warning image), which appeared on the side of the pack. Furthermore, among adults, an additional treatment group viewed a hypothetical advertisement that included one of the proposed required warnings, which encompassed approximately 20 percent of the upper right area of the advertisement, while a control group viewed a hypothetical advertisement with a warning statement in the same location (but without a warning image) that was presented using the size and format currently required by FCLAA. The study tested the relative efficacy of each proposed required warning relative to the text-only control for that warning statement for the various outcomes measured.

Each respondent viewed either a single cigarette package or advertisement that displayed one of the proposed required warnings or a text-only warning. Respondents answered questions about their immediate reactions to the cigarette package or advertisement, related attitudes and beliefs about smoking, as well as intentions to quit or start smoking. At the end of the survey, subjects were asked to recall which warning statement and image they saw earlier in the survey to assess the accuracy of recall. In addition, 1 week after completing the survey, subjects were re-contacted and asked to recall the warning statement and image to which they were exposed. Overall, the following key outcomes were measured after exposure to one of the required warnings or the text-only control, and/or at 1 week follow-up:

- Salience—The study examined emotional and cognitive responses to the cigarette packages and advertisements that bore health warnings. Participants provided ratings of their responses to the packages and advertisements. The ratings were aggregated to create two scales: (A) An emotional reaction scale, which included ratings on how the warning made the respondent feel, such as ''depressed,'' ''discouraged,'' and ''afraid''; and (B) a cognitive reaction scale, which included ratings on what the respondent thought about the warning, such as ''believable,'' ''meaningful,'' and ''convincing''.[3]

Regression analyses were used to assess the relative impact of treatment conditions on ratings as compared to the text-only control.

- Recall—The study measured participants' recall of the nine warning statements after exposure to either one of the proposed required warnings or the text-only control (baseline). Participants were also re-contacted after 1 week and asked about their recall of the warning statement they had viewed (1 week follow-up). The results were analyzed to determine whether exposure to the proposed required warnings elicited higher recall of the warning statements than exposure to the text-only controls. In addition, in the treatment groups (*i.e.,* participants who viewed one of the proposed required warnings), recall of the image was assessed at baseline and at 1-week follow-up. Because the control group did not view an image, the impact of the proposed required warnings on image recall was measured against one of the proposed required warnings for each warning statement that had been selected to be the referent image and statistically assessing whether recall of the images associated with the other proposed required warnings was higher or lower than recall of the referent image.
- Influence on Beliefs—The study assessed whether the proposed required warnings had a significant impact on beliefs about the health risks of smoking to regular smokers relative to the text-only control, as well as whether they had a significant impact on beliefs about the health risks of secondhand smoke exposure to nonsmokers relative to the text-only control.
- Behavioral Intentions—The study assessed whether the proposed required warnings may have a significant impact on cessation, by assessing smokers' intentions to quit smoking (*i.e.,* asking participants how likely it is that they would try to quit smoking within the next 30 days). In youth, the study assessed whether the proposed required warnings may have a significant impact on potential initiation, using a measure of how likely youth felt they were to be smoking 1 year from now.

As the study report (Ref. 49) explains, the outcomes examined were selected based on established theories of message processing and health-related behavior change, which suggest that immediate emotional and cognitive reactions to messages, and recall of messages, are part of a process that eventually leads to

[2] While the numerical results reported in the study report (Ref. 49) were correct, and while all of the results discussed in this rule are accurately described, some of the descriptors contained in the study report were in error. An errata sheet for the study report (Ref. 50), which lists all the errors and the corrections, has been prepared and is being placed in the docket. These errors did not adversely impact commenters' ability to convey their assessment of the images and the study results in their comments. To the extent some comments included inaccurate statements about the study results in their significant comments as a result of the errors, we recognized the inaccuracy and were able to discern the material points in the comment and evaluate them appropriately, as is reflected in the comment summaries and responses.

[3] Some additional cognitive measures, including the reaction item ''the pack was difficult to look at'' (or, for the adult sample viewing the print ad, ''the ad was difficult to look at'') were also evaluated but were not reported as part of the composite cognitive reaction scale. These items were not sufficiently correlated with the other cognitive measures to include in the composite measure.

changes in beliefs and intentions and ultimately to behavior change.

2. Use of FDA's Research Study Results in Selection of Images

As described in section III.A of this document, in order to determine which color graphic images to require in the final rule, we considered a number of factors, including the results from our research study. We carefully examined the research results for the 36 proposed required warnings on all the different outcomes in determining which images to require in this final rule. However, the responses on the salience measures served as a primary basis for distinguishing among the 36 proposed required warnings for a number of reasons.

First, many of the proposed required warnings elicited significant impacts on the salience measures (emotional and cognitive measures), which the research literature suggests are likely to be related to behavior change (Ref. 51). For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers can result in viewers attaching a negative affect to smoking (*i.e.,* feel bad about smoking), thus undermining the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38).

In comparison to the salience measures, fewer of the proposed required warnings elicited significant impacts on the beliefs measures in our research study, and on the whole the proposed required warnings did not elicit strong responses on the intentions measures. Given the design of our research study, where participants had only a single exposure to one proposed required warning, it is not surprising that the proposed required warnings did not consistently show effects on these beliefs and intentions measures, which are more eventual outcomes in the behavior change process than the salience responses, which occur more immediately. However, this does limit the utility of these longer-term measures in discriminating across the proposed required warnings. Thus, given the design of the study, the results on the salience measures, which the research literature indicates are predictors of more eventual behavioral outcomes, were considered to be more meaningful than the results on the beliefs and intentions measures in discriminating between the images.

In addition, we gave greater weight to outcomes on the salience measures than to outcomes on the statement recall measures for several reasons. First, there is evidence to suggest that, while recall of associated warning message statements may be reduced in the short term by moderately or highly graphic pictorial warnings versus text-only controls or less graphic pictorial warnings, these warnings still increase intentions to quit through evoked emotional responses (Ref. 52). Second, as described previously, participants in the research study were exposed to a single viewing of the proposed required warnings, which does not allow for assessment of the effect that repetitive viewing of the required warnings may have on recall. Recall can be expected to increase in real world settings where consumers will be exposed to the warnings multiple times. Third, recall was generally high for all the proposed required warnings, even where there was not a significant difference compared to the text-only control or where recall was significantly lower for the proposed required warning than for the text-only control. For example, for the nine required warnings that we selected for use in this final rule, the research study shows that recall of both the textual warning statements and the color graphic images was high at both baseline and at 1-week follow-up, exceeding 50 percent on all measures, and, in many cases, exceeding 80 percent.

3. Comments on FDA's Research Study

FDA received a number of comments related to its research study in the docket for the proposed rule, which are summarized and responded to in the following paragraphs.

a. *Study design.* Several comments addressed the cross-sectional design of the study.

(Comment 22) Several comments, including comments from cancer researchers, nonprofit organizations, and academics noted that participants in the study were exposed to a proposed required warning only once in a controlled environment. These comments stated that the single exposure study design makes it impossible to assess long term or actual effects of the proposed required warnings. Two of these comments recommended that FDA conduct longitudinal research or post-market surveillance to assess actual long-term effects.

(Response) We agree that the study design does not permit us to reach firm conclusions about the long-term, real-world effects of the proposed required warnings on the measured outcomes. As noted previously, the purpose of the study was not to assess actual effects but to assess the relative effects of the proposed required warnings on various outcomes. Data on the relative effects of the various proposed required warnings provided a more objective and scientific basis to help select which required warnings should be included in the final regulation. A cross-sectional design with a single exposure under experimental conditions is appropriate for assessing relative effects. For absolute effects, the scientific literature presented in the preamble to the proposed rule provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.

However, we recognize the value of conducting an ongoing evaluation of the effects of the required warnings after they enter the marketplace, and we intend to monitor and evaluate their ability to effectively communicate the negative health consequences of smoking. This evaluation will provide information regarding whether the required warnings effectively reach the appropriate target audiences, wear out of the required warnings, and whether and what changes to the required warnings may be appropriate in any future rulemaking on this subject.

(Comment 23) A comment from tobacco product manufacturers stated that a longitudinal study demonstrating that the required warnings would have actual effects on smoking prevalence was necessary to support the final regulation.

(Response) We appreciate the value of longitudinal studies but disagree that such a study is necessary to support the final regulation. As discussed previously, our research study assessed the relative efficacy of the 36 proposed required warnings published with the NPRM, and the cross-sectional study design was appropriate for that purpose. The scientific literature presented in the preamble to the proposed rule provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.

(Comment 24) Several comments discussed behavioral models similar to that described in FDA's research study (*see* Ref. 49) and explained how those models provide a rationale for how health warnings can effectively communicate risk information about the harmful effects of tobacco use. For example, one comment from a researcher working on an international project to evaluate the impact of graphic health warnings for tobacco products stated that the primary objectives of health warnings are to educate and inform smokers and nonsmokers about the many negative health consequences of smoking and to provide information that can enhance their efficacy for quitting. The comment noted that effective health warnings increase knowledge and thoughts about the harms of cigarettes, the extent to which the smoker could personally experience a smoking-related disease, and as a result, increase motivation to quit smoking. Another academic who also is conducting research on graphic health warnings commented that a wide variety of research suggests that health warnings with pictures are significantly more likely to draw attention, result in greater information processing, and improve memory for warnings than text-only warnings. A comment from a researcher with expertise in risk perceptions and decisionmaking stated that changes in smoking behavior based on warning labels appear to require four steps: (1) Immediate, negative affective reactions to the potential consequences of smoking; (2) associations of these emotional reactions to smoking cues; (3) increases in perceptions of the risks of smoking, and finally (4) increases in quit contemplation and reductions in smoking behaviors.

(Response) We agree that the design of our research study is consistent with established social science models (in psychology, economics, and related fields) of risk communication and health behavior change. The purpose of graphic health warnings is to effectively communicate the negative health consequences of cigarette use to smokers and nonsmokers, which is critical given the seriousness of these consequences. Greater understanding of those health effects will motivate some smokers to stop smoking and prevent some nonsmokers from starting to smoke. The preamble to the proposed rule presented a detailed discussion of the scientific literature to substantiate our conclusion that graphic health warnings can be an effective means of communicating important health information about the risks of smoking (*see* 75 FR 69524 at 69531 through 69533). These comments provide additional support for that conclusion.

b. *Study results.* Several comments discussed the results from FDA's research study.

(Comment 25) Several comments, including comments from academics, nonprofit organizations, and health professional organizations, stated that FDA's research study provides data consistent with the overall literature demonstrating the effectiveness of graphic health warnings. For example, one comment stated that in general the study results are consistent with prior findings that the addition of graphic images to health warnings is beneficial in comparison to text-only warnings. Another comment stated that, based upon the FDA study and the existing scientific literature, it is possible to conclude that the proposed graphic warnings are likely to be effective.

Other comments, including comments from tobacco product manufacturers, advertising industry associations, and a public policy organization, asserted that FDA's research study fails to provide evidence of efficacy. These comments stated that the study did not show evidence that the proposed required warnings would actually affect prevalence of smoking, and failed to demonstrate sufficient evidence that the proposed required warnings would significantly affect consumer knowledge of the risks of smoking or actual behavior change.

(Response) We agree that the study is generally consistent with the existing scientific evidence demonstrating that graphic health warnings can effectively communicate the negative consequences of cigarette smoking, and by doing so, can encourage smoking cessation and discourage smoking initiation. We disagree that the study results do not support the efficacy of the warnings. We presented substantial research in the preamble to the proposed rule supporting the efficacy of graphic health warnings (75 FR 69524 at 69531 through 69534), and the results of our research study are consistent with that research.

c. *Study outcome measures.* Numerous comments discussed the key outcomes measured in FDA's research study.

(Comment 26) FDA received a wide variety of comments concerning the use of emotional reactions to assess the relative effectiveness of the proposed graphic warnings. A number of comments, including those from academics, medical institutions, and public health groups, supported the inclusion of emotional reaction measures. These comments stated that graphic health warnings that elicit strong emotional reactions, especially negative feelings, are more effective in communicating the negative health consequences of smoking and in motivating healthier behaviors than warnings that do not elicit emotional reactions, and indicate that these effects are well established in the scientific literature.

For example, one comment stated that the scientific literature shows that graphic depictions of the negative health effects of smoking arouse reasonable fears and are associated with greater consideration of health risks, increases in motivations to quit, and ultimately with attempts at cessation. Another comment stated that theoretical models and studies in communications and social psychology suggest that graphic health warnings can be effective because they elicit greater emotional engagement with the information provided and it is that engagement that drives behavior change. Another comment from an academic researcher stated that considerable psychological research suggests that risk is more readily communicated by information that arouses emotional associations with the activity. Emotional reactions can be readily accessed from memory by mere presentation of the stimulus, and appear to be powerful predictors of smoking behavior. Yet another comment stated that growing evidence from controlled experiments and survey research indicates that, compared to text-only warnings, graphic health warnings evoke stronger emotional responses and increase motivations to quit or not start smoking. The comment indicated that these studies are consistent with cognition and neuroscience research demonstrating that relative to linguistic or text information, imagery-based information can be processed more rapidly, evoke stronger emotional responses, induce greater cognitive processing and attitude change and can be recalled more easily.

However, other comments stated that reliance on emotional measures for assessing graphic health warnings is inappropriate. A joint comment from tobacco product manufacturers stated that the study measured only the effect of eliciting strong emotional and cognitive reactions, which confirms that the warnings were intended not to inform consumers with purely factual and uncontroversial information, but rather to shock consumers into adopting the Government's preferred course of conduct. Another tobacco product manufacturer commented that, to the extent FDA selected images based on emotional or cognitive reactions and not

on ability to inform consumers about the health risks of smoking, the regulations would not pass constitutional muster. A comment from a public policy organization commented that emotional and cognitive responses are irrelevant measures of effectiveness if there is no behavior response.

(Response) On the basis of our review of the relevant scientific literature and the feedback received in the docket, we conclude that our inclusion of emotional reaction measures to evaluate the relative effects of the 36 proposed required warnings was appropriate and is consistent with well-established principles in the scientific literature. As discussed in the study report that was placed in the docket (Ref. 49) and in other comments summarized in previously in this document, eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warning is better processed, understood, and remembered. Thus, these responses can enhance the effective communication of the health warning message. These responses in turn influence short-term outcomes, such as later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke. As attitudes and beliefs change, they eventually lead to changes in intentions to quit or to start smoking and then later can lead to lower likelihood of smoking initiation and greater likelihood of successful cessation.

We disagree that use of emotional reaction measurements demonstrates the Agency's intent to advocate a preferred position or course of conduct. Each of the nine graphic warnings required by the final regulations communicates negative health consequences of smoking that are well-established in the scientific literature. Consistent with the Tobacco Control Act, the purpose of these required warnings is to communicate effectively and graphically the very real, scientifically established adverse health consequences of smoking. The overall body of scientific evidence indicates that health warnings that evoke strong emotional responses enhance an individual's ability to process the warning information, leading to increased knowledge and thoughts about the harms of cigarettes and the extent to which the individual could personally experience a smoking-related disease. Increased knowledge and thoughts about the negative consequences of smoking, in turn, are reasonably likely to result in more informed and healthier behaviors, such as trying to quit smoking or deciding not to start.

(Comment 27) We also received two comments concerning the cognitive measure used in the study. A comment filed by tobacco product manufacturers observed that ''looks cool'' was one of the measured cognitive reactions. The comment stated that the study analysis omits responses on whether the warnings ''looked cool,'' and contended that if a substantial number of participants viewed a warning as ''looks cool,'' the warning would be unlikely to have the intended effect. The comment concluded that the ratings for the ''looks cool'' measure do not appear to have been neutral; the comment stated that regression results for the ''looks cool'' measure indicates that this measure elicited one of the strongest estimated effects of the study and the results go in the opposite direction of effectively communicating health risk information.

(Response) We disagree that data concerning the ''looks cool'' outcome was omitted or that the results for this outcome go in the opposite direction of the intended effect of communicating the negative health consequences of smoking. Although the ''looks cool'' outcome was not included in the reported composite cognitive measure, the study report (Ref. 49) includes the results for this measure in its appendices. The measure was reverse coded, so that a higher value corresponded with the intended directionality for other measures. Thus, a high value for ''looks cool'' corresponds to a response of ''strongly disagree'' from the respondent. The data presented in the appendices demonstrate that for each of the nine selected required warnings, significantly more participants disagreed that the warning ''looked cool'' than participants who viewed the text-only control warning. Eight of the nine required warnings elicited significantly higher ratings than the text-only control warning across all target audiences. Ratings for the ninth required warning, which includes the textual statement ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' show that significantly more adults disagreed that the selected required warning ''looked cool.'' Responses for young adults and youth were in the appropriate direction, but the responses were not significantly different from the text-only control warning.

(Comment 28) We also received a comment concerning the believability measure. This comment raised a concern that some of the 36 proposed required warnings may be perceived as unrealistic because they did not vividly portray immediate health risks, which could lead some smokers to discount the warning. The comment recognized that a believability measure was included in the study as part of the cognitive reaction scale, but stated that specific results for believability were not reported, and recommended that FDA examine the mean scores of the specific believability items in conjunction with other important measures included in the study.

(Response) We agree with the comment that believability is a helpful measure for assessing the relative effectiveness of warning images. All of the selected images scored significantly higher than the controls on the cognition measures, which included ratings on how meaningful the warning was, whether it was informative, and whether it was believable. While the results do not include mean scores for believability and other individual measures, the appendices include the parameter estimates from regression analyses on these individual measures. The results show that, in most cases, the images selected for the nine required warnings scored significantly better than the control with respect to believability.

(Comment 29) One comment stated that the statement recall measure is less important and less relevant to decisions about smoking than negative affective reactions because the warning statements are now believed by smokers and nonsmokers.

(Response) Statement recall was appropriately included as part of the assessment of the relative effectiveness of the 36 proposed required warnings. As discussed in section II.C of this document, while both smokers and nonsmokers have some understanding about some of the risks of smoking, there are significant gaps in their knowledge, including about the magnitude and severity of the risks of smoking. We also note that, as explained in section III.B.2 of this document, although we carefully examined the research results on all the study measures for the 36 proposed required warnings, including recall, the responses on the salience measures served as a more important basis than recall for distinguishing among the 36 proposed required warnings.

(Comment 30) A joint comment submitted by tobacco product manufacturers asserted that the study fails to demonstrate that the published graphic warnings will have any discernible effects on smoking risk beliefs.

(Response) We disagree with this comment. Four of the nine selected required warnings did show a significant impact on beliefs about the health risks of smoking relative to the text-only control among at least one study population. In addition, there is substantial evidence in the scientific literature showing that graphic health warnings effectively increase consumer understanding of the health risks of smoking. In the preamble to the proposed rule (75 FR 69524 at 69531 through 69533), we presented substantial research showing that graphic health warnings significantly increase consumer thoughts about and understanding of the health risks of smoking after they were introduced in other countries. In addition, as discussed previously in this document, considerable scientific evidence shows that health warnings that elicit strong emotional and cognitive reactions are better processed and more effectively communicate information about the negative health consequences of smoking. Each of the nine required warnings elicited strong effects on the emotional and cognitive reaction scales, which indicates that these warning will effectively communication information about the negative health consequences of smoking.

Based on the results of our research study and the existing scientific literature, we conclude that graphic health warnings, including the nine selected required warnings, are likely to increase consumer knowledge and understanding of the health risks of smoking.

(Comment 31) A comment submitted by tobacco product manufacturers criticized the study's use of intentions to measure behavioral change and stated that FDA should have presented data showing actual effects on behavior.

(Response) We disagree that intentions are an inappropriate variable for assessing potential behavioral changes. While measures of intended behavioral outcomes do not perfectly predict a future behavior outcome, it is a necessary precursor. The scientific literature indicates that one's intentions to quit smoking must be increased before one makes the actual quit attempt. Thus, we conclude that it was appropriate in our research study to assess quit intentions as a proxy for behavior change. In accordance with Executive Order 13563, after the rule is in effect we will be undertaking analysis to better understand the behavioral effects of the warnings.

(Comment 32) Several comments raised concerns that the lack of strong statistically significant results concerning intentions in FDA's research study is an indication that the required warnings will not be effective. For example, a comment submitted by tobacco product manufacturers stated that the results of FDA's research study show that graphic health warnings will not result in a statistically significant reduction in youth initiation or overall prevalence of smoking, and thus, confirms that the warnings will not be effective.

(Response) We disagree that our study results indicate that the required warnings will not be effective. It is important to recognize that FDA's research study was not designed or intended to produce evidence demonstrating actual effects on behavior. Rather, the study was designed to provide data concerning the relative effects of the graphic health warnings in order to provide a more objective and scientific basis for our selection of the set of nine required warnings in the final regulation. There is considerable evidence in the scientific literature demonstrating that graphic health warnings effectively increase awareness of the health risks of smoking, which is the principal purpose of the warnings, and that this awareness in turn can influence smoking intentions and behaviors. We included significant research to substantiate this conclusion in the preamble to the proposed rule (*see* 75 FR 69524 at 69531 through 69533). For example, as discussed in the proposed rule, a 2007 report from an expert IOM panel that evaluated the existing scientific evidence on health warnings concludes that the available scientific evidence indicates that larger, graphic health warnings would promote greater public understanding of the health risks of using tobacco and would help to reduce consumption (Ref. 3).

FDA's research study cannot be viewed in isolation from the overall body of scientific evidence evaluating the efficacy of graphic health warnings. While the research study itself did not provide evidence of strong effects on intentions (which, as noted in section III.B.2 of this document, is not surprising given the single-exposure design of the study), the overall body of scientific literature does provide sufficient evidence that the required warnings, by increasing public understanding of and thoughts about the health risks of smoking, will be effective in encouraging smoking cessation and discouraging smoking initiation.

A number of comments provide additional support for our conclusion. For example, a comment from a researcher conducting an international longitudinal study on graphic health warnings states that studies show that graphic depictions of smoking's adverse effects on the body are associated with greater consideration of health risks, increases in motivations to quit smoking, and ultimately, attempts at cessation. A comment by a researcher with expertise in risk perceptions and decisionmaking concludes that emotional associations to smoking appear to be powerful predictors of smoking behavior and may well be causally implicated in efforts to either stop or start smoking.

(Comment 33) A comment from tobacco product manufacturers stated that the responses to the ''smoking urges'' questions included in the study would provide a better measure for assessing whether the proposed required warnings affected smoking behavior and, referring to the responses regarding these questions, the comment asserts that, on balance, seeing the proposed required warnings increased the desire to have a cigarette rather than decreased it.

(Response) We disagree that our research study shows that, on balance, seeing the proposed required warnings increased the desire to have a cigarette. The ''smoking urges'' measures were reverse coded, so that a higher value corresponded with the intended directionality for other measures in the study. Thus, a high value corresponds to a response of ''strongly disagree'' from the respondent. The data presented in the study report appendices (Ref. 49, study report) show that, for three of the nine selected required warnings, significantly more participants in at least one target group disagreed with the statement that they wanted a cigarette than participants exposed to the text-only control warning. For one of the selected required warnings, significantly more adult participants who viewed the warning on a cigarette pack disagreed that they wanted a cigarette, but significantly more adults who viewed the warning in a cigarette advertisement agreed. For one of the selected required warnings, significantly more participants in one target audience agreed that they wanted a cigarette than participants exposed to the text-only control warning. Results for the remaining selected required warnings and sample groups were not significantly different from the text-only control warning.

Thus, on balance, the study does not show that exposure to the final set of nine images increased the desire to smoke a cigarette among study participants. As discussed in the previous response, the overall body of

scientific literature provides ample evidence that the required warnings, by increasing public understanding of and thoughts about the health risks of smoking, are likely to encourage smoking cessation and discourage smoking initiation. Data from our research study regarding ''smoking urges'' provide no basis for calling into question that evidence.

d. *Study limitations and issues regarding methodology.* A number of comments discussed a wide variety of issues concerning limitations of FDA's research study and raised various issues concerning the study methodology.

(Comment 34) Several comments, including comments from health institutions, nonprofit organizations, and academics, raised concerns that the demographics of FDA's research study did not include adequate sample sizes for minority populations and persons of lower income or lower education status. These comments noted that the findings of the study therefore may not be relevant to populations with high smoking prevalence and to those consumers who might be most impacted by graphic health warnings. Some of the comments recommended further testing in these populations.

(Response) We recognize the importance of reaching populations with high smoking prevalence, including various racial/ethnic groups and persons of lower income or lower education status. The study report provides analyses of the relative effects of the images within various sub-groups, separating samples by gender, race, and education. The analyses, for the most part, confirm that the relative effects of the images are consistent across groups. As such, we have determined that the required warnings will help to effectively convey the negative health consequences of smoking to a wide range of audiences, including different racial and ethnic populations and different socioeconomic groups.

(Comment 35) A comment from tobacco product manufacturers criticized the study methodology because it did not include a nationally representative sample of participants and claimed that this failure biased the study results. The comment stated that the study report (Ref. 49, study report) fails to disclose basic sampling information and provides no indication that those conducting the study adjusted for the effect of choosing participants by soliciting volunteers. The comment concluded that this failure was significant because the participants in the study may not reflect the population of interest and may bias the statistical estimates.

(Response) We disagree that the study results are invalid due to the demographic composition of the sample. The research study was not intended to be a survey of the national population, but rather a study using random assignment to study conditions. The study included individuals from certain target groups, particularly current smokers and youth who may be susceptible to initiation of smoking. Statistical methods were used to assess the relative impact of each of the proposed required warnings on various outcomes, rather than to assess the absolute impact one would expect to observe in the U.S. population as a whole.

(Comment 36) One comment raised a concern that lack of adequate pretesting of the proposed required warnings evaluated in FDA's research study could compromise the overall effectiveness of the pool of images tested. The comment stated that it would have been more helpful to conduct pilot testing with a very large group of images (at least 20 per textual warning statement) to ensure testing and selection of the most effective graphic warnings.

(Response) We agree that more extensive pretesting may have been useful. However, we disagree with the suggestion that the overall effectiveness of the required warnings could be compromised by the inability to conduct additional pretesting prior to the research study. The results of the research study as well as research submitted by others during this rulemaking proceeding indicate that the overall efficacy of the pool of proposed required warnings is quite strong. Based on those data, as well as the overall scientific literature, we conclude that the required warnings will effectively communicate the negative health consequences of smoking to smokers and nonsmokers.

(Comment 37) A comment submitted by tobacco product manufacturers asserted that selection bias is a serious methodological flaw of the study. The comment stated that participants were recruited from an Internet panel and offered the opportunity to participate in the research study, creating a selection bias that was compounded by the fact that the invitation to participate stated that the study was funded by FDA. The comment noted that there is no indication that the study corrected for the selection bias and opines that one would not expect the selection bias to be neutral given the identification of FDA as the sponsor of the study.

(Response) We disagree that selection bias is a serious methodological flaw of the study. Although we acknowledge the potential for selection bias, we disagree that this potential bias was likely to significantly affect the results of the study. Even if participants who approve (or disapprove) of FDA were more likely to participate in the study, one would expect that bias would affect all of the experimental conditions, including the text-only control warnings. A bias of this sort would affect the absolute effects of the warnings in general, but not the pattern of relative effectiveness of individual warnings. As a result, selection bias does not invalidate the results of the study, which provides insight on the relative effectiveness of the various warnings under consideration.

(Comment 38) A comment from tobacco product manufacturers stated that FDA's research study is seriously flawed because 32 percent of the participants dropped out of the study before completing the questionnaire. The comment stated that quitting the survey was not likely to be a random event and may have been a result of smokers who are not receptive to graphic health warnings dropping out. If so, the comment suggested that this would have significantly overstated the results of the study.

(Response) We disagree that the drop-out rate observed in the study undermines the validity of the results of the study. Table 3–1 from the methodology report displays the total number of individuals entering the study. However, these values represent the total number of individuals who entered the study's ''landing page,'' which is the site to which invitees link from the e-mail invitation. The invitation from e-Rewards, as well as the landing page, refers to the study as a ''Study about Consumer Products.'' There were no references to FDA, smoking, or tobacco in either the invitation or the landing page. Though it is true that a number of invitees chose not to continue after seeing the invitation or the landing page, their decision not to participate cannot be attributed to a bias for or against FDA or the implementation of graphic health warnings on cigarettes.

In addition, the number of individuals identified as ''Quits'' in table 3–1 of the methodology report includes individuals who quit after viewing the landing page and those who quit after having been informed of FDA's involvement and that the survey concerned smoking or tobacco. Of those individuals identified as ''Quits'', only a very small number were in the latter group (*i.e.,* quit after being informed of FDA's involvement and that the survey concerned smoking or tobacco). For

example, of the 13,673 respondents who entered the adult pack survey (the point in time when they viewed the study's landing page), 2,179 chose at some point to discontinue. Of these, only 148 individuals, or about 1.1 percent of those entering the study, chose to discontinue the survey after being informed of FDA's involvement and that the survey concerned smoking or tobacco. A similar pattern exists for all of the study samples: In the adult pack follow-up sample 23 individuals, or 0.6 percent, chose to discontinue after being informed; in the adult ad study sample 193 individuals, or 2.1 percent, chose to discontinue after being informed; in the adult ad follow-up sample 26 individuals, or 0.7 percent, chose to discontinue after being informed; in the young adult study sample 152 individuals, or 1.3 percent, chose to discontinue after being informed; in the young adult follow-up sample 11 individuals, or 0.3 percent, chose to discontinue after being informed; in the youth study sample 104 individuals, or 0.3 percent, chose to discontinue after being informed; and in the youth follow-up sample 13 individuals, or 0.5 percent, chose to discontinue after being informed. The drop-out rate, as calculated here, varies across the study samples but never exceeds 2.1 percent. Therefore, we do not agree that the drop-out rate invalidates the results of the study.

(Comment 39) A comment from tobacco product manufacturers stated that the youth component of FDA's research study is subject to a response bias. The comment stated that the study failed to address the risk that the youth participants might alter their responses due to a concern that their parents might see the results.

(Response) We disagree that the youth sample is likely subject to a response bias. Youth participants were told at the outset of the study that their responses would be kept confidential. Once the study was complete, other household members could not retrieve those responses. Moreover, if youth participants were concerned about parental awareness of their participation, it would likely have resulted in a decision not to participate rather than a decision to alter their responses.

(Comment 40) A comment from tobacco product manufacturers raised a concern that the youth sample is subject to a selection bias because participants were derived from families whose parents also participated in the study.

(Response) We disagree. As discussed in section 2.2.3 of the methodology report (included in the docket as part of the study report (Ref. 49, study report)), most of the youth were sampled from a separate youth panel, which was independent of the adult panel. Some of the youth were sampled from the households of the adult panel. However, those in the latter group were sampled independently and randomly from the adults that participated in the study. Although possible, it is unlikely that both a parent and child from a single household received an invitation for the study and completed the study.

(Comment 41) A comment from tobacco product manufacturers objects to the manner in which the study assessed emotional and cognitive reactions. The comment states that the study weighted the responses to multiple questions, but fails to disclose the weights used and the justification for those weights, and states that without information on the weighting system, one cannot assess these measures for bias.

(Response) We disagree with this comment. Section 4.2 of the methodology report for our research study (included in the docket as part of the study report (Ref. 49, study report)) indicates that a factor analysis was used to determine the appropriate items to include within each scale. A weighting scheme was not used. Rather, items were combined using a simple summative scale. Use of a simple summative scale is a widely-used method of analyzing these data.

(Comment 42) A comment from tobacco product manufacturers states that the study used an inappropriate methodology by measuring risk awareness and smoking intentions on a scale. The comment states that evaluating these measures on a scale is inappropriate for testing awareness of a fact and also resulted in the authors making subjective and undisclosed decisions about how to weight those values.

(Response) We disagree. It is appropriate to measure the impact of a warning on the strength of an individual's awareness, beliefs, and intentions. To do this, one must use a scaled response, rather than a dichotomous response, to each question. In the research study, items were not weighted within each scale. Rather, they were combined using a simple summation of ratings. This is a widely-used methodology for this type of study.

(Comment 43) A report attached to the comment from tobacco product manufacturers criticizes FDA's research study for failing to assess baseline knowledge among participants to determine whether the proposed required warnings increased awareness of the health effects of smoking.

(Response) The lack of an assessment of baseline knowledge does not make the study results less reliable or invalid. In a study such as FDA's research study, responses to the control conditions serve as proxies for baseline knowledge, awareness, beliefs, and intentions. Comparing the treatment responses to those of the control allow for an assessment of the potential impact the treatment has on baseline measures.

C. Comments to the Docket

FDA received hundreds of comments on the 36 proposed required warnings; the comments relating to each proposed required warning are discussed in sections III.D and III.E of this document. Some comments discussed the 36 proposed required warnings generally or discussed different styles or themes used in the set of proposed required warnings. These comments are summarized and responded to in this section.

As explained in section III.A of this document, we considered the comments submitted to the docket as we determined which color graphic images to require to accompany the nine textual warning statements in the final rule. We did not simply count the number of comments received supporting or opposing the use of a particular image as a way to measure the relative effectiveness of our proposed images or of images recommended by comments, but rather evaluated the substantive input contained in the comments to help inform our decisions in selecting or not selecting a particular image and to obtain other relevant information related to research on the images. Many of the comments contained information about the submitter's personal opinions, beliefs, and attitudes related to various images. While this information is helpful in understanding how people might interpret various images and in raising issues for further exploration, this type of qualitative information is not as useful as quantitative assessments of the relative effectiveness of the 36 proposed required warnings at conveying information about the negative health consequences of smoking, such as the assessment provided in FDA's research study.

Furthermore, as described in more detail in the comment summaries and responses in sections III.D and III.E of this document, some of the information contained in comments that criticized or opposed the use of various proposed images suggested that the images evoked negative emotional reactions in the viewer. The research literature,

however, suggests that warnings that evoke these reactions can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 44).

1. Comments Submitting Research on FDA's Proposed Required Warnings

We received several comments, including comments from academics, a nonprofit organization, and a prevention specialist, that described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed required warnings on various outcomes. We address that research and our responses to these comments in the comment summaries and responses in this section. The information contained in these comments about particular proposed required warnings is also discussed as applicable in sections III.D and III.E of this document.

As is discussed in the summaries in this section, the nine required warnings we have selected for use on cigarette packages and in cigarette advertisements generally performed well in the studies discussed in these comments. These comments indicate that the findings from our own research study are robust, as they have generally been confirmed under the various different study designs utilized in the research discussed in these comments.

However, in contrast to our own research study, we did not have access to the raw data or to all the statistical analyses for the studies discussed in these comments. In addition, the design of some of these studies did not allow for an assessment of the relative effectiveness of FDA's 36 proposed required warnings. This limited the utility of the information provided in the submissions.

Thus, while we carefully considered the information provided in these submissions, the results of our own study were more helpful in making research-based selection choices.

(Comment 44) One study was submitted by a group from a medical institution and by a collaborating academic who has conducted research on graphic health warnings. Participants were recruited from an Internet panel of adults, young adults, and youth. The report for the study states that it was intended to assess the potential effectiveness of FDA's 36 proposed required warnings. Among other things, participants were asked to provide certain demographic information as well as information concerning their smoking status and attitudes and beliefs about smoking. In addition, the study tested nine ''sets'' of warnings, one for each of the textual warning statements required by the Tobacco Control Act. Each set included each of the proposed required warnings published with the proposed rule for use with the specific textual warning statement as well as at least one alternative warning. Each participant was randomly assigned to view and rate two sets of health warnings.

Warnings within each set were first rated individually on a scale of 1 to 10 and then participants were asked to rank order the entire set for perceived effectiveness for discouraging smoking. The comment presented the rating and ranking scores for the health warnings. The comment also presented preliminary statistical analyses for the overall ranking scores; statistical data were not presented for individual ratings for the individual measures assessed. The comment concludes that preliminary results from the study show that warnings that were more explicit about the health risks of smoking were rated as being more effective among both adults and youth. The academic who conducted the study similarly concluded that health warnings that were more explicit and that elicited greater emotional reactions were rated as being most effective, and the researcher recommended that FDA select certain graphic warnings that received high rating and ranking scores in the study (including required warnings proposed by FDA as well as graphic warnings that have been used in other countries).

(Response) The results of this study are generally consistent with the results of the scientific literature and the study sponsored by FDA. This study shows that the existing cigarette warnings are not salient among either adults or youth. Among other responses, 50.3 percent of adults responded that they never or rarely noticed the health warnings on cigarette packs, while 23.7 percent stated that they often or very often noticed the warnings. Among youth, 63.3 percent responded that they never or rarely noticed the health warnings on cigarette packs, while 12.9 percent stated that they often or very often noticed the warning. The graphic warnings selected for inclusion in the final regulation generally performed relatively well in both this study and in FDA's research study. It is difficult to assess the results of this study more specifically without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 45) A study was submitted by a researcher with expertise in risk perceptions and decisionmaking. Participants were young adult college students, including smokers, nonsmokers, and ''vulnerable'' nonsmokers. The study assessed emotional reactions, risk perceptions, and smoking aversion. Participants were randomized into four conditions, with each viewing 18 graphic warnings. Two conditions viewed graphic warnings being used in other countries, one condition viewed 18 graphic warnings published with the proposed rule, and the fourth condition viewed the proposed FDA graphic warnings plus three graphic warnings from other jurisdictions. According to the comment, warnings ''that were perceived as more graphic, more intense, less good, and more fearful produced more thoughts about not wanting to smoke.'' The comment concludes that, compared to the viewed warnings being used in other countries, the FDA proposed required warnings did not maximize thoughts of health risk perceptions or smoking aversion, although the differences between the warnings from other jurisdictions and FDA's proposed required warnings were marginal.

(Response) The nine required warnings that we have selected performed relatively well in this study. Many performed as well as the warnings from other jurisdictions and some performed better. It is difficult to assess the results of this study more specifically, however, without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 46) A study was submitted by a group of behavioral scientists whose research focuses on cognitive, emotional, and imagery processes that influence how people respond to messages about health risks. Their experimental study evaluated the 36 proposed required warnings published with the proposed rule. Participants were young adults ages 18 to 25, and included smokers and nonsmokers. Each participant viewed 18 of the 36 proposed required warnings and was asked to rate each on the following measures: Perceived comprehension, worry about the health risks of smoking, and the extent to which the warning discouraged the participant from wanting to smoke a cigarette. The comment states that the study provides strong support that most of the graphic warnings proposed by FDA are perceived by young adult smokers as easy to understand, as enhancing worry about the health risks of smoking, and as discouraging young adult smokers from wanting to smoke. The comment states that the results of the study are consistent with the growing body of

evidence showing that, compared to text-only warnings, graphic warnings can evoke stronger emotional responses and reduce motivations to smoke.

(Response) The nine required warnings that we have selected performed relatively well in this study. It is difficult to assess the results of this study more specifically without additional information concerning the study protocol, methods, and statistical analyses.

(Comment 47) A study was submitted by two researchers at a university-based public policy center. The comment states that the study, of young adult and adult smokers, was conducted to assess limitations of the FDA study and to identify ways to increase the impact of the warnings. The study used the same online survey firm as that used in the FDA study, although respondents who participated in the FDA study were not eligible to participate in this study. The study was limited to four of the nine warning statements required by the Tobacco Control Act. The graphic warnings assessed for each of these four statements included some of the proposed FDA warnings, these same proposed warnings with additional text or color added, and some graphic warnings used in Canada. Graphic warnings were compared against a text-only control warning that appeared on the side of a cigarette pack. The study used two indices to assess efficacy. The first assessment was perceived effectiveness in discouraging someone from smoking. For the second assessment, participants were asked to imagine themselves smoking a cigarette and then to report how good or bad they would feel smoking a cigarette. The comment states that in three of the four warning messages required by the Tobacco Control Act, a single exposure to a large graphic warning was more effective in creating immediate negative emotional associations with the act of smoking than exposure to the text-only warning. The comment states that the study did not show that the single exposure affected immediate plans to quit smoking; the authors of the comment note that a brief test following a single exposure is unlikely to detect this effect, and that they would expect quit intentions to increase through repeated exposures to the warnings.

(Response) The proposed required warnings published by FDA and included in this study performed relatively well in this study. It is difficult to assess the results of this study more specifically without additional information concerning the study and the statistical analyses.

(Comment 48) An organization of high school students submitted the results of a study they conducted to assess the efficacy of the 36 proposed required warnings published with the proposed rule. Organization members recruited participants from their high schools and communities. Each participant viewed 18 of the proposed required warnings and was asked to rate each warning for perceived effectiveness in stopping someone from smoking. Findings were reported as arithmetic means and modes. The comment concludes that study respondents generally believed that the most effective images were the more graphic images.

(Response) We note that the nine required warnings we selected generally rated highly in this study.

(Comment 49) One comment contained the results of a study conducted by two individuals among college students at a U.S. university. In this study, 63 college students, apparently including both smokers and nonsmokers, were shown the 36 proposed required warnings and asked to rate them on a scale of 1 to 7 on their perceived effectiveness in helping smokers' intent to quit. According to the comment, certain demographic information also was obtained from participants. The comment identifies the five proposed required warnings that were ranked as being the most effective warnings and the five proposed required warnings that were ranked as being the least effective. According to the comment, demographic factors did not affect the rating scores. The only factor identified as having an impact on rating was smoking status, with participants who had a history of smoking more likely to rate the graphic warnings as being effective than subjects who did not have any history of smoking.

In another comment, submitted by a self-identified prevention specialist from a U.S. public school district, 1,339 high school students viewed the 36 proposed required warnings and were asked ''which image would change your mind about smoking.'' The comment identified the ''top three'' proposed required warnings.

(Response) We note that the proposed required warnings chosen as ''most effective'' include some of the nine required warnings we selected. Neither of these comments included sufficient information or data with which to further assess the results or conclusions.

2. Other Comments

FDA also received a number of other comments that discussed the proposed required warnings generally or highlighted issues that applied to some or all of the proposed required warnings. These comments are summarized and responded to in the following paragraphs.

(Comment 50) Many comments stated that graphic health warnings that elicit strong emotional responses are most effective in communicating the negative health consequences of smoking and in encouraging smoking cessation and discouraging smoking initiation. Most of these comments recommended that FDA select the warnings that evoke the strongest emotional responses. Some of these comments cited graphic warnings used in other countries or international research showing that images that trigger emotional responses promote greater awareness and better recollection of the health risks of smoking. Some of these comments also stated that warnings that trigger these responses retain their effectiveness longer. Some of these comments recommended that FDA select graphic warnings that portray graphically disturbing images or images that evoke fear or disgust.

(Response) We agree that eliciting strong emotional responses helps communicate health information. The overall body of scientific literature indicates that health warnings that evoke strong emotional reactions enhance an individual's ability to process the warning information. This leads to increased knowledge and thoughts about the health risks of smoking and the extent to which an individual could personally experience a smoking-related disease, which can in turn motivate positive behaviors. For example, the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions (*see* Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an immediate emotional response from viewers confer negative affect to smoking cues and undermine the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37–38). In FDA's study, eight of the nine selected required warnings elicited strong emotional reactions across all target audiences. As is further discussed in section III.D of this document, the ninth selected required warning, which, unlike the other eight required warnings, contains a warning statement that is framed in a positive manner, also

showed significant effects on the emotional reaction scale in one study population. Given the manner in which this ninth warning is framed, it is not expected to arouse the same level of response on the emotional reaction scale used in FDA's research study as the other eight warning messages (*see* section III.D of this document).

Some of the required warnings we selected include images that may be more emotionally disturbing to certain individuals than others. As we discussed in the preamble to the proposed rule, the use of health warnings with disturbing tonal qualities appears to be effective (75 FR 69524 at 69534). But research also indicates that other types of graphic images, including some that individuals do not find frightening or disturbing, can also be effective in communicating the health risks of smoking (*Id.*). The set of nine graphic warnings we selected includes a balanced set of images in order to reach the broadest target audience of smokers and potential smokers.

(Comment 51) Some comments raised concerns about the quality of the proposed required warnings published by FDA. Some believed that the proposed required warnings were weaker than those used in other countries, and thus, would be less impactful than those in use in other countries. A few comments said the images were overdone and insulting, and a few indicated that the submitters believed that the visuals were poorly crafted.

(Response) We disagree with these comments. We have chosen a balanced set of images for use with the required warnings, and these warnings are generally consistent with the graphic health warnings used in other countries. The results from our research study and the overall body of scientific literature on graphic warnings provide a strong basis for concluding that the nine selected required warnings will effectively communicate the negative health risks of smoking to smokers and potential smokers.

(Comment 52) Some comments raised concerns that the proposed required warnings were too explicit and too visually disturbing. Some of these comments raised concerns that the images were too disturbing for children to see, and others indicated that nonsmokers should not have to be subjected to ''gross'' images when they go into retail establishments. Two comments raised concerns that images that showed humans in distress or human remains were disrespectful and degrading. One comment stated that the proposed warnings crossed the line and were an effort to manipulate people to stop smoking or not to start.

(Response) We disagree. The set of nine required warnings we selected include a balanced set of images. Some individuals may find certain images more visually disturbing than others. The images are not intended to shock or disturb, but rather to effectively educate and inform smokers and potential smokers about the serious health consequences of smoking. Each of the nine graphic warnings communicates negative health consequences of smoking that are well-documented in the scientific literature. By appropriately conveying the serious health consequences in a truthful, forthright manner, the images contain information that may disturb some viewers because the severe, life-threatening and sometimes disfiguring health effects of smoking *are* disturbing. The overall body of scientific evidence indicates that larger, graphic health warnings will effectively communicate these risks. We do not agree that these warnings are disrespectful or degrading.

(Comment 53) A number of comments advocated for the selection of a set of images that could communicate with the diverse U.S. population, and emphasized the importance of human diversity in the images, in part to help ensure the images reach people of low socioeconomic status that are more likely to be smokers and/or to have lower literacy. The comments stated that graphic health warnings are an especially important communication tool for these population groups. A few comments also raised concerns that not enough of the 36 proposed required warnings depicted younger people, and indicated this could reduce their impact among youth.

(Response) We agree that it is important to select a set of images that can communicate with the diverse U.S. population. As discussed in section III.A of this document, we considered the need for diversity when making image selections, and the images selected include a diversity of human images (*e.g.,* race, gender, age), as well as a diversity of styles (*e.g.,* photographic versus illustrative) and themes. This is consistent with the evidence base for graphic health warnings from countries that have already implemented such warnings (*see* Ref. 40 at p. 46 and Ref. 11).

(Comment 54) A number of comments raised concerns that some of the proposed graphic warnings included graphic illustration or ''cartoon-style'' images. Some of these comments stated that these warnings might trivialize the serious health risks of smoking or diminish the importance of the warnings, with some asserting that this style is contradictory to the serious messages being conveyed. One comment believed that these warnings would soften the message, while another believed the graphic illustration warnings were ''harsh.'' Some comments stated that these warnings would negatively affect the believability of the warnings and would not be taken seriously by youth. One comment expressed concern that the graphic illustration style images might resonate with youth, but would not be effective with young adults or adults. It was also noted in the comments that the images presented in this style may inadvertently suggest approval of tobacco use to low-literacy populations that do not comprehend the accompanying textual statement, and that these images could allow smokers to deny the health consequences that are presented. Another comment stated that the research suggests ''cartoon-style'' images and overly conceptual images are easily dismissed by smokers.

(Response) We disagree with the contention that the use of graphic illustration style images is categorically inappropriate. One of the required warnings we selected is presented in this style. As discussed in section III.B of this document, our research study shows that the selected required warnings, including the required warning that includes a graphic illustration style image, showed strong effects in terms of emotional reaction scale, cognitive reaction scale (including believability), and the ''difficult to look at'' measure. Given these results, we concluded that the graphic illustration style can be an effective style for communicating the negative health risks of smoking, including to a diverse range of viewers. In addition, it is important to include a variety of different styles in the final set of warnings. As discussed in the preamble to the proposed rule, a varied set of warnings is consistent with the scientific literature, facilitates better targeting of specific groups whose interests may vary, and has been shown to be effective in delaying or counteracting wear out of the warnings (75 FR 69524 at 69534).

(Comment 55) A number of comments advocated that FDA select only required warnings with photographic images. Some of these comments stated that the use of photographic images was important to realistically portray the negative health consequences of smoking and to provide a real-life quality to the warnings. One comment stated that photographic images were needed to ensure that smokers and

potential smokers understood that the depicted health consequence could really happen and to provide a more physical connection. One comment stated that photographic images would be more engaging and remembered than images presented in other styles. One comment stated that warnings with abstract imagery that require individuals to ''connect the dots'' and draw inferences present an unnecessary and counterproductive hurdle for viewers, and are unlikely to have an effect on smokers.

(Response) We agree that graphic warnings with photographic images can effectively communicate the negative health consequences of smoking, and most of the required warnings we selected include photographic images. The existing scientific literature, the experience of other countries, and the results of our research study show that graphic warnings using photographic images can effectively communicate the negative health consequences of smoking. At the same time, we do not agree that photographic images are the only style of imagery capable of effectively communicating these health risks. A balanced set of warnings with a variety of image styles is more likely to effectively reach a broad group of target audiences, and we note that graphic warnings used in many other countries include a mix of imagery, including photographic and other styles.

(Comment 56) Some comments stated that graphic warnings will not be effective in deterring smoking. One comment stated that smokers already know the health risks of smoking and are very brand loyal, so graphic images will not affect their smoking decisions. Another comment stated that youth will not be deterred by pictures and the graphic warnings could instead make smoking more enticing to youth. One comment stated that smokers are addicted to cigarettes and ''flashy'' pictures will not stop them from smoking but instead will only encourage them to cover the pictures. On the other hand, other comments concluded that graphic health warnings are likely to affect smoking decisions. One comment stated that graphic warnings will deter initiation, and another stated that the warnings will lead to a decrease in cigarette sales. One comment stated that graphic warnings will reach people who otherwise would not read text-only warnings.

(Response) As previously discussed, we concluded that large graphic warnings are effective in conveying the health risks of smoking, influencing consumer awareness and knowledge of those risks and having an impact on smoking intentions. We disagree with comments stating that required warnings will not be effective. We have determined that the set of required warnings we have selected will effectively convey the negative health consequences of smoking, which will help discourage nonsmokers, including children and adolescents, from starting to smoke cigarettes, and help encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.

(Comment 57) Several comments stated that images that depict realistic suffering caused by tobacco use are more effective in promoting cessation than images that portray death.

(Response) We agree that graphic warnings that depict the realistic suffering caused by tobacco use can be effective at communicating the negative health consequences of smoking, and some of the required warnings we selected include such images. At the same time, we do not agree that such images are the only images capable of effectively communicating the negative health consequences of smoking. A balanced set of warnings with a variety of image themes is most likely to maximize the effectiveness of the selected required warnings among a broad group of target audiences, and notes that graphic warnings used in many other countries include a mix of imagery. As discussed in the preamble to the proposed rule, the existing research indicates that the use of a variety of health warnings broadens the reach of the warnings, and is effective in counteracting overexposure and delaying wear out of the warnings (75 FR 69524 at 69534).

(Comment 58) One comment stated that most of the proposed images are illustrations rather than graphic warnings, in that they are meaningful only to people who are already aware of the information in the accompanying textual warning.

(Response) Consistent with the requirements of section 201 of the Tobacco Control Act, we have developed color graphic images that depict the negative health consequences of smoking to accompany the nine new warning statements provided by Congress in the Tobacco Control Act. The graphic health warnings, referred to as ''required warnings'' in the NPRM and in this final rule, consist of the combination of each textual warning statement and the accompanying color graphic image we selected for use with each statement. The submitter of this comment seems to misunderstand how the images are to be used; they were not developed to serve as stand-alone warning messages, but rather to accompany textual warning statements. Although we disagree with the contention in this comment that the images are only meaningful in conjunction with the information in the accompanying textual warning, the images are required to be presented at all times with this accompanying information.

D. Selected Images

This section discusses the nine color graphic images that we selected for use with the textual warning statements set forth in section 201 of the Tobacco Control Act and the factors that influenced each selection decision, including the results from our research study, the substantive comments received in the docket, the relevant scientific literature, and any other considerations weighed, such as the diversity a particular image contributes to the overall set of required warnings.

The document entitled ''Proposed Required Warning Images'' that was included in the docket for the proposed rule displayed each of the 36 proposed required warnings (consisting of the proposed images and accompanying warning statements) on two consecutive pages, with one display showing the warning statement accompanying the image in black text on a white background and one display showing it in white text on a black background. The images are referred to in this section by the pages on which they appear in the ''Proposed Required Warning Images'' document and by the descriptive names used for each image in the study report (Ref. 49) summarizing the results of our research study.

In this section's discussion of the results from our research study for each selected image, the endpoints that the images showed a statistically significant effect on in one or more of the study populations (adult smokers aged 25 or older, young adult smokers aged 18 to 24, and youth who currently smoke or who are susceptible to smoking aged 13 to 17) are described. This discussion also notes the level of significance of the effects by providing p-values: ($p<0.05$), ($p<0.01$), and ($p<0.001$). The p-value is reflective of the percent chance the finding could have happened by coincidence. For example, for a finding that is significant at 0.1 percent ($p<0.001$), there is less than one chance in a thousand that the finding happened by coincidence. The full description of our research study and the analyses are contained in the study report (Ref. 49, study report) that was placed in the docket for the proposed rule.

The required warnings, consisting of the nine color graphic images we selected and the textual warning statements, are contained in a document titled ''Cigarette Required Warnings,'' as is further discussed in section V of this document.

1. ''WARNING: Cigarettes are Addictive''

We selected the image which appears on pages one and two of the document ''Proposed Required Warning Images,'' referred to as ''hole in throat,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in all three study populations, as well as on the cognitive reaction scale in adults. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image also had a significant impact ($p<0.05$) on adult [4] beliefs about the health risks of smoking for smokers, and a significant impact ($p<0.05$) on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, relative to the text-only control.

However, young adults viewing the image had significantly lower statement recall at one week follow-up than those who viewed the text-only control (55.9 percent versus 74.3 percent), as did adults viewing a hypothetical advertisement containing the proposed required warning (64.1 percent versus 87.7 percent). However, recall of the statement was generally high for the image (ranging from 55.9 percent to 86.3 percent), even where it was significantly lower than for the text-only control, and we conclude that repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 59) FDA received a large number of comments supporting the use of the image ''hole in throat,'' including comments from individuals (including former smokers), public health advocacy groups, academics, State and local public health agencies, and health care professionals. Many comments stated that this image is the best image for use with this warning statement. Some comments indicated that the image was appropriately compelling and effectively communicates the risks of smoking. Other comments stated that the image will be an effective deterrent to smoking by making a smoker think twice before buying cigarettes and/or by making children think twice before starting to smoke. Several comments also indicated that the image concretely conveys the health harms of smoking.

(Response) We selected this image for use with this warning statement.

(Comment 60) One comment supported use of this image in part because of the diversity reflected in the image, and noted that it could be a Latino smoker or a man of color, which could make it more relevant than other proposed images with low socioeconomic status smokers. Another comment noted that the image targets a critical demographic group by portraying an image of a man.

(Response) We agree that it is beneficial to have a diverse set of images that communicates with a wide range of audiences, including population subgroups with higher smoking prevalence rates. In light of this, we selected a set of nine required warnings (including the image ''hole in throat,'' which portrays a man of color) that includes a variety of human images that are broadly representative of the overall population.

(Comment 61) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. Additionally, this image was one of two images deemed effective in another submitter's survey of comparative effectiveness of the 36 proposed required warnings at stopping someone from smoking, and it received the highest overall rating of the images examined for use with this statement in another submitter's study of the potential effectiveness of the images.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 62) FDA also received some comments that opposed the use of the image ''hole in throat.'' One comment noted that the image was ''too gross to be effective,'' while another comment stated that it ''offend[s] against human dignity.'' In addition, one comment stated that the image would only have a one-time shock value, and another comment indicated that the image was too vague in nature.

(Response) We disagree with these comments. The image effectively and concretely communicates the negative health consequences of smoking. The image clearly portrays the addictive nature of cigarettes, depicting a man who is still smoking despite prior evidence (a stoma in his neck) of surgery for cancer. As discussed, this image had a highly significant effect ($p<0.001$) on all salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The research literature indicates that images that evoke emotional reactions can promote greater awareness and better recollection of the health risks of smoking, and can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Ref. 20, 44, and 45).

Furthermore, contrary to the assertion that the image will only have a one-time shock value, the research literature suggests that more vivid warnings are more likely to retain their salience over time (Ref. 3 at p. C–4 and Ref. 41).

2. ''WARNING: Tobacco Smoke Can Harm Your Children''

We selected the image which appears on pages 9 and 10 of the document ''Proposed Required Warning Images,'' referred to as ''smoke approaching baby,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and

[4] Throughout this section, the results on individual study measures discussed for the adult study population are results from the adult sample viewing the hypothetical cigarette package (as opposed to the sample viewing the hypothetical advertisement), unless otherwise noted.

difficult to look at measure) in the adult and youth samples. In young adults, the image also had a significant effect on all the salience measures (emotional reaction scale ($p<0.01$), cognitive reaction scale ($p<0.001$), and difficult to look at measure ($p<0.05$)).

The image had a significant effect ($p<0.05$) on recall of the warning statement at baseline compared to the control for adults and youth. The image also had a significant effect ($p<0.05$) on statement recall at 1 week follow-up in young adults. The image also showed some of the largest effect sizes for image recall (at baseline and at 1 week follow-up) in adults and young adults across the images proposed for use with this warning statement.

The image had a statistically significant effect ($p<0.05$) on youth intentions to not smoke in the next year, with 71.6 percent of youth viewing the image reporting that they would not be likely to smoke in the next year compared to 56.9 percent of youth viewing the text-only control.

As is discussed in further detail in section III.E of this document, three other images proposed for use with this warning statement, ''smoke at toddler,'' ''girl crying,'' and ''girl in oxygen mask,'' also had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). While several of the images proposed for use with this warning statement could effectively convey the negative health consequences of tobacco smoke exposure for nonsmokers (and in particular, children), we ultimately considered ''smoke approaching baby'' to have the strongest overall research results of the images proposed for use with this warning statement for multiple reasons.

First, two of the images that also showed significant effects on all the salience measures across the study populations, ''girl crying'' and ''girl in oxygen mask,'' were negatively associated with beliefs about the health risks of secondhand smoke exposure for nonsmokers in the adult sample. In other words, adults who viewed these images were less likely to believe that nonsmokers will suffer from negative health effects related to secondhand smoke exposure than adults who viewed the text-only control.

As described in section III.B of this document, we determined that the salience results from our research study are the most meaningful basis for making distinctions among the images given the design limitations of the research study, which exposed each participant to each image only once, and thus may not be able to accurately distinguish the relative effects of the images on more eventual outcomes, such as changes in beliefs, as reliably as their effects on more immediate emotional and cognitive reactions. However, the negative results observed on the secondhand smoke beliefs measure for the images ''girl crying'' and ''girl in oxygen mask'' were of concern, particularly given that the subject of the warning statement is the health risks of secondhand smoke exposure for children. Thus, ''smoke approaching baby'' was considered a preferable alternative to these two images.

Furthermore, ''smoke approaching baby'' was associated with youth reporting that they would be less likely to be smoking 1 year from now.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 63) FDA received several comments supporting the use of the image ''smoke approaching baby,'' including comments from individuals, a public health advocacy group, and State and local public health agencies. Some of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. One comment stated that the image will clearly inform parents that when they smoke in the presence of their children, their children will also be inhaling toxins, and another comment noted that the image realistically shows secondhand smoke exposure and health effects. Some comments noted that the image will deter smoking, with one comment noting that the depiction of an innocent baby will resonate with parents and cause them to think about their children's health before smoking.

(Response) We selected this image for use with this warning statement.

(Comment 64) FDA also received some comments expressing support for the diversity reflected in the image. One comment stated that the image will appeal to different age and other demographic groups, while another comment noted that the child in the image could be African-American, Hispanic, Latino, Native American, and/or Native Hawaiian or Pacific Islander, and suggested that the image could resonate with a variety of important population subgroups. The comment also noted that Latino parents say the health of their children is a motivating factor in their decision to quit smoking.

(Response) It is important to have a diverse set of images that communicate with a wide range of audiences, including a variety of population subgroups. In order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''smoke approaching baby,'' that includes a variety of human images that are broadly representative of the overall population.

(Comment 65) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, it was rated highly on its ease of comprehension and induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control in one submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 66) FDA also received some comments critical of the image ''smoke approaching baby.'' These comments suggested that the child does not appear to be suffering harms to his health and/or looks too healthy. One of these comments also stated that the image was associated with youth reporting that they would be more likely to be smoking 1 year from now, and advised against its use.

(Response) We do not agree that the image does not depict the health hazards of secondhand smoke. Graphic depictions of the visible effects of disease are not the only way of communicating the health risks of secondhand smoke for children (*see* Ref. 11), some of which (such as impaired lung growth), are not necessarily externally visible in a photograph of a child exposed to secondhand smoke. Furthermore, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. As evidenced by the significant effects the image had on the salience measures compared to the text-only control across the populations participating in FDA's research study, the required warning depicts the health consequences of

secondhand smoke exposure in a manner that has an impact on both smokers and potential smokers. Thus, we conclude that the required warning effectively conveys the message that exposure to tobacco smoke is harmful for children.

We also note that the comment stating that the image was associated with youth reporting that they would be more likely to be smoking 1 year from now is incorrect. In fact, the image had a statistically significant effect on decreasing youth intentions to smoke (*see* Ref. 49 at p. 4–4; *see also* Ref. 50). As stated previously, 71.6 percent of youth viewing this image reported that they would *not* be likely to smoke in the next year, compared to 56.9 percent of youth viewing the text-only control.

3. ''WARNING: Cigarettes Cause Fatal Lung Disease''

We selected the image which appears on pages 25 and 26 of the document ''Proposed Required Warning Images,'' referred to as ''healthy/diseased lungs,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image also showed some of the largest effect sizes for image recall (at baseline and at 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 67) FDA received a large number of comments supporting the use of the image ''healthy/diseased lungs,'' including comments from individuals, public health advocacy groups, medical organizations, academics, State and local public health agencies, and health care professionals. Many comments indicated that this image is the best image for use with this warning statement, with one stating that the image dramatically depicts a health consequence of smoking, and another noting that it was appropriately gripping and compelling.

Several comments noted that, based on FDA's research results, this image is the clear choice among the four images proposed by FDA for use with this warning statement. Some comments noted that similar images have been used effectively in other countries that require graphic health warnings on cigarette packages. One comment noted that this image could reach a younger audience, and hopefully prevent them from starting to smoke.

(Response) We selected this image for use with this warning statement.

(Comment 68) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. Another comment also submitted research suggesting that this image was the highest rated for potential effectiveness among the set of images proposed for use with this warning statement. Another submitter showed that, in a survey, respondents rated this image as one of the most effective of the 36 proposed images for encouraging smokers to quit smoking. The image was also identified in a survey of high school students as one of the ''top three'' proposed required warnings (out of 36) in another submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 69) FDA also received some comments critical of the image ''healthy/diseased lungs.'' One comment noted that the image was ''too gross to be effective,'' while several comments expressed the opposite belief, with some suggesting that the diseased pair of lungs should be more damaged.

(Response) The image ''healthy/diseased lungs'' is an appropriate image that effectively conveys the negative health consequences of smoking. While, as reflected in the above summary, some comments expressed a belief that the image of the diseased lung is ''too gross'' and some expressed a belief that the image is too healthy in appearance, the image effectively evoked emotional and cognitive reactions in viewers in FDA's research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

4. ''WARNING: Cigarettes Cause Cancer''

We selected the image which appears on pages 33 and 34 of the document ''Proposed Required Warning Images,'' referred to as ''cancerous lesion on lip,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and had the numerically largest effects on the cognitive reaction scale in young adults and youth. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are related to behavior change.

The image also had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers, and a significant impact ($p<0.01$) on beliefs about the health risks of secondhand smoke exposure for nonsmokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

The image also showed some of the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement, though it showed lower correct recall of the warning statement compared to the control in adults at 1 week follow-up (68.3 percent versus 85.1 percent). However, recall of the statement was generally high at 1 week follow-up among study participants who viewed this image (ranging from 68.3 percent to 77 percent), and, based on the scientific literature, we conclude that repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to

outcomes on the salience measures than to outcomes on the recall measures.

As is discussed in further detail in section III.E of this document, another image proposed for use with this warning statement, ''deathly ill woman,'' also had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three samples (adults, young adults, and youth). While we agree that this image, similar to the selected image of ''cancerous lesion on lip,'' is a very strong image that effectively conveys the negative health consequences of smoking, we ultimately chose ''cancerous lesion on lip'' for use with this warning statement for several reasons.

First, ''cancerous lesion on lip'' was the only image among the images proposed for use with this warning statement that had a positive impact on beliefs about the health risks of smoking and secondhand smoke exposure in one of the study samples (adults viewing a hypothetical advertisement).

Furthermore, as is stated in several comments (see the following paragraphs), the selected image, ''cancerous lesion on lip,'' is likely to have particular relevance for youth. As explained in some of these comments, the research literature suggests that youth are likely to relate to and be susceptible to cigarette warnings depicting the negative short-term impacts of smoking on their personal appearance, including their lips and teeth (Ref. 53).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 70) FDA received a large number of comments supporting the use of the image ''cancerous lesion on lip,'' including comments from individuals, public health advocacy groups, a medical organization, academics, State and local public health agencies, and health care professionals. Several comments suggested that FDA should use this image because it has a very high potential to reach consumers and positively influence their behavior.

A few comments also specifically addressed the benefits of using an image that shows the public that cigarettes cause oral cancers, noting that public awareness of this negative health consequence is low, and that many smokers and nonsmokers only relate cigarettes to lung cancer (*see also* section II.C of this document regarding consumers' lack of knowledge regarding the health risks of smoking).

Multiple comments also noted that, based on FDA's research results, this image was the best choice among the four images proposed for use with this warning statement, significantly outperforming ''white cigarette burning'' and ''red cigarette burning,'' and slightly outperforming ''deathly ill woman.''

(Response) We selected this image for use with this warning statement.

(Comment 71) Several comments noted that the image could be especially effective with younger audiences and could positively influence such audiences by illustrating how the health effects caused by smoking negatively affect their physical appearance. The comments indicated that adolescents can relate to and will be susceptible to this message.

(Response) We agree with these comments. It is important to include content in the required warnings that is relevant to youth. The image ''cancerous lesion on lip'' has the potential to positively impact youth behavior, in addition to adult and young adult behavior.

(Comment 72) As mentioned in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image, along with ''deathly ill woman,'' was one of the most effective of the images proposed for use with this warning statement. In addition, this image was rated as the most effective of the 36 proposed images in another submitter's survey of comparative effectiveness of the images in helping smokers quit. It was also the highest rated image among the set of images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, and was identified by high school students as one of the ''top three'' proposed required warnings (out of 36) in another submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 73) FDA also received some comments critical of the image ''cancerous lesion on lip.'' Two comments indicated that the image was ''too gross'' to be effective, while another comment stated that it borders on the offensive. In contrast, some comments suggested that the image should be more graphic. Another comment suggested that oral cancer was an odd choice of cancers to depict in the graphic warning.

(Response) We disagree with these comments. With respect to the comments stating that the image was ''too gross'' or that it was offensive, the research literature indicates that images that evoke strong emotional reactions can promote greater awareness and better recollection of the health risks of smoking and can increase the likelihood smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

With respect to the suggestion that the image is not graphic enough, as discussed previously, this image had a highly significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth), which in turn suggests that the image has the potential to motivate positive behavior change (*Id.*).

Furthermore, the choice of cancers depicted in the required warning is appropriate, and will help inform the public that cigarettes cause oral cancers, and thus increase public awareness of the negative health consequences of smoking.

5. ''WARNING: Cigarettes Cause Strokes and Heart Disease''

We selected the image which appears on pages 39 and 40 of the document ''Proposed Required Warning Images,'' referred to as ''oxygen mask on man's face,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in all the study populations. These impacts are important, as the research literature suggests that graphic warnings that evoke responses of this kind are

likely to increase awareness of the health risks of smoking and increase the likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

The image also showed some of the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 74) FDA received a large number of comments supporting the use of the image ''oxygen mask on man's face,'' including comments from individuals, medical organizations, public health advocacy groups, health care professionals, State public health agencies, and academics. Many of these comments indicated that this image is the best image for use with this warning statement, while some also noted that the image will make smokers think twice about continuing to smoke. Some comments also noted that the image is beneficial in that it will inform the public of negative consequences of smoking aside from lung disease.

Some comments also noted that, based on FDA's research results, this image was the best choice for use with this warning statement, noting that it elicited the highest scores on the emotional reaction scale of the images tested for use with this statement in FDA's research study.

(Response) We selected this image for use with this warning statement.

(Comment 75) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. In another submitter's study, this image was the highest-rated of the FDA-proposed images for use with this warning statement; however, this study also evaluated two images used with similar warning statements in other countries (one of open heart surgery, one of a bloody brain), and noted that they rated higher than FDA's proposed images.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 76) FDA also received some comments critical of the image ''oxygen mask on man's face.'' One comment noted that the image was ''too gross to be effective,'' and one comment stated that the image should feature a younger person to highlight the fact that heart attacks and stroke can occur in young smokers as well as in older smokers.

(Response) The image ''oxygen mask on man's face'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree with the statement that the image is ''too gross to be effective;'' the image effectively elicited emotional and cognitive reactions in viewers in our research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

While we agree with the statement in the comment that heart disease and strokes can occur in young smokers as well as in older smokers, the selected required warning will effectively communicate with a range of audiences, including consumers of different ages. As described previously, ''oxygen mask on man's face'' had a significant effect ($p<0.001$) on all the salience measures (emotion measures, cognition measures, and difficult to look at measure) in all three study populations (adults, young adults, and youth). We considered the variety and diversity reflected in the images in making selection decisions, and took into account the importance of selecting a set of required warnings that includes a diversity of styles (*e.g.,* photographic versus illustrative), themes, and human images (*e.g.,* race, gender, age). While the person shown in this image is an older man, some of the images show younger people. Overall, the nine selected required warnings will effectively communicate to a wide range of consumers, including both young and older smokers.

6. ''WARNING: Smoking During Pregnancy Can Harm Your Baby''

We selected the image which appears on pages 45 and 46 of the document ''Proposed Required Warning Images,'' referred to as ''baby in incubator,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image had a significant effect ($p<0.01$) on recall of the warning statement at baseline compared to the text-only control in youth. The image also had a significant effect ($p<0.05$) on statement recall at follow-up in young adults, and showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults and youth across the images proposed for use with this warning statement.

The image had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in adults, although it had a negative significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in youth. Thus, the results on this beliefs measure were mixed for ''baby in incubator.'' However, given the strength of the effects observed for this image on the salience measures, the required warning that includes the ''baby in incubator'' image is likely to increase awareness of the health risks of smoking and increase the likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 77) FDA received a number of comments supporting the use of the image ''baby in incubator,'' including comments from individuals, a community organization, a public health advocacy group, health care professionals, a State public health agency, and academics. Several of these comments indicated that this image is the best image for use with this warning statement, with some noting that the image effectively shows how smoking during pregnancy can damage a baby's health. One comment noted that the image could stimulate discussion about how smoking affects pregnancy among youth.

One comment also noted that the image ''baby in incubator'' outperformed the other image proposed for use with this warning statement in FDA's research study on the key criteria that have proven most meaningful.

(Response) We selected this image for use with this warning statement.

(Comment 78) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concluded that this image was the most effective of the images proposed for use with this warning statement. However, in another submitter's study, this image was evaluated against images used in other countries, one of which was very similar in composition to ''baby in incubator'' but which was a photograph rather than a graphic illustration. In that submitter's study, the photographic image was rated significantly higher than ''baby in incubator.''

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 79) FDA also received a number of comments critical of the image ''baby in incubator.'' The majority of these comments objected to the graphic illustration style used for the image, with some submitters approving of the concept but stating that a photograph would be more impactful, and some indicating that the style is inappropriate, either because it downplays the seriousness of the risk described in the required warning or because it would inappropriately appeal to youth without discouraging them from smoking.

Some comments indicated that the lettering style used in the image was difficult to read, and one comment stated that the results from FDA's research study for this image, while better than the results for the other image proposed for use with this warning statement (''pacifier & ashtray''), were not compelling.

One comment stated that the image bordered on the offensive.

(Response) The image ''baby in incubator'' is an appropriate image that effectively conveys the negative health consequences of smoking. As discussed in section III.C of this document, we are aware that many comments received in the docket expressed concern about the use of graphic illustration style images and expressed a belief that this style was not strong enough to elicit appropriate reactions. However, as discussed in section III.C of this document, we disagree with the contention that the use of graphic illustration style images is categorically inappropriate. As the results from our research study demonstrate, the ''baby in incubator'' image effectively elicited emotional and cognitive reactions, showing a highly significant effect ($p<0.001$) on these measures in all study populations, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

In addition, based on the study results, we also do not agree that the image is inappropriately offensive or that our research results for this image are not compelling. Based on the overall feedback received, we also disagree that the text in the proposed warning is difficult to read.

7. ''WARNING: Smoking Can Kill you''

We selected the image which appears on pages 49 and 50 of the document ''Proposed Required Warning Images,'' referred to as ''man with chest staples,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). The image had the numerically largest effects of the images proposed for use with this warning statement on the salience measures. As discussed in section III.B of this document, these salience impacts are important, as the research literature suggests that they are likely to be related to behavior change.

The image was also associated with higher intentions to quit smoking compared to the text-only control ($p<0.05$) in adults.

The proposed required warning featuring the ''man with chest staples'' image showed some of the largest effect sizes for image recall among the images proposed for this warning statement at baseline in all study populations and at 1 week follow-up in young adults and youth.

Young adults viewing the image had significantly lower recall of the warning statement than those viewing the text-only control at baseline (76.2 percent versus 92.3 percent) and 1 week follow-up (78.9 percent versus 91.3 percent). However, recall of the statement was generally high at baseline and follow-up among study participants who viewed this image (ranging from 76.2 percent to 90.4 percent), and repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 80) FDA received a large number of comments supporting the use of the image ''man with chest staples,'' including comments from individuals (including former smokers), public health advocacy groups, medical organizations, health care professionals, State and local public health agencies, and academics. Many of these comments indicated that this image is the best image for use with this warning statement, while some also noted that the image is appropriately attention-grabbing or powerful and that it will make smokers think twice about continuing to smoke, or help them smoke less. Some comments also noted that the image is an excellent way of driving home the message that smoking can kill you. One comment stated that the image is a strong, solid concept that has been used effectively in other countries that require graphic health warnings on cigarette packages.

Some comments stated that, based on FDA's research results, this image is the best choice for use with this warning statement, noting that it elicited the highest scores on the emotional reaction scale of the images tested for use with this statement in FDA's research study, and had other positive results.

(Response) We selected this image for use with this warning statement.

(Comment 81) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example,

in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, it was noted that, based on respondents' rating and ranking of this image's effectiveness, the image clearly stands out as the highest rated of the images FDA proposed for use with this warning statement.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 82) FDA also received some comments critical of the image ''man with chest staples.'' One comment stated that the image was ''too gross to be effective,'' while another stated the image ''offend[s] against human dignity.'' A few comments suggested that the person in the image should look worse (*e.g.,* paler, weaker, thinner, like he had suffered more), and some comments suggested the person's death should be more clearly tied to smoking by the image. One comment indicated that persons unfamiliar with an autopsy may not understand the image.

(Response) The image ''man with chest staples'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree that the image ''is too gross to be effective'' or that it ''offend[s] against human dignity;'' the image shows a realistic outcome of the negative health consequences caused by smoking, and effectively elicited emotional and cognitive reactions in viewers in our research study. This in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

Viewers will understand that the image shows someone who has died from a smoking-related cause. Although we agree that not all viewers will necessarily be familiar with an autopsy scar, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. The results observed in our research study suggest that viewers from all age groups understood and reacted to this image in desirable ways. The figure shown is appropriate; although some of the negative health consequences of smoking may lead to the effects on appearance suggested in the comments (*e.g.,* significant disease-related weight loss), other consequences, such as heart attacks, can kill smokers without first causing these effects.

8. ''WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers''

We selected the image which appears on pages 57 and 58 of the document ''Proposed Required Warning Images,'' referred to as ''woman crying,'' for use with this warning statement.

In our research study, this image had a significant effect ($p<0.001$) on the emotional reaction scale in all three study populations (adults, young adults, and youth). It also showed significant effects on the difficult to look at measure in all study populations (adults ($p<0.01$), young adults ($p<0.001$), and youth ($p<0.001$)), and significant effects on the cognitive reaction scale in all study populations (adults ($p<0.05$), young adults ($p<0.001$), and youth ($p<0.001$)). This image was the only image proposed for use with this warning statement that showed significant effects on all the salience measures in our research study.

The image also had a significant impact ($p<0.05$) on beliefs about the health risks of smoking for smokers in young adults.

The proposed required warning that included this image also showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults, young adults, and youth across the images proposed for this warning statement. Youth viewing the image had significantly lower recall of the warning statement than those viewing the text-only control at baseline (52.4 percent versus 68.9 percent). However, recall of the statement was generally high among study participants who viewed this image, and repetitive viewing of the required warning is likely to increase recall. As explained in section III.C of this document, we gave greater weight to outcomes on the salience measures than to outcomes on the recall measures.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 83) FDA received several comments supporting the use of the image ''woman crying,'' including comments from individuals (including former smokers) and public health advocacy groups. Some of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. One comment stated that the image stood out as particularly effective among the proposed required warnings because it shows the devastating effects secondhand smoke can have on people who have tried to protect themselves by not smoking, and indicated that the image will remind smokers that they are harming their loved ones and others around them as well as themselves. Others noted that the image sends a powerful message.

One comment indicated that the image outperformed the other images proposed for use with this warning statement on the emotional reaction scale and the difficult to look at measure in FDA's research, and noted that it appears to be a cut above the other images.

(Response) We selected this image for use with this warning statement.

(Comment 84) One comment approved of the diversity reflected in the image (which shows an African-American woman).

(Response) We agree that it is beneficial to have a diverse set of images that communicate with a wide range of audiences, including a variety of population subgroups. In order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''woman crying,'' that includes a variety of human images that are broadly representative of the overall population.

(Comment 85) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. For example, this image induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study.

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 86) FDA also received some comments critical of the image ''woman crying.'' One comment indicated that the image borders on the

offensive, while another stated it is too sensational to be effective.

Other comments suggested that the image did not directly portray a health consequence of secondhand smoke, or that the image is not clearly tied to secondhand smoke. One comment also suggested that the image should not be used because it did not have an impact on beliefs about the health harms of secondhand smoke or on quit intentions in FDA's research study.

(Response) We disagree with these comments. The image ''woman crying'' is an appropriate image that effectively conveys the negative health consequences of smoking. We do not agree that the image is offensive or too sensational; the image is a realistic portrayal of how the negative health consequences caused by exposure to secondhand smoke can affect people. It effectively elicited emotional and cognitive reactions in those who viewed it in our research study, which in turn suggests that the image has the potential to promote greater awareness of the health risks of smoking and motivate positive behavioral outcomes, including an increased likelihood that smokers will reduce their smoking, make an attempt to quit, or quit altogether (Refs. 20, 44, and 45).

We do not agree that the image does not depict a health consequence of secondhand smoke. Graphic depictions of the visible effects of disease are not the only way of communicating the health risks of secondhand smoke exposure (*see* Ref. 11). The negative health consequences caused by secondhand smoke exposure, including fatal lung disease, have many dimensions, including emotional suffering. This image highlights that dimension. Furthermore, it is important to keep in mind that the image is not used in isolation, but accompanies the textual warning statement, which provides additional context for what is shown. As evidenced by the image's significant impact on the salience measures across the populations participating in our research study, the proposed required warning effectively depicts the health consequences of secondhand smoke exposure, including the suffering endured by those experiencing these health consequences.

9. ''WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health''

We selected the image which appears on pages 67 and 68 of the document ''Proposed Required Warning Images,'' referred to as ''man I Quit t-shirt,'' for use with this warning statement.

In our research study, the image had a statistically significant effect on the emotional reaction scale in young adults ($p<0.05$), and on the cognitive reaction scale in adults ($p<0.05$), young adults ($p<0.01$), and youth ($p<0.001$).

The proposed required warning that included this image also showed the largest effect sizes for image recall (at baseline and 1 week follow-up) in adults, young adults, and youth across the images proposed for this warning statement.

Although this image, along with the other images proposed for use with this warning statement, did not elicit the magnitude of reactions on the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) that some of the images proposed for use with other warning statements did, this is likely a result of the information being conveyed in the warning statement, which emphasizes the positive health benefits of quitting smoking. The content of this required warning is not expected to arouse the same level of response on some of the salience measures as the other messages.

However, the research literature suggests that warnings that focus on the benefits of quitting are effective at encouraging cessation, and suggests that positive, self-efficacy messages can be used effectively as one component of graphic health warnings to increase smokers' motivations and confidence about quitting (Ref. 40 at pp. 35, 39–41). The research literature also highlights the importance of including one or more warnings that provide solutions, such as the ''man I Quit t-shirt'' required warning, in a set of warnings conveying the negative health consequences of smoking. Specifically, the literature recommends that, in addition to communicating the health risks of smoking, some warnings should also provide information on how to avoid these risks (*i.e.,* by quitting), in order to optimize the effectiveness of the overall set of warning messages (*see* Ref. 48 and Ref. 40 at p. 37).

As is discussed in further detail in section III.E of this document, another image proposed for use with this warning statement, ''cigarettes in toilet bowl,'' also had significant effects on the emotional reaction scale in some study populations and on the cognitive reaction scale, as well as showing positive effects on other study measures. While this image, similar to the selected image (''man I Quit t-shirt''), could be effectively used with this warning statement, we ultimately selected ''man I Quit t-shirt'' for use with this warning statement based on a consideration of multiple factors, including the feedback received in the docket, which is discussed in the comment summaries in the following paragraphs and in section III.E of this document.

Furthermore, as noted in section III.A of this document, in order to ensure that the final set of required warnings effectively communicates risk information to a diverse range of audiences, we selected a set of nine required warnings, including the image ''man I Quit t-shirt,'' that includes a variety of human images that are broadly representative of the overall population. The image ''man I Quit t-shirt'' contributes to the variety seen in the final set of images by picturing a man who is younger than the men in the other required warning images. Additionally, as reflected in the comment summary, the man shown in the image is perceived by many viewers as strong and ''macho,'' suggesting that the image has the potential to reach and effectively communicate with a demographic group that has been heavily targeted by tobacco industry cigarette advertising (*see* Ref. 54 at p. 151). The depiction of men as strong, powerful, macho, rugged, and independent, and the association of these characteristics with cigarette brands, has long been a prominent theme in tobacco industry advertising (*Id.* at p. 151), and targeted marketing efforts by the tobacco industry have led to greater smoking uptake and lower cessation rates in targeted subgroups (*Id.* at p. 211).

We received a number of comments on this image, which we have summarized and responded to in the following paragraphs.

(Comment 87) FDA received a number of comments supporting the use of the image ''man I Quit t-shirt,'' including comments from individuals, public health advocacy groups, medical organizations, and State and local public health agencies. Many of these comments indicated that this image is the best image of the ones proposed for use with this warning statement. Several of the comments discussed specific favorable aspects of the image or potential effects of the image, including that the image models a positive behavior, is compelling, and that it will encourage others to quit. Several comments believed that the image could reach a critical demographic group by showing a younger, ''cool,'' ''macho'' man and suggesting that it is manly and/or cool to quit smoking. Some comments also suggested that the image is positive in that it shows that quitting is a heroic decision.

(Response) We selected this image for use with this warning statement.

(Comment 88) As described in section III.C of this document, some comments submitted to the docket described the results of scientific investigations that the submitters had conducted to examine the potential effectiveness of FDA's proposed images on various outcomes. This image was discussed in some of these comments. In one submitter's study, the image ''man I Quit T-shirt'' was the highest rated of the images proposed by FDA for use with this warning statement among adults. This study also tested a version of the required warning that had been manipulated to add a quitline number; this version was rated and ranked as the most effective warning overall among study participants. In another submitter's study, this image was rated highly on its ease of comprehension, but led to lower worry relative to a text-only control (but as the researcher noted, the message in this warning is reassuring: ''Quitting smoking now greatly reduces serious risks to your health'').

(Response) As discussed in section III.C of this document, we carefully considered the comments submitted to the docket that described the results of studies conducted by the submitters on our proposed required warnings. The results summarized in these comments are generally supportive of our image selection decisions.

(Comment 89) FDA also received some comments critical of the image ''man I Quit t-shirt.'' Some comments indicated that the image does not convey a health consequence of smoking, while one indicated that the text was difficult to read. One comment also noted that the image failed to show an effect on some measures in FDA's research study, and another indicated that the image is banal.

(Response) We disagree with these comments. The image ''man I Quit t-shirt'' is an appropriate image. Consumers can be educated about the negative health consequences of smoking in a variety of ways. While the other required warnings discuss and portray the consequences of starting or continuing to smoke (which has been shown to be one effective way to educate consumers), another method of increasing awareness and knowledge about the negative consequences of a behavior is to disseminate messages that discuss the positive health benefits of refraining from a behavior (Ref. 55). Studies attest to the potential effectiveness of warnings that adopt such an approach (Ref. 40 at p. 35). Accordingly, the warning statement used in this required warning, ''Quitting smoking now greatly reduces serious risks to your health,'' is framed in a positive manner, discussing the health benefits of ceasing to smoke, and the image is consistent with this text. This required warning, particularly as part of the overall set of required warnings, will help educate consumers about the negative health consequences of smoking and help encourage positive behavior (*see* Ref. 40 at pp. 35 and 40).

Based on the overall feedback received and the results from our research study, we also disagree that the text in the proposed warning is difficult to read or that the image is banal.

10. Image for Advertisements With a Small Surface Area

In addition to proposing 36 required warnings for use on cigarette packages and in cigarette advertisements in the NPRM, we also proposed two other color graphics for use solely in advertisements with a small surface area of less than 12 square inches (75 FR 69524 at 69539). As we explained in the NPRM, these two proposed color graphics differ in their composition from the other proposed images in that the details of these two color graphics should be clear, conspicuous, and legible even when the image is reduced in size to occupy 20 percent of a surface with an area of less than 12 square inches (75 FR 69524 at 69535). We proposed that whichever of these options was selected would be used in combination with one of the nine textual statements only in advertisements with a small surface area (*i.e.,* less than 12 square inches). However, as we noted in the NPRM, even an advertisement with a relatively small surface area would need to be large enough so that the required graphic and accompanying textual warning statement are clear, conspicuous, and legible (75 FR 69524 at 69539).

We selected the image which appears on page 75 of the document entitled ''Proposed Required Warning Images'' for use with the textual warning statements solely in advertisements with a small surface area (defined as less than 12 square inches). This image depicts a black exclamation mark enclosed within a red equilateral triangle.

As stated previously, FDA proposed two images for use solely with the textual warning statements in advertisements with a small surface area; the selected image described in the previous paragraph and an image of a burning cigarette enclosed in a red circle with a red bar across it. We did not receive any comments on either of the proposed images.

Versions of both of these images have been used in other contexts. For example, the image of an exclamation mark enclosed within a triangle is often used to draw attention to a warning of danger or hazards that could result in personal injury or a threat to health (*see, e.g.,* 16 CFR 1211.15, 16 CFR 1407.3; 16 CFR 1500.19; and Ref. 56). The image of a burning cigarette enclosed in a red circle with a red bar across it is the international ''No Smoking'' symbol (Ref. 56) and is often used on signs and placards to denote an area where smoking is prohibited (*see, e.g.,* 14 CFR 23.853, 49 CFR 374.201).

In light of the other contexts in which the two proposed images are used, we selected the image of the exclamation mark enclosed within a red equilateral triangle, as we believe this image is more appropriate than the other proposed image for use in the required warnings. As stated, this image is commonly used to draw attention to a warning of danger which could result in personal injury or a threat to health, which is consistent with its purpose in cigarette advertisements with a small surface area. Many consumers have likely been exposed to similar symbols in other contexts and, as a result, are likely to recognize and understand that the image is drawing attention to a warning of a threat to health.

E. Non-Selected Images

This section discusses the 27 color graphic images that we proposed but have not selected for use at this time, and the factors that influenced the decision not to use each image, including the research results for the images, the comments received in the docket, and the relevant scientific literature.

Consistent with the discussion of selected images in section III.D of this document, the images are referred to in this section by the pages on which they appear in the ''Proposed Required Warning Images'' document and by the descriptive names used in the study report (Ref. 49, study report) summarizing the results of FDA's research study.

1. ''WARNING: Cigarettes Are Addictive''

As discussed in section III.D of this document, we selected the image ''hole in throat'' for use with the statement, ''WARNING: Cigarettes are addictive.'' We proposed three other images for use with this statement: ''cigarette injection,'' which appears on pages 3 and 4 of the document ''Proposed Required Warning Images;'' ''red puppet,'' which appears on pages 5 and

6 of the document ''Proposed Required Warning Images;'' and ''woman in rain,'' which appears on pages 7 and 8 of the document ''Proposed Required Warning Images.''

Cigarette Injection. The image ''cigarette injection'' had strong overall research results in FDA's research study, including significant effects on the emotional and cognitive reaction scales in all three study populations and significant effects on the difficult to look at measure in adults and young adults. It also showed higher correct recall of the warning statement compared to the control in adults and young adults at baseline, and was associated with higher intentions to quit compared to the control for young adults. The image also had a positive significant impact on adult beliefs about the health risks of smoking for smokers in adults viewing the hypothetical cigarette package with the proposed required warning, although it had a negative significant impact on this same measure in adults viewing the hypothetical cigarette advertisement featuring this proposed required warning.

The image selected for use with this warning statement, ''hole in throat,'' had numerically larger effects than this image (''cigarette injection'') on the salience measures (emotional and cognitive reaction scales, difficult to look at measure) in all three study populations. As discussed in section III.B of this document, the research literature suggests that the salience measures used in FDA's study are likely to be related to behavior change.

In addition, the selected image, ''hole in throat,'' enhanced the diversity of the overall set of selected images by helping ensure the human images broadly represent the U.S. population. Although ''cigarette injection'' offered variety in terms of style in that it uses a graphic illustration style as opposed to the photographic style used in most of the selected images, this style is incorporated in the final set of required warnings with the image used for the warning statement ''Smoking during pregnancy can harm your baby.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 90) FDA received several comments that supported the use of the image ''cigarette injection,'' including comments from individuals, public health advocacy groups, and a State public health agency. Some of the comments stated that the image would be an effective smoking deterrent. Several of the comments noted that the image would help smokers understand that, although cigarettes are legal products, they are just as addictive as illegal drugs like heroin. One comment indicated that the image would be particularly effective with underage smokers.

FDA also received several comments that opposed the use of the image ''cigarette injection.'' Many of these comments objected to the graphic illustration style used in the image, with some stating it would be ineffective or less effective than a photographic image, and some indicating it would detract from the seriousness of the message being conveyed. Some comments also expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

A few comments also objected to the comparison of legal cigarette products with illegal drugs, with one comment indicating this downplayed the seriousness of intravenous drug use, and another comment noting that the analogy of cigarette use to heroin use could cause consumers to discount the message if they believe that cigarette and heroin use are not comparable.

Some comments also stated that the image could be misunderstood or was too abstract, and one comment stated that the image does not illustrate adverse health effects.

One comment noted that the proposed required warning featuring the ''cigarette injection'' image was not rated highly on its ease of comprehension in a research study the submitter conducted on the 36 proposed required warnings, though it did show a significant effect on worry and feeling discouraged from wanting to smoke relative to a text-only control.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

Red puppet. In FDA's research study, the image ''red puppet'' had significant effects on the emotional and cognitive reaction scales in all three study populations. It also showed higher correct recall of the warning statement compared to the control in young adults at 1 week follow-up.

However, the selected image, ''hole in throat,'' had numerically larger effects than this image on the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) in all three study populations. In addition, looking across the different measures used in the research study, both the image ''hole in throat'' and the image ''cigarette injection'' had stronger overall research results than this image.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 91) FDA received several comments that supported the use of the image ''red puppet,'' including comments from individuals, a public health advocacy group, and from State and local public health agencies. Some of the comments stated that the image is likely to be effective, and one stated that it would impact underage smokers. Another noted that it was a clever image.

FDA also received several comments that opposed the use of the image ''red puppet.'' Some of these comments stated that the image style was less effective than a photographic image. One comment expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

Several comments expressed concern that the image would not be understood by some consumers, including youth and some racial and ethnic minorities, who might not understand and identify with the picture of a marionette, or draw the analogy between the manipulation suggested by the image of the puppet and addiction.

A few comments stated the image does not convey a health consequence of smoking, while one comment stated that the results from FDA's research study for this image did not support its selection from among the images proposed for use with this warning statement.

Three comments noted that the proposed required warning featuring the ''red puppet'' image was not highly rated in research studies conducted by the submitters. One comment noted that the image did not increase worry relative to a text-only label or discourage respondents from smoking relative to a text-only label in the submitter's study, while two others noted that the image was ranked as one of the least effective of the proposed images by respondents in the submitters' studies.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

Woman in rain. In FDA's research study, the image ''woman in rain'' had a significant effect on the difficult to look at measure in adults and young adults. The image also had a significant impact on adult beliefs about the health risks of smoking for smokers compared to the control.

Looking across the different measures used in FDA's research study, this image was relatively less effective than other images proposed for this warning statement, including the image selected for use in the required warnings ''hole in throat.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 92) FDA received multiple comments that supported the use of the image ''woman in rain,'' including comments from individuals, a community organization, and a State public health agency. Some of the comments stated that the image is likely to be effective, and one stated that smokers would be able to relate to the image.

FDA also received a number of comments that opposed the use of the image ''woman in rain.'' Some of these comments stated that the image would not be effective and is not emotionally arousing, while some stated that it shows a very weak harm (*i.e.,* standing in the rain). Another comment stated that the image makes smoking seem like a normal behavior.

Several comments expressed concern that the image would not be understood by consumers, indicating it was too vague in nature and requires a high analytical ability to understand.

Several comments stated the image does not convey a health consequence of smoking, while three comments stated that the results from FDA's research study for this image did not support its selection from among the images proposed for use with this warning statement.

Two comments noted that the proposed required warning featuring the ''woman in rain'' image was not highly rated in research studies conducted by the submitters. One comment noted that the image was not rated highly on its ease of comprehension and did not increase worry relative to a text-only label or discourage respondents from smoking relative to a text-only label in the submitter's study, while another noted that the image was ranked as one of the least effective of the 36 proposed images by respondents in the submitter's study.

(Response) We did not select this image for use in a required warning and instead have selected the image ''hole in throat'' for the reasons given in section III.D of this document.

2. ''WARNING: Tobacco Smoke Can Harm Your Children''

As discussed in section III.D of this document, we selected the image ''smoke approaching baby'' for use with the statement, ''WARNING: Tobacco Smoke Can Harm Your Children.'' FDA proposed five other images for use with this statement: ''Smoke at toddler,'' which appears on pages 11 and 12 of the document ''Proposed Required Warning Images;'' ''smoke at baby,'' which appears on pages 13 and 14 of the document ''Proposed Required Warning Images;'' ''girl crying,'' which appears on pages 15 and 16 of the document ''Proposed Required Warning Images;'' ''warning in child lettering,'' which appears on pages 17 and 18 of the document ''Proposed Required Warning Images;'' and ''girl in oxygen mask,'' which appears on pages 19 and 20 of the document ''Proposed Required Warning Images.''

Smoke at toddler. In FDA's research study, the image ''smoke at toddler'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' also had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 93) FDA received a number of comments that supported the use of the image ''smoke at toddler,'' including comments from individuals, a medical organization, public health advocacy groups, academics, and State and local public health agencies. Some of these comments indicated that the image would cause people to reconsider smoking due to the harm it can cause to others, especially a child or a baby.

Three comments noted that the image showed positive impacts in research studies conducted by the submitters. Specifically, in one submitter's study this image had the relatively greatest impact in discouraging respondents from wanting to smoke of the images proposed for use with this warning statement. In another submitter's study of the potential effectiveness of the images, this image received the highest overall rating of the images proposed for use with this warning statement. In addition, it was one of the two highest rated images of the FDA images proposed for use with this warning statement in another submitter's study.

FDA also received several comments that opposed use of the image ''smoke at toddler.'' Multiple comments stated that the image would be perceived as demeaning to smokers by suggesting they blow smoke directly at their children, and one comment cited the image as an unreal portrayal. Another comment expressed concern that the image would prompt denial among smokers, who would interpret the image to mean that their children are not at risk if they do not blow smoke directly at them. One comment said the image does not depict a negative health consequence of smoking, while another comment stated the image was too positive, in that the child looked too happy. Finally, another comment stated that other images tested in FDA's research study for use with this warning statement elicited higher scores on the emotional and cognitive reaction scales than this image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Smoke at baby. In FDA's research study, the image ''smoke at baby'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth) and significant effects on the difficult to look at measure in adults and youth. It also showed higher correct recall of the warning statement compared to the control in adults and young adults at 1 week follow-up.

However, as discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 94) FDA received several comments that supported the use of the image ''smoke at baby,'' including comments from individuals, a community organization, a medical organization, academics, and a State public health agency. Some of these comments indicated that the image would cause people to reconsider smoking due to the harm it can cause to children, and one comment noted that the image evokes a strong emotional reaction, clearly communicating that it is wrong to engage in the behavior portrayed in the image.

Two comments noted that the image showed positive impacts in research

studies conducted by the submitters. Specifically, this image had a significant impact in discouraging respondents from wanting to smoke in one submitter's study, and it was one of the two highest-rated images of the FDA images proposed for use with this warning statement in another submitter's study.

FDA also received several comments that opposed the use of the image ''smoke at baby.'' Many of these comments objected to the graphic illustration style used in the image, with some stating it would be ineffective or less effective than a photographic image, and some indicating it would detract from the seriousness of the message being conveyed. Some comments also expressed concern that the style would inappropriately appeal to youth without deterring them from smoking.

Multiple comments stated that the image would be perceived as demeaning to smokers by suggesting they blow smoke directly at their children, and one comment cited the image as an unreal portrayal. Another comment expressed concern that the image would prompt denial among smokers, who would interpret the image to mean that their children are not at risk if they do not blow smoke directly at them.

A couple of comments stated that other images tested in FDA's research study for use with this warning statement outperformed this image, with one noting that other images elicited higher scores on the emotional reaction scale and difficult to look at measure than this image, and another noting that other images had higher scores on the quit intentions and recall measures than this image.

One comment expressed concern that the image could be perceived to mean that mothers who smoke should not breastfeed their children. Another comment stated that the text used in the proposed required warning was difficult to read.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Girl crying. In FDA's research study, the image ''girl crying'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth). It also showed higher correct recall of the warning statement compared to the control in adults at baseline, and higher correct recall of the warning statement at 1 week follow-up compared to the text-only control for adults and young adults. Youth who viewed the image also reported that they would be significantly less likely to be smoking 1 year from now compared to youth who viewed the control.

However, the image had a significant negative impact on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, *i.e.,* adults who viewed the image were less likely to believe that nonsmokers will suffer from negative health effects due to secondhand smoke exposure than adults who viewed the text-only control.

As discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations. Thus, while ''girl crying'' showed positive effects on several important measures in FDA's research study, the selected image was considered to be a stronger choice, as it also showed positive effects on several important measures and did not show any negative effects.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 95) FDA received several comments that supported the use of the image ''girl crying,'' including comments from individuals and from a State public health agency. Some comments noted that the submitter found this image to be the most effective of the images proposed for use with this warning statement, and others noted it would appropriately elicit negative emotions in viewers.

FDA also received several comments that opposed use of the image ''girl crying.'' Multiple comments stated that it was not clear why the girl was crying, and one comment stated that the image does not depict a health consequence of secondhand smoke exposure. One comment indicated that the image was too sensational to be effective, and another comment cited the image as an unreal portrayal, stating that young children do not know they are being harmed when they are exposed to smoke and thus would not cry as a result of such exposure, and noted that this is what makes secondhand smoke exposure so insidious. One comment indicated that other images tested in FDA's research study for use with this warning statement had superior overall results to this image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Warning in child lettering. In FDA's research study, the image ''warning in child lettering'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also showed higher correct recall of the warning statement compared to the control in adults and young adults at baseline, and higher correct recall of the warning statement at 1 week follow-up compared to the control for adults, young adults, and youth. However, ''warning in child lettering'' showed lower correct recall of the image at baseline and follow-up for adults, young adults, and youth compared to the other images.

Looking across the different measures used in FDA's research study, this image was relatively less effective than other images proposed for use with this warning statement, including the image selected for use in the required warnings, ''smoke approaching baby.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 96) FDA received several comments that supported the use of the image ''warning in child lettering,'' including comments from individuals, a public health advocacy group, a medical organization, and a State public health agency. Some comments felt the use of child's handwriting in the image would be especially impactful with parents, and one comment noted that this image would have wide appeal, resonating with parents of any race or ethnicity.

FDA also received several comments that opposed use of the image ''warning in child lettering.'' Multiple comments objected to the image style, indicating that a photographic depiction would be more effective at deterring people from smoking, with one comment noting that the image style would be inappropriately appealing to youth without discouraging them from smoking. One comment indicated that the image does not depict a negative health consequence of smoking, and another indicated that the image was not eye-catching.

Two comments noted that other images proposed for use with this warning statement had superior overall results compared to this image in FDA's research study and stated that FDA should not select this image for use in the required warning. In addition, two comments noted that the image was not highly rated in research studies conducted by the submitters. One comment noted that the image was

ranked as the least effective of the 36 proposed images by respondents in the submitter's study, while another noted that the image was ranked the lowest by a considerable margin of the images proposed for use with this warning statement in the submitter's study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

Girl in oxygen mask. In FDA's research study, the image ''girl in oxygen mask'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the image had a significant negative impact on adult beliefs about the health risks of secondhand smoke exposure for nonsmokers, *i.e.,* adults who viewed the image were less likely to believe that nonsmokers will suffer from negative health effects due to secondhand smoke exposure than adults who viewed the text-only control.

As discussed in section III.D of this document, the selected image, ''smoke approaching baby,'' had significant impacts on all the salience measures in all three study populations, and also showed significant impacts on recall and behavioral intentions in some populations. Thus, the selected image was considered to be a stronger choice than ''girl in oxygen mask,'' as it showed positive effects on several important measures, but did not show any negative effects.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 97) FDA received a number of comments that supported the use of the image ''girl in oxygen mask,'' including comments from individuals, a public health advocacy group, a medical organization, a health care professional, and a State public health agency, with some comments noting that the image clearly conveys the message that smoke exposure can harm children, and powerfully shows the consequences of smoking.

FDA also received several comments that opposed use of the image ''girl in oxygen mask.'' Some comments noted that it was unclear that the person portrayed in the image was a child, and suggested that the image would be more persuasive if the person shown were younger. One comment expressed concern that persons of low socioeconomic status would not understand the image, and a few comments suggested that the image should show more severe disease or more clear association between the girl's illness and smoke exposure.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''smoke approaching baby'' for the reasons given in section III.D of this document.

3. ''WARNING: Cigarettes Cause Fatal Lung Disease''

As discussed in section III.D of this document, FDA selected the image ''healthy/diseased lungs'' for use with the statement, ''WARNING: Cigarettes cause fatal lung disease.'' FDA proposed three other images for use with this statement: ''toe tag,'' which appears on pages 21 and 22 of the document ''Proposed Required Warning Images;'' ''lungs full of cigarettes,'' which appears on pages 23 and 24 of the document ''Proposed Required Warning Images;'' and ''Dr. [doctor] with X-ray,'' which appears on pages 27 and 28 of the document ''Proposed Required Warning Images.''

Toe tag. In FDA's research study, the image ''toe tag'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had the numerically largest effects of the images proposed for use with this warning statement on all the salience measures in all three study populations.

The image ''toe tag'' prompted lower correct recall of the warning statement than the text-only control at baseline among youth.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 98) FDA received a number of comments that supported the use of the image ''toe tag,'' including comments from individuals, a medical organization, public health advocacy groups, academics, and State and local public health agencies. Some of these comments indicated that the image is the best choice for use with this warning statement. It was also noted that the image effectively communicates the risks of smoking and would effectively deter smokers.

Some comments noted that the image showed positive effects in research studies conducted by the submitters. Specifically, this image was rated highly on its ease of comprehension and induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study. The image was also one of the five images rated most effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''toe tag,'' with some submitters indicating that consumers, and in particular minority populations, might not understand what the image of a toe tag signifies. Some comments stated that the image ''offend[s] against human dignity'' or is ''too sensational to be effective,'' while it was alternatively stated that the image should be more graphic or show more suffering. It was also noted in the comments that the image did not test as well as other images proposed for use with this warning statement in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

Lungs full of cigarettes. In FDA's research study, the image ''lungs full of cigarettes'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, as discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had the numerically largest effects of the images proposed for use with this warning statement on all the salience measures in all three study populations.

Among young adults, the image ''lungs full of cigarettes'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control. The required warning featuring this image also prompted higher correct recall of the image at baseline and follow-up among adults and youth than some of the other images proposed for use with this warning statement.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 99) FDA received some comments that supported the use of the image ''lungs full of cigarettes,'' including comments from individuals and State and local public health agencies. Some of these comments indicated that the image is the best choice for use with this warning statement, while some also noted that

the image is particularly appropriate for use with the warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. However, the image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''lungs full of cigarettes,'' with some submitters indicating that consumers might not understand the image, and some comments stating that the image should show the consequences of lung disease on a real person or on real lungs and suggesting that the proposed image did not depict health consequences in an understandable, hard-hitting manner. One comment noted that the secondary message highlighted by the use of bold face emphasis in this proposed required warning (''I cause disease''), could be interpreted as blaming smokers for their addiction, and expressed concern that this could undermine the proposed required warning's ability to communicate effectively with smokers. One comment also stated that the image did not show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

Dr. with X-ray. In FDA's research study, the image ''Dr. [doctor] with X-ray'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also had significant effects on the difficult to look at measure in adults and youth.

As discussed in section III.D of this document, the selected image, ''healthy/diseased lungs,'' had significant effects on all the salience measures in all study populations, and had the largest numerical effects of the images proposed for use with this warning statement on the salience measures.

Among young adults, the image ''Dr. with X-ray'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control, as well as higher correct recall of the warning statement at follow-up among youth and the adult sample that viewed a hypothetical advertisement featuring this proposed required warning.

However, among young adults, as well as among the adult sample who viewed a hypothetical advertisement featuring this image, ''Dr. with X-ray'' was negatively associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers (*i.e.,* participants viewing this image were less likely to believe that nonsmokers will suffer health consequences related to secondhand smoke exposure than participants viewing the text-only control).

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 100) FDA received some comments that supported the use of the image ''Dr. with X-ray,'' including comments from individuals, a public health advocacy group, a community organization, and a State public health agency. These comments noted that the ''Dr. with X-ray'' image is particularly appropriate for use with the warning statement, or expressed the view that the image is the best choice for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed required warnings. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was one of the five images rated least effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images, and it was also rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''Dr. with X-ray,'' with some submitters indicating that the X-ray shown in the image is unclear and that the image would not be understood by consumers, and some indicating that it was too vague or clinical in nature and did not effectively convey the full impact of lung disease. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study, and that it showed negative effects on the beliefs measure among some of the study participants.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''healthy/diseased lungs'' for the reasons given in section III.D of this document.

4. ''WARNING: Cigarettes Cause Cancer''

As discussed in section III.D of this document, FDA selected the image ''cancerous lesion on lip'' for use with the statement, ''WARNING: Cigarettes cause cancer.'' FDA proposed three other images for use with this statement: ''Deathly ill woman,'' which appears on pages 29 and 30 of the document ''Proposed Required Warning Images;'' ''white cigarette burning,'' which appears on pages 31 and 32 of the document ''Proposed Required Warning Images;'' and ''red cigarette burning,'' which appears on pages 35 and 36 of the document ''Proposed Required Warning Images.''

Deathly ill woman. The image ''deathly ill woman'' had strong overall research results in FDA's research study, including significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, overall the selected image, ''cancerous lesion on lip,'' had slightly higher numerical scores on the emotional and cognitive reaction scales than this image.

Among adults, the image ''deathly ill woman'' prompted lower correct recall of the warning statement at baseline and at 1 week follow-up. However, the image showed some of the largest effect sizes for image recall (baseline and follow-up) across the images proposed for use with this warning statement.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 101) FDA received a large number of comments that supported the use of the image ''deathly ill woman,'' including comments from individuals, public health advocacy groups, medical organizations, academics, and State and local public health agencies. Many of these comments indicated that this image is the best image for use with this warning statement, with some stating that the image would communicate effectively to women and other comments approving of the image's accurate portrayal of the effects cancer can have on personal appearance.

Some comments noted that the image showed positive impacts in research studies conducted by the submitters. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter concludes that this image, along with ''cancerous lesion on lip,'' was the most effective of the images proposed for use with this warning statement. The image was also one of the five images rated most effective among the images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images. It was also one of two images rated effective among FDA's 36 proposed color graphic in another submitter's study of the effectiveness of the images at stopping someone from smoking, and it was identified by high school students as one of the ''top three'' proposed required warnings in another submitter's study.

FDA also received comments that opposed the use of the image ''deathly ill woman.'' Some comments noted that the image ''offend[s] against human dignity,'' while one stated it was ''too sensational to be effective.'' Conversely, some comments indicated that the image should show more obvious signs of illness. It was also noted in the comments that the image did not show desirable effects on all the measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

White cigarette burning. In FDA's research study, the image ''white cigarette burning'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). It also had significant effects on the difficult to look at measure in adults.

As discussed in section III.D of this document, the selected image, ''cancerous lesion on lip,'' had significant effects on all the salience measures in all study populations, and showed some of the numerically largest effects on these measures of all the images proposed for use with this warning statement.

Among youth, the image ''white cigarette burning'' prompted higher correct recall of the warning statement at baseline than the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 102) FDA received some comments that supported the use of the image ''white cigarette burning,'' including comments from individuals and from State and local public health agencies. These comments noted that the ''white cigarette burning'' image is particularly appropriate for use with the warning statement, or expressed the submitter's preference that the image be used with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''white cigarette burning,'' with some submitters indicating that the image does not depict the negative health consequences of smoking or that the image is not appropriately evocative of cancer, and some noting that the image is unclear and will not be understood by consumers. Some comments also criticized the design of the image, and one stated that the image is not presented in color as required by the Tobacco Control Act. Some comments also noted that this image of a burning cigarette could trigger cravings in smokers. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study. One comment noted that the secondary message highlighted by the use of bold face emphasis in this proposed required warning (''I cause cancer'') could be interpreted as blaming smokers, and expressed concern that this could undermine the proposed required warning's ability to communicate effectively with smokers.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

Red cigarette burning. In FDA's research study, the image ''red cigarette burning'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the selected image, ''cancerous lesion on lip,'' generally had numerically larger effects than this image on the salience measures.

Among adults, young adults, and youth, the image ''red cigarette burning'' prompted lower correct recall of the warning statement at baseline and at 1 week follow-up. The proposed required warning featuring this image also prompted relatively lower recall of the image at baseline and at 1 week follow-up among adults, young adults, and youth than ''cancerous lesion on lip.''

Youth viewing the image ''red cigarette burning'' reported being more likely to be smoking 1 year from now than youth viewing the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 103) FDA received some comments that supported the use of the image ''red cigarette burning,'' including comments from individuals, a public health advocacy group, and from State and local public health agencies. These comments noted that the ''red cigarette burning'' image is particularly appropriate for use with the warning statement, or expressed the submitter's preference that the image be used with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, particular aspects of the image were evaluated, and the submitter reported that the use of the color red to accentuate the warning content in ''red cigarette burning'' was effective. However, the image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, and the image was rated as one of the five least effective images used in FDA's 36 proposed required warnings in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red cigarette burning,'' with some submitters indicating that the image does not depict the negative health consequences of smoking or that the image is not appropriately evocative of cancer. Some comments also criticized the design of the image, with one stating that it looked like an image from a cigarette advertisement. Some comments also noted that this image of a burning cigarette could trigger cravings in smokers. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study and showed some undesirable effects. Some comments also suggested that other cancers, including bladder cancer, should be added to the cancers listed in the image.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''cancerous lesion on lip'' for the reasons given in section III.D of this document.

5. ''WARNING: Cigarettes Cause Strokes and Heart Disease''

As discussed in section III.D of this document, FDA selected the image ''oxygen mask on man's face'' for use with the statement, ''WARNING: Cigarettes cause strokes and heart disease.'' FDA proposed three other images for use with this statement: ''hand with oxygen mask,'' which appears on pages 37 and 38 of the document ''Proposed Required Warning Images;'' ''red lightning with heart,'' which appears on pages 41 and 42 of the document ''Proposed Required Warning Images;'' and ''man in pain with hand on chest,'' which appears on pages 43 and 44 of the document ''Proposed Required Warning Images.''

Hand with oxygen mask. In FDA's research study, the image ''hand with oxygen mask'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in all three study populations (adults, young adults, and youth).

However, the selected image, ''oxygen mask on man's face,'' also had significant effects on all the salience measures, and generally had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure.

Adults viewing the image ''hand with oxygen mask'' reported being less likely to quit smoking within the next month than adults viewing the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 104) FDA received some comments that supported the use of the image ''hand with oxygen mask,'' including comments from individuals, a community organization, and State public health agencies. These comments noted that the ''hand with oxygen mask'' image is the best image for use with the warning statement or stated that the image was appropriate for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension and induced relatively greater worry and led to higher ratings of feeling discouraged from wanting to smoke than a text-only control in one submitter's study. However, the image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''hand with oxygen mask,'' with some submitters indicating that the image is hard to understand or not appropriately compelling. Some comments also stated that the image would be more appropriate for use with a statement about lung-related health consequences (such as COPD). It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study and showed some undesirable effects.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

Red lightning with heart. In FDA's research study, the image ''red lightning with heart'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). The image also had significant effects on the difficult to look at measure in adults and young adults.

However, the selected image, ''oxygen mask on man's face,'' had significant effects on all the salience measures in all the study populations, and it generally had numerically larger effects than this image on the salience measures.

Among adults, young adults, and youth, the image ''red lightning with heart'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up among youth than the selected image, ''oxygen mask on man's face.''

FDA received several comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 105) FDA received a few comments that supported the use of the image ''red lightning with heart,'' including comments from State and local public health agencies, which noted that this image is appropriate for use with the warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red lightning with heart,'' with some submitters criticizing the design of the image, which was characterized as too conceptual and not easily understandable. Some comments also criticized the illustration style, stating that it does not have the impact a photograph would have, and would not compel or move viewers, and may inappropriately appeal to youth without discouraging them from smoking. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

Man in pain with hand on chest. In FDA's research study, the image ''man in pain with hand on chest'' had significant effects on the emotional reaction scale in all three study populations (adults, young adults, and youth). The image also had significant effects on the cognitive reaction scale in young adults and youth, as well as in

adults viewing a hypothetical advertisement containing ''man in pain with hand on chest.'' The image also had significant effects on the difficult to look at measure in adults and youth.

However, the selected image, ''oxygen mask on man's face,'' had significant effects on all the salience measures in all the study populations, and had numerically larger effects than this image on the salience measures.

Among youth, the image ''man in pain with hand on chest'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline among adults than ''oxygen mask on man's face.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 106) FDA received several comments that supported the use of the image ''man in pain with hand on chest,'' including comments from individuals, public health advocacy groups, a health care professional, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some comments noting that the image appropriately shows how painful heart attacks can be.

As discussed in section III.C of this document, some comments submitted to the docket described results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. However, the image was rated as less effective than the selected image, ''oxygen mask on man's face,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man in pain with hand on chest.'' Some comments indicated that the image looks like a man with a headache or other ailment rather than a man suffering from heart disease or a stroke, and a few comments indicated the man's hand should be closer to his left side (where his heart is). Some comments stated that the image should feature a younger person to drive home the message that heart disease and strokes can affect young smokers as well as older smokers. One comment suggested that the man shown in the image should be replaced with a man of color. It was also stated in the comments that the image failed to show large effects on salience measures or to show desirable effects on other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''oxygen mask on man's face'' for the reasons given in section III.D of this document.

6. ''WARNING: Smoking During Pregnancy Can Harm Your Baby''

As discussed in section III.D of this document, FDA selected the image ''baby in incubator'' for use with the statement, ''WARNING: Smoking during pregnancy can harm your baby.'' FDA proposed one other image for use with this statement: ''pacifier & ashtray,'' which appears on pages 47 and 48 of the document ''Proposed Required Warning Images.''

Pacifier & ashtray. In FDA's research study, the image ''pacifier & ashtray'' had significant effects on the emotional and cognitive reaction scales in all three study populations (adults, young adults, and youth). The image also had significant effects on the difficult to look at measure in adults and youth.

However, the selected image, ''baby in incubator,'' had significant effects on all the salience measures in all the study populations, and had numerically larger effects than this image on all the salience measures.

Among young adults, the image ''pacifier & ashtray'' prompted higher correct recall of the warning statement at baseline and at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up among adults, young adults, and youth than the selected image, ''baby in incubator.''

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 107) FDA received several comments that supported the use of the image ''pacifier & ashtray,'' including comments from individuals, public health advocacy groups, and State and local public health agencies. In general, these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image is compelling and powerful.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was also rated as the most effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, but an image used in another country was rated significantly higher than either of FDA's proposed images in this study (however, as discussed in section III.A of this document, at this time FDA does not believe it is necessary or appropriate to use graphic warnings used in other countries in place of the images developed by FDA).

FDA also received several comments that opposed use of the image ''pacifier & ashtray,'' with some submitters criticizing the design of the image, which was characterized as too symbolic and abstract to be understood, and as lacking in emotional impact. Some comments stated that the image does not show a health consequence of smoking, and some indicated the image is not graphic enough. A few comments also noted that the image would be more appropriate for a warning related to post-partum secondhand smoke-related risks, rather than a pregnancy warning, because pacifiers are used post- rather than pre-partum. One comment stated that the background used for the textual warning statement in the image looks unprofessional. It was also stated in the comments that the image failed to show large effects on the salience measures or to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''baby in incubator'' for the reasons given in section III.D of this document.

7. ''WARNING: Smoking Can Kill You''

As discussed in section III.D of this document, FDA selected the image ''man with chest staples'' for use with the statement, ''WARNING: Smoking can kill you.'' FDA proposed three other images for use with this statement: ''red coffin with body,'' which appears on pages 51 and 52 of the document ''Proposed Required Warning Images;'' ''man in casket,'' which appears on pages 53 and 54 of the document ''Proposed Required Warning Images;'' and ''cigarettes = RIP,'' which appears

on pages 55 and 56 of the document ''Proposed Required Warning Images.''

Red coffin with body. In FDA's research study, the image ''red coffin with body'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the cognitive reaction scale in young adults.

However, the selected image, ''man with chest staples,'' had a significant effect on all the salience measures in all study populations, and had numerically larger effects than this image on these measures.

Among adults, the image ''red coffin with body'' prompted higher correct recall of the warning statement at baseline than the text-only control.

The image also had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 108) FDA received several comments that supported the use of the image ''red coffin with body,'' including comments from individuals and a community organization. Several of these comments indicated that this image is the best choice for use with this warning statement, with some approving of the colors used in the image and some noting that the image gets the message across in a straightforward manner.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''red coffin with body,'' with some submitters stating that the image is too conceptual and not easily understandable. Several comments stated that the image is not impactful and is unlikely to be effective, with some indicating the image would be more effective if it were a photograph of an actual person. It was also suggested in the comments that the image style may inappropriately appeal to youth without discouraging them from smoking. Some comments noted that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

Man in casket. In FDA's research study, the image ''man in casket'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the cognitive reaction scale in young adults.

However, the selected image, ''man with chest staples,'' had significant effects on all the salience measures, and generally had numerically larger effects than this image on these measures.

Among youth, the image ''man in casket'' prompted higher correct recall of the warning statement at baseline than the text-only control. However, among young adults, the image ''man in casket'' prompted lower correct recall of the warning statement at baseline than the text-only control.

The image also had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 109) FDA received several comments that supported the use of the image ''man in casket,'' including comments from individuals, a public health advocacy group, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image grabs viewers' attention and clearly depicts death.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. In another submitter's study, particular aspects of the image were evaluated, and the proposed required warning containing the image ''man in casket'' was found to be significantly more effective at discouraging others from smoking than a text-only statement on the side of a cigarette package. However, the image was rated as less effective than the selected image, ''man with chest staples,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man in casket.'' Multiple comments stated the image looks staged because the man pictured does not look like he is dead or like he suffered from smoking-related disease. It was also suggested in the comments that the image may not be understood by all cultures. The image was also criticized as lacking a clear association to smoking. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

Cigarettes = RIP. In FDA's research study, the image ''cigarettes = RIP'' had significant effects on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) in adults and youth. It also had a significant effect on the emotional and cognitive reaction scales in young adults.

However, the selected image, ''man with chest staples,'' had significant effects on all the salience measures in all the study populations, and generally had numerically larger effects than this image on these measures.

Among adults, the image ''cigarettes = RIP'' prompted higher correct recall of the warning statement at baseline than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''man with chest staples.''

The image had a significant impact on beliefs about the health risks of smoking for smokers relative to the text-only control in the adult sample that viewed a hypothetical advertisement containing the proposed required warning.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 110) FDA received several comments that supported the use of the image ''cigarettes = RIP,'' including comments from individuals and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image gets the message across in a straightforward manner, and one stating that the image will get the attention of youth tobacco users.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''cigarettes = RIP,'' with some submitters stating that the image is too conceptual or indirect and lacks impact, and will not be effective in deterring smoking. Several comments expressed concern that consumers, including individuals from various cultures with limited English proficiency and children, might not understand what the shapes of the cigarette package and tombstone represent, or understand the abbreviation (''RIP'') used in the image. Some comments criticized the style of the image, with some characterizing it as low quality and others objecting on the grounds that it downplays the seriousness of the risk being conveyed and may inappropriately appeal to youth without discouraging them from smoking. It was also stated in the comments that the image failed to show large effects on the salience measures or to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man with chest staples'' for the reasons given in section III.D of this document.

8. ''WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers''

As discussed in section III.D of this document, FDA selected the image ''woman crying'' for use with the statement, ''WARNING: Tobacco smoke causes fatal lung disease.'' FDA proposed four other images for use with this statement: ''graveyard,'' which appears on pages 59 and 60 of the document ''Proposed Required Warning Images;'' ''man smoke at woman,'' which appears on pages 61 and 62 of the document ''Proposed Required Warning Images;'' ''woman smoke at man,'' which appears on pages 63 and 64 of the document ''Proposed Required Warning Images;'' and ''man hands up & smoke,'' which appears on pages 65 and 66 of the document ''Proposed Required Warning Images.''

Graveyard. In FDA's research study, the image ''graveyard'' had significant effects on the emotional reaction scale in all three study populations (adults, young adults, and youth). The image also had significant effects on the cognitive reaction scale in young adults and youth, and on the difficult to look at measure in youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and it generally had numerically larger effects than this image on all the salience measures.

Among adults and youth, the image ''graveyard'' prompted lower correct recall of the warning statement at baseline than the text-only control. Among young adults, the image prompted lower correct recall of the warning statement at 1 week follow-up than the text-only control.

The image ''graveyard'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 111) FDA received several comments that supported the use of the image ''graveyard,'' including comments from individuals, a community organization, and a State public health agency. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image gets the message across in a straightforward manner, and some noting the image could deter people from starting to smoke.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. This image was also rated as the most effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images, although an image used in another country was rated more highly than this image.

FDA also received several comments that opposed use of the image ''graveyard.'' Some comments indicated that the image would not be effective, noting that it is easy to disregard or, alternatively, too sensational to be effective. It was also stated in the comments that the image did not show large impacts on the emotional reaction scale and failed to show desirable effects on some other measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Man smoke at woman. In FDA's research study, the image ''man smoke at woman'' had significant effects on the emotional and cognitive reaction scales in adults, young adults, and youth. The image also had significant effects on the difficult to look at measure in youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure in all study populations.

The proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

The image ''man smoke at woman'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 112) FDA received several comments that supported the use of the image ''man smoke at woman,'' including comments from individuals and State public health agencies. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image would make smokers think about how their habit may cause others to avoid them. It was also noted that the image effectively shows how innocent bystanders are affected by smokers.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, in one submitter's study, participants rated this image highly on its ease of comprehension. It also induced relatively greater worry and feelings of discouragement from wanting to smoke than a text-only control. The submitter also concluded that the image was the most effective of the images proposed for use with this warning statement. However, the image was rated as one of the less effective images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man smoke at woman.'' Some comments indicated that the image is not realistic, stating that smokers do not blow smoke at their friends. One comment indicated that the image failed to portray an obvious health consequence of secondhand smoke, and multiple comments indicated that the image conveyed a bad message by showing the nonsmoker covering her nose and mouth, stating that these actions do not protect you from secondhand smoke. It was also noted in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Woman smoke at man. In FDA's research study, the image ''woman smoke at man'' had significant effects on the emotional reaction scale in adults, young adults, and youth. The image also had significant effects on the cognitive reaction scale in young adults and youth, and on the difficult to look at measure in adults and youth.

However, the selected image, ''woman crying,'' had significant effects on the salience measures in all study populations, and it had numerically larger effects than this image on the emotional reaction scale and the difficult to look at measure in all study populations.

Among adults, the image ''woman smoke at man'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, among young adults, the image prompted lower correct recall of the warning statement at baseline than the text-only control. The proposed required warning featuring this image also prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

The image ''woman smoke at man'' had a significant impact on young adult's intentions to quit smoking in the next month compared to the text-only control.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 113) FDA received several comments that supported the use of the image ''woman smoke at man,'' including comments from individuals, a public health advocacy group, a medical organization, and State and local public health agencies. Several of these comments indicated that this image is the best choice for use with this warning statement, with some noting that the image will make smokers think about how their actions negatively affect social situations.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study but failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as one of the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''woman smoke at man.'' Some comments indicated that the image would not be effective, suggesting that it is not impactful and probably would not stop people from smoking. One comment indicated that the image fails to portray an obvious health consequence of secondhand smoke, and another was critical of the actions of the nonsmoker in the image, noting that covering your nose and mouth does not protect you from secondhand smoke. It was also stated in the comments that the image failed to show desirable effects on some measures in FDA's research study.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

Man hands up & smoke. In FDA's research study, the image ''man hands up & smoke'' had significant effects on the emotional reaction scale in all study populations (adults, young adults, and youth) and on the cognitive reaction scale in young adults and youth.

However, the selected image, ''woman crying,'' had significant effects on all the salience measures in all study populations, and it had numerically larger effects than this image on all these measures.

The proposed required warning featuring the image ''man hands up & smoke'' also prompted relatively lower correct recall of the image at baseline and at 1 week follow-up than the selected image, ''woman crying.''

FDA received several comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 114) FDA received some comments that supported the use of the image ''man hands up & smoke,'' including comments from individuals and a State public health agency. These comments generally indicated that this image would be the best choice for use with this warning statement.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image was rated highly on its ease of comprehension compared to a text-only control in one submitter's study, but it failed to show an effect on other study measures (worry, discouragement from smoking). The image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''man hands up & smoke.'' Some comments indicated that the image is unrealistic in that it looks like the man is in fog or a house fire as opposed to being affected by secondhand smoke. One comment indicated that the image does not portray a health consequence of secondhand smoke; it was also stated in the comments the image is ineffective and unintentionally humorous. One comment stated that the image failed to show large effects on salience measures or to show desirable effects on other measures in FDA's research study and indicated it should not be selected.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''woman crying'' for the reasons given in section III.D of this document.

9. ''WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health''

As discussed in section III.D of this document, FDA selected the image ''man I Quit t-shirt'' for use with the statement, ''WARNING: Quitting smoking now greatly reduces serious risks to your health.'' FDA proposed two other images for use with this statement: ''cigarettes in toilet bowl,'' which appears on pages 69 and 70 of the document ''Proposed Required Warning Images;'' and ''woman blowing bubble,'' which appears on pages 71 and 72 of the document ''Proposed Required Warning Images.''

Cigarettes in toilet bowl. In FDA's research study, the image ''cigarettes in toilet bowl'' had significant effects on the emotional reaction scale in adults and young adults and significant effect on the cognitive reaction scale in all study populations (adults, young adults, and youth).

Among youth, the image ''cigarettes in toilet bowl'' prompted higher correct recall of the warning statement at 1 week follow-up than the text-only control. However, the proposed required warning featuring this image prompted relatively lower recall of the image at baseline and at 1 week follow-up than the selected image, ''man I Quit t-shirt.''

The image ''cigarettes in toilet bowl'' had a significant impact on beliefs about the health risks of smoking for smokers in young adults.

FDA received a number of comments on this image, which the Agency has summarized and responded to in the following paragraphs.

(Comment 115) FDA received some comments that supported the use of the image ''cigarettes in toilet bowl,'' including comments from individuals, a community organization, and a local public health agency. Some comments noted that this image is the best choice for use with this warning statement, and it was also noted in the comments that the image is effective because it creates an association between cigarettes and other undesirable things that belong in a toilet bowl.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image failed to show any significant effects in one submitter's study on measures of ease of comprehension, worry, and feeling discouraged from smoking compared to a text-only control. In addition, the image was rated as less effective than the selected image, ''man I Quit t-shirt,'' in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''cigarettes in toilet bowl.'' These comments noted that the image is not clear or does not convey a health consequence of smoking. It was also noted that the image is not easily understood, or alternatively, that it is banal. Multiple comments expressed concern about what is shown in the image, stating that it recommends a bad or unhealthy action (*i.e.,* flushing cigarettes down a toilet, which the comments stated could clog the toilet and pollute the environment). Some comments also stated that the statement was difficult to read in the ''cigarettes in toilet bowl'' image. It was also stated in the comments that the image did not show large effects on the emotional and cognitive reaction scales in FDA's research study and failed to show desirable effects on other measures.

(Response) We are not selecting this image for use in a required warning and instead have selected the image ''man I Quit t-shirt'' for the reasons given in section III.D of this document.

Woman blowing bubble. In FDA's research study, the image ''woman blowing bubble'' had a significant effect on the cognitive reaction scale in youth.

The image ''woman blowing bubble'' had a negative impact on youth beliefs about the health risks of smoking for smokers and for nonsmokers (*i.e.,* youth who viewed this image were less likely to believe that smokers will suffer negative health consequences or that nonsmokers exposed to secondhand smoke will suffer negative health consequences than youth who viewed the text-only control). Furthermore, the adult sample that viewed a hypothetical advertisement containing the proposed required warning reported that they were less likely to quit smoking in the next 30 days compared to adults who viewed the text-only control.

(Comment 116) FDA received some comments that supported the use of the image ''woman blowing bubble,'' including comments from individuals, a public health advocacy group, and a State public health agency. Multiple comments noted that the image appropriately shows how quitting smoking allows for a better lung capacity or noted that it effectively conveys the idea that there are beneficial effects of quitting.

As discussed in section III.C of this document, some comments submitted to the docket described the results of research conducted by the submitters to examine the potential effectiveness of FDA's proposed images. This image was discussed in some of these comments. Specifically, this image led to lower levels of worry and lower reports of feeling discouraged from smoking relative to a text-only control in one submitter's study. In addition, the image was rated as the least effective of the images proposed by FDA for use with this warning statement in another submitter's study of the potential effectiveness of the images.

FDA also received several comments that opposed use of the image ''woman blowing bubble.'' Multiple comments stated that the image is confusing and is not appropriately compelling and would not be effective in encouraging smokers to quit. Some comments indicated that the image does not effectively convey the message contained in the warning statement, and some noted that the image is banal or, alternatively, too positive. Multiple comments also stated the image is hard to understand, and that smokers may not comprehend the association between the image and the warning statement. It was also stated that the image would inappropriately appeal to youth without discouraging them from smoking, and that the image is inappropriate because it is sexually suggestive. It was also noted in the comments that the image showed negative results on some measures in FDA's research study, and failed to show desirable effects on other measures.

(Response) We are not selecting this image for use in a required warning and have instead selected the image ''man I Quit t-shirt'' for the reasons given in section III.D of this document.

10. Image for Advertisements With a Small Surface Area

As discussed in section III.D of this document, FDA selected the image which appears on page 75 of the document entitled ''Proposed Required Warning Images'' for use with the textual warning statements solely in advertisements with a small surface area (defined as less than 12 square inches). We also proposed one other image for use with this statement, which appears on page 74 of the document entitled ''Proposed Required Warning Images.''

The proposed image on page 74 depicts a burning cigarette enclosed by a red circle with a red bar across the image. We did not receive any comments on either of the proposed images.

As explained in section III.D of this document, we have selected the image of a black exclamation mark enclosed within a red equilateral triangle for use

in advertisements with a small surface area because we have concluded that the common purpose of this image, to denote a warning of a threat to health or of a hazard which could result in personal injury, makes it the most appropriate for use in the required warning context.

IV. Comments Regarding Textual Warning Statements

A. Changes to Textual Warning Statements

As we explained in the proposed rule, section 202(b) of the Tobacco Control Act, amending section 4 of FCLAA (15 U.S.C. 1333), gives us the authority to adjust the format, type size, color graphics, and text of any of the required warning statements if such a change ''would promote greater public understanding of the risks associated with the use of tobacco products.'' In addition, under section 4(d) of FCLAA, FDA may adjust the type size, text, and format of the warning statements as the Agency determines appropriate ''so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.'' Such adjustments, including adjustments to the text and format of some of the warning statements, were included with some of the proposed warnings (75 FR 69524 at 69534). We did not receive comments about these adjustments. Two of the warning statements we have selected for this final rule are presented in all uppercase letters, as they were in the proposal. In addition, one of the proposed required warnings, ''baby in incubator,'' was presented without the signal word ''WARNING.'' The research literature on graphic health warnings indicates that signal words, such as ''Warning,'' have been found to enhance the noticeability of safety warnings and convey the degree of risk (*see* Ref. 40 at p. 33). In the final rule, we are thus not removing the word ''WARNING'' from this required warning, such that the text in this required warning is the same as the text presented in section 201 of the Tobacco Control Act (''WARNING: Smoking during pregnancy can harm your baby'').

Moreover, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products. As is discussed in more detail in section V.B.6 of this document, a reference to a cessation resource has been included in the final required warnings.

Although we did not receive any comments about the adjustments we made to the text of some of the warning statements in the 36 proposed required warnings, we received numerous comments requesting other changes to the textual statements for the new required warnings, including requests to strengthen the text, to add additional information to the text or to otherwise modify the text of the warnings statements. We also received requests to substitute alternative warning statements for some or all of the textual statements and to expand the warning statements by adding additional statements regarding smoking-related risks. The comments, and our responses, are summarized in the following paragraphs. We also received numerous comments about our proposal to include a reference to a cessation resource in the required warnings; these comments and our responses are summarized in section V.B.6 of this document.

(Comment 117) Several comments suggested that some of the textual warning statements should be changed to include language asserted to be stronger and more direct. For example, multiple comments suggested that the statement, ''WARNING: Tobacco smoke can harm your children,'' should be reworded to be more assertive, for example, to state ''Tobacco smoke harms your children.'' One comment referenced the conclusion from the 2010 Surgeon General's report that there is no risk-free level of exposure to secondhand smoke as support for this modification (Ref. 37). Similarly, multiple comments recommended that FDA change the warning statement, ''WARNING: Smoking during pregnancy can harm your baby,'' to be more strongly worded. For instance, comments suggested this statement could instead be worded as ''WARNING: Smoking during pregnancy harms your baby'' or ''WARNING: Smoking when pregnant harms your baby'' or ''WARNING: Smoking harms your baby'' or ''WARNING: Smoking harms the fetus and babies.'' Multiple comments also suggested the warning statement ''WARNING: Smoking can kill you'' should not be worded in a conditional manner. One comment suggested that the text could instead state ''Smoking kills.''

Similarly, FDA received a number of comments suggesting other modifications that individuals, public health advocacy groups, health care professionals, community organizations, and other groups believed would augment the nine statements. For example, one comment from a public health advocacy group suggested that the statement ''Cigarettes are addictive'' be modified to state ''Cigarettes are HIGHLY addictive,'' while another comment suggested the statement read ''Cigarettes are addictive and shorten your life.'' Similarly, a comment from a health care professional suggested the warning should state ''Cigarettes are addictive and deadly.'' Another comment from a nonprofit foundation suggested that the statement ''Cigarettes cause strokes and heart disease'' be modified to state ''Cigarettes cause strokes, heart disease, and amputations.''

(Response) Section 202(b) of the Tobacco Control Act gives FDA the authority to change the textual warning statements if such a change would promote greater public understanding of the health risks associated with smoking. However, at this point, we decline to make the recommended changes. We are adopting the nine textual statements mandated by Congress in section 4(a)(1) of FCLAA. The nine new textual warning statements objectively communicate some of the major health risks associated with smoking in an effective manner. The new textual statements represent a significant improvement over the current set of warnings in that they are specific, unambiguous, and succinctly describe documented outcomes of cigarette use and exposure. We conclude that these nine new statements will effectively convey the major health risks of smoking, which will help discourage nonsmokers from initiating cigarette use, and encourage current smokers to consider cessation, particularly when combined with graphic images depicting the negative health consequences of smoking.

However, we intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. Such research will help inform us regarding whether to propose changes to the textual warning statements, such as by using stronger or more direct language, in a future rulemaking.

(Comment 118) Many comments recommended that FDA include additional textual information to give further context for the health warnings. For example, comments requested that FDA add information such as research statistics, factual testimonials, or other explanatory text to further enhance the effectiveness of the new required warnings. Several of the comments suggested specific text for particular warning statements; for example, one comment suggested the warning

statement related to addiction be accompanied by the following explanatory text: ''Studies have shown that tobacco can be harder to quit than heroin or cocaine.'' Other comments suggested that the statement ''WARNING: Cigarettes cause cancer'' be modified to add explanatory text about specific cancers caused by cigarettes, including cancers of the mouth, throat, esophagus, lungs, kidney, bladder, pancreas, stomach, cervix, and bone marrow. Another comment suggested that the statement ''Cigarettes cause strokes and heart disease'' be accompanied by explanatory text stating ''Cigarette smoking doubles your chances of strokes and can cause heart attacks'' and that the statement ''Cigarettes cause fatal lung disease'' be accompanied by explanatory text stating that ''Every cigarette you smoke increases your chances of dying from lung disease.'' In addition, the comment suggested that the statement ''Tobacco smoke causes fatal lung disease in nonsmokers'' be accompanied by explanatory text stating ''You're not the only one smoking cigarettes. The smoke is not just inhaled by smokers, it becomes second-hand smoke, which contains more than 50 cancer agents.'' Another comment suggested adding information to the required warnings that state alternatives to smoking, such as exercise and healthy eating.

(Response) We decline to make such changes at this time. As stated previously, the nine new textual warning statements mandated by Congress in section 4(a)(1) of FCLAA objectively communicate some of the major health risks associated with smoking in an effective manner. In addition, research has shown that warning statements that are short and to the point and that are presented in larger fonts sizes are likely to be more effective (Ref. 40 at p. 33). If the additional requested information were added to the required warnings, the resulting warning statements would be longer, and the font size of the warning statements would likely decrease in order for the information to fit within the specified area. This could undercut the effectiveness of the warnings (*see, e.g.,* Ref. 57). If research later indicates that adding such information to the new required warnings will promote a greater understanding of the risks associated with smoking, we will consider making these changes using our authority under section 202(b) of the Tobacco Control Act.

(Comment 119) One comment suggested that the warning statements that reference ''tobacco smoke'' should be modified to instead reference ''cigarette smoke'' to apply more directly to the target audience.

(Response) We disagree that this change is warranted. The statements in section 4(a)(1) of FCLAA, including those that reference ''tobacco smoke,'' are scientifically accurate, and we do not believe that consumers will fail to understand that the warning statements referencing ''tobacco smoke'' apply to the products on which they appear (*i.e.,* cigarettes), which are tobacco products.

(Comment 120) FDA received a number of comments suggesting that some of the negative health effects that are the subject of individual warning statements be replaced with other warnings. For example, one comment from a medical organization suggested that the statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' should instead focus on heart attacks, stating that the magnitude of fatal heart disease caused by secondhand smoke exposure is greater than the magnitude of fatal lung disease caused by secondhand smoke exposure. One comment from an individual suggested that FDA use other warnings about the health harms of smoking instead of the warning about addiction.

Another comment suggested that there should be fewer warnings regarding the health risks of secondhand smoke to babies and children and more warnings directed at young teens and pre-teens. One comment stated that the warnings about smoking during pregnancy and about the harms of tobacco smoke to children are only relevant to those who are pregnant or who have children and suggested that these warnings are thus less impactful than the other warning statements.

However, other comments stated that the warnings about the risks of smoking during pregnancy and about the health risks of secondhand smoke to children address important health issues, will help make smokers aware that they are harming innocent people around them, and will help smokers appreciate the severity and magnitude of some of the lesser-known risks of smoking. One comment from an individual noted that secondhand smoke kills an estimated 45,000 nonsmokers who live with smokers from heart disease each year, as well as increasing the risk of SIDS, acute respiratory infections, ear problems, and severe asthma in children, and causing respiratory symptoms and slowing lung growth in children.

(Response) We decline to amend the warning statements as suggested by the comments. As stated previously, the nine textual statements provided by Congress in section 4(a)(1) of FCLAA appropriately communicate important health risks of smoking. Furthermore, we disagree with the suggestion that there should be fewer warnings about the health risks of smoking during pregnancy and of secondhand smoke to children. These warnings comprise two of the nine warning statements, and we agree with the comments indicating that these warnings communicate information about important health issues and will help smokers understand some of the significant health harms caused by cigarettes. In addition, while these warnings may be especially impactful with parents and expectant parents, using a variety of messages, including messages that may particularly impact certain audiences, will strengthen the overall impact of the required warnings (Ref. 40 at pp. 7–8).

Similarly, we disagree with the suggestion that the warning about addiction should be replaced by a warning about other health hazards. As discussed in the preamble to the proposed rule (75 FR 69524 at 69528 through 69529), the magnitude of public health harm caused by cigarettes is inextricably linked to the addictive nature of these products (Ref. 16 at p. 14 and Ref. 3 at p. xi), and many people, particularly adolescents, have a poor understanding of how difficult it is to quit smoking due to the addictive nature of cigarettes (Ref. 3 at p. 91). Thus, we conclude this is an important and appropriate health warning.

(Comment 121) One comment suggested that graphic health warnings on cigarette packages and advertisements should have one broad warning that states: ''Cigarette smoking may cause cancer, death, and other serious life-threatening health hazards.'' Another comment suggested one broad warning that states: ''Smoking Can Kill You.''

(Response) We disagree. We are not aware of any scientific evidence that one broad warning statement would be more effective in communicating the multitude of health risks to smokers and nonsmokers in all age categories than the nine specific textual warnings specified in section 4(a) of FCLAA.

As noted in the proposed rule, evidence shows that warnings about specific health risks, such as cancer, heart disease, and stroke, are more effective than general warnings (75 FR 69524 at 69533 through 69534). Utilizing a single broad statement like the ones proposed in the comments would also fail to communicate important information about the detrimental effects associated with secondhand smoke—and messages about secondhand smoke have been effective in moving smokers to consider

the health risks associating with smoking (75 FR 69524 at 69534). For example, the new set of warnings includes the following statement: ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.'' This important warning would be lost if we chose to use just one of the suggested broad warning statements. In addition, one of the new required warnings clearly notifies smokers that if they quit smoking, they can greatly reduce serious risks to their health. Again, that important message would be lost if we were to use just one of the suggested broad statements.

(Comment 122) One comment stated that the ninth warning statement provided by Congress in the Tobacco Control Act, ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' should appear on all packages after one of the other eight warning statements.

(Response) We disagree that such a change is warranted. As discussed in section V.B.6 of this document, we have included a reference to a cessation resource in the required warnings, which we conclude is more appropriate than including the ninth warning statement in all the required warnings.

(Comment 123) Many comments suggested that FDA add additional warning statements to state that cigarette smoking may increase the risk of other diseases such as bladder cancer, impotence, blindness, or COPD. One comment stated that medical studies have shown that women who smoke a pack of cigarettes a day double the risk of orofacial cleft birth defects in their children, and suggested that a warning be added to include this risk and pictures of children with this birth defect (*citing, e.g.,* Ref. 58). One comment also suggested that the required warnings indicate that smoking may increase the risk of breast cancer. Another comment suggested including messages about short-term effects of smoking, such as nutritional deficiencies.

(Response) We decline to add additional warning statements, as suggested in these comments. At this point, we have determined the nine textual statements mandated by Congress in section 4(a)(1) of FCLAA appropriately communicate major health risks of smoking. As stated previously, we intend to monitor the effects of these required warnings once they are put into use. We will conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy. We intend to use the results of our monitoring and such research to determine whether changes should be made to the nine textual statements in a future rulemaking. We recognize that cigarettes cause negative health consequences in both smokers and nonsmokers beyond those addressed in the nine warning statements provided by Congress, and will take this into account in making future determinations as to whether the textual statements should be revised by rulemaking.

(Comment 124) A few comments also suggested that when FDA initiates a new rulemaking to establish its next set of graphic warnings, the Agency should consider adding health warnings that refer to other smoking-related diseases that are not specifically mentioned in this first set of required warnings.

(Response) We intend to periodically review the required warnings to assess their effectiveness and determine whether the warnings are suffering from wear out. During this review, we intend to examine the scientific literature and possibly conduct our own research to determine if additional textual warnings about the scientifically documented negative health consequences of smoking are appropriate.

(Comment 125) One comment suggested that FDA utilize different warnings with featured messages targeted to specific audiences based on their different attitudes and beliefs. As an example, this comment pointed to the Canadian health warning directed at young males, which stresses that tobacco can make the smoker impotent (Ref. 55).

(Response) We conclude that the nine textual statements required by Congress in section 4(a)(1) of FCLAA are appropriate. In addition, we have selected color graphics to accompany the new warning statements that use a variety of different fonts, typography, and layouts; depict a variety of human subjects; and use a variety of styles, including photographic and graphic illustrations. The required warnings will reach a wide variety of audiences including youth, young adult, and adult smokers and nonsmokers. For information on FDA's selection of images, see section III of this document.

As previously stated, we intend to monitor the effects of these required warnings once they are put into use. If our monitoring finds that the messages are not reaching an appropriately broad population and that targeted messages would be more effective, we will consider revising the textual statements in a future rulemaking.

(Comment 126) One comment suggested that FDA require a standard pack size and shape, which would help to ensure the readability of warnings.

(Response) We do not believe it is necessary to adopt a standard pack size and shape. We have taken steps to ensure that the required warnings will be conspicuous and legible on cigarette packages and in advertisements.

B. Attribution to the Surgeon General

Section 4(a)(1) of FCLAA contains the nine new textual warning statements that, when combined with a graphic image, comprise the required warning. Congress did not include an attribution to the Surgeon General in the new textual warning statements, as it has done in past laws on cigarette health warnings. Accordingly, when we issued our proposed rule and released the 36 proposed required warnings, the textual warning statements did not include a reference to the Surgeon General. A number of comments, including those from former Surgeons General and Commissioned Public Health Service Officers, questioned why the new health warnings no longer contain any attribution to the ''Surgeon General.'' A summary of the comments and our response regarding this issue is included in the following paragraphs.

(Comment 127) The comments noted that, since Surgeon General Luther Terry's 1964 report highlighting the adverse health effects of tobacco use, the Office of the Surgeon General has been inextricably linked to smoking prevention and that the reduction in smoking rates since the initial report and the advent of the first Surgeon General's warning is due to the public confidence associated with the Surgeon General's recommendations. In addition, they claimed that the new warnings would be less effective without the Surgeon General attribution. Two other comments also suggested that FDA include ''the federal government logo'' on the health warnings to communicate that the Department of Health and Human Services (HHS) endorses the health message. Another comment from a public health advocacy group suggested that the warning statements add a reference to FDA and/or the U.S. Government to legitimize the warnings. In contrast, one comment stated that it did not support continued use of the Surgeon General attribution, but if FDA decides to include the attribution, it should be placed on the side of the package where it does not detract from the new health warnings.

(Response) We agree with comments highlighting the benefits of the Surgeon General's work in the area of smoking prevention, but we decline to add the ''Surgeon General'' attribution to the

required warnings at this time. Congress did not include an attribution to the Surgeon General as it has done in the past. In addition, there is inconsistency among the limited scientific literature as to whether the attribution of health warnings to government sources enhances their credibility (*see, e.g.,* Refs. 42, 36, 57, and 59). Attribution to a government resource may increase believability of the information; however, if the government is generally disliked or mistrusted, a government source attribution may result in rejection of the health warning (Ref. 11).

One 1997 study found that the attribution to a government source, including the U.S. Surgeon General, did increase the credibility and viewers' intentions to comply with the warnings for cigarettes (Ref. 57). Similarly, in a study conducted prior to Israel's decision to require new cigarette warnings on packages, researchers found that consumers preferred warnings with attribution to a government source or medical research rather than warnings without attribution (Ref. 59).

However, in a developmental study assessing appropriate attributes for new cigarette warnings in Australia, researchers found that the mention of ''government'' in an attribution reminded smokers that the government collects tax revenue from cigarettes and led smokers to challenge the sincerity of the government in issuing cigarette health warnings (Ref. 48). Similarly, researchers for the European Commission in the European Union looked at respondents' reactions to three potential attributions for cigarette warnings: (1) Government/regulatory bodies; (2) health authorities/cancer charities; and (3) tobacco industry (Ref. 42). They found smokers did not respond well to regulatory bodies as a potential source for cigarette warning messages, believing that government bodies did not care about their smoking behavior or were motivated by self-interest (*Id.*).

Moreover, even though the 1997 study did find benefits associated with government source attribution, researchers also noted the potential trade-offs associated with government attribution (Ref. 57). They noted the surface area restrictions associated with warnings and that the amount of information that one can give without losing readers is limited (*Id.*). They also noted that the addition of attribution information may require the use of smaller font size, which may impact legibility and noticeability of the warning (*Id.*). In fact, as we noted in the preamble to the proposed rule, the length and font size of the existing warnings contribute to their ineffectiveness, and larger font sizes enhance the noticeability of cigarette warnings (75 FR 69524 at 69530 and 69534; Ref. 40 at 30–31). Therefore, given the inconsistency in the available research and the potential tradeoffs associated with including a government source attribution in the required warnings, we conclude that there is insufficient evidence to support addition of an attribution at this time.

We will continue to work in partnership with other components within HHS to educate consumers about the risks of smoking. FDA and others also will continue to conduct research regarding the efficacy of required warnings. If such research indicates that adding the Surgeon General attribution to the cigarette required warnings will improve their efficacy, we will consider adding a government attribution as part of a future rulemaking to update the warnings.

C. Foreign Language Translations

As we explained in the preamble to the proposed rule, consistent with section 4(b) of FCLAA, proposed § 1141.10(b)(2) would mandate that the textual component of the required warning appear in the English language in cigarette advertisements with two exceptions. First, per proposed § 1141.10(b)(2)(i), if an advertisement appears in a non-English language publication, the textual portion of the required warning would need to appear in the predominant language of the publication. Second, per proposed § 1141.10(b)(2)(ii), if an advertisement is in an English language publication but the advertisement itself is presented in a language other than English, the textual portion of the required warning would need to be presented in the same foreign language principally used in the advertisement. To accommodate the potential need for Spanish language translations of the textual warning statements, we included Spanish translations with the proposed rule. We received several comments regarding foreign language translations in advertisements and one comment requesting the use of foreign language translations on packages. We have summarized and responded to these comments in the following paragraphs.

(Comment 128) One comment indicated that the submitter was pleased to see Spanish translations of the warnings, but asked that FDA continue to work with as many languages as possible.

(Response) We understand the importance of ensuring that the textual portion of the required warnings is translated accurately so that the message is appropriately communicated to foreign language speakers. As indicated in the NPRM, we included Spanish language translations in recognition of the fact that Spanish is the foreign language most commonly used for cigarette advertisements in the United States (75 FR 69524 at 69537 through 69538). We also will work with any advertiser who plans to advertise cigarettes in *any* non-English language publication, or who plans to utilize a non-English advertisement in an English-language publication in accordance with § 1141.10(b)(2)(ii). Specifically, upon request, we will assist advertisers in generating a true and accurate translation of the textual statements for the nine new required warnings for use in advertisements that are subject to § 1141.10(b)(2).

(Comment 129) One comment expressed concerns that foreign language translations sometimes can be ''too literal'' and could inappropriately impact the meaning of the warning statement.

(Response) We are sensitive to this concern, and the final rule requires that any translation of the required warning statements results in a true and accurate foreign language version of the warning statements. As stated in the previous response, we will assist any advertiser who plans to advertise cigarettes with a foreign language translation of the required warnings.

(Comment 130) One comment stated that all cigarette advertisements in predominantly Spanish speaking areas, such as Puerto Rico, and in Spanish language publications should include warnings in Spanish. Another comment recommended that the required warnings in advertisements be in the language of the publication or advertisement.

(Response) We agree in certain circumstances. As stated in the proposed rule and required in § 1141.10(b)(2), any advertisement that appears in a Spanish language publication must present the textual portion of the required warning in Spanish (*see* § 1141.10(b)(2)(i)). In addition, for advertisements in English language publications, if the advertisement itself is presented in Spanish, the required warning in the advertisement also must be in Spanish (*see* § 1141.10(b)(2)(ii)). However, if an English language publication that includes English language advertisements is sold in predominantly Spanish speaking areas, the textual component of the required warnings will still be required to appear in

English, as specified by section 4 of FCLAA.

We conclude that these requirements will appropriately ensure that the target audience of any advertisement is able to read and understand both the promotional content of the advertisement and the important warning information.

(Comment 131) One comment requested that the required warnings on all cigarette packages exported to Puerto Rico and Latin America be in Spanish.

(Response) We decline to adopt this request. Section 4(b)(2) of FCLAA and § 1141.10(b)(2) require translation of required warnings for certain advertisements only. Neither FCLAA nor the Tobacco Control Act requires foreign language warnings on cigarette packages sold or distributed within the United States, including within the Commonwealth of Puerto Rico. Furthermore, with limited exceptions, FCLAA does not apply to packages of cigarettes for export from the United States.

V. Description of the Final Rule

A. Overview of the Final Rule

This final rule adds new part 1141 to Title 21 of the Code of Federal Regulations, requiring new warnings on cigarette packages and in cigarette advertisements. These new required warnings consist of the nine textual warning statements set forth in section 201 of the Tobacco Control Act accompanied by color graphic images depicting the negative health consequences of smoking. We have selected nine images, such that each required warning consists of one of the nine textual warning statements and an accompanying color graphic.

As required by section 201 of the Tobacco Control Act, the rule requires the new warnings to appear prominently on cigarette packages and in advertisements, occupying at least 50 percent of the area of the front and rear panels of cigarette packages and the top 20 percent of the area of advertisements. We also have exercised our authority under sections 201 and 202 of the Tobacco Control Act, which allow FDA to adjust the type size, text, and format of the textual warning statements. For example, under section 4(d) of FCLAA (as amended by section 201 of the Tobacco Control Act), FDA may adjust the type size, text, and format as we determine appropriate so that both the textual warning statements and the accompanying graphics are clear, conspicuous, legible, and appear within the specified area. Such adjustments, including adjustments to the type size and the addition of information regarding a cessation resource, are included for the required warnings in this final rule. In addition, we are requiring a reference to 1–800–QUIT–NOW as part of the required warnings in accordance with section 906(d) of the FD&C Act as appropriate for the protection of the public health.

B. Description of Final Regulations and Responses to Comments

1. Section 1141.1—Scope

In the proposed rule, proposed § 1141.1 set forth the scope of the proposed regulations. In particular, proposed § 1141.1(b) limited the applicability of the proposed requirements by clarifying that they would not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution in the United States. Proposed § 1141(c) described situations where a cigarette retailer would not be in violation of the proposed rule for displaying or selling cigarette packages that do not comply with the rule, so long as certain conditions were met (75 FR 69524 at 69535). We received several comments regarding the scope of the regulation, which we have summarized and responded to in the following paragraphs.

(Comment 132) One comment requested that all imported cigarettes and tobacco products have required warnings to come into U.S. ports and be sold in the United States and its territories, including Puerto Rico.

(Response) We agree that imported cigarette packages must bear a required warning in accordance with section 4 of FCLAA and part 1141. Section 1141.10 provides that it is unlawful for any person to import for sale or distribution within the United States any cigarettes the package of which fails to bear one of the required warnings on both the front and rear panels. Section 1141.3 defines United States to include specified U.S. territories, including Puerto Rico. In addition, as explained in section V.B.2 of this document, we are revising the definition of importer to clarify that the term importer includes any person who imports any cigarette, regardless of where it was manufactured. With respect to whether other tobacco products should have required warnings, we have determined that issue is outside the scope of this rulemaking.

(Comment 133) One comment supported the imposition of the required warnings on all cigarette packages manufactured in the United States, including all exported cigarette packages. The comment said that it would be unconscionable for FDA to protect residents in the United States and not the rest of the world when they are smoking U.S.-made products. According to this comment, cigarettes that are being exported are essentially bought in the United States and these products are under the FDA's jurisdiction.

(Response) We disagree that it is appropriate to impose a requirement that cigarettes that are manufactured in the United States for export bear a required warning. Section 4(a) of FCLAA applies to cigarettes packages that are ''for sale or distribution within the United States.'' Section 12 of FCLAA provides:

> Packages of cigarettes manufactured, imported, or packaged (1) for export from the Unites States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the Untied States shall be exempt from the requirements of this Act, but such exemptions shall not apply to cigarettes manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(15 U.S.C. 1340). In addition, many other countries impose their own warning requirements on cigarette packages sold in those countries.

(Comment 134) One comment requested that FDA exercise enforcement discretion for retailers and distributors selling cigarettes that do not bear a specified warning label because retailers do not control the labeling of the products supplied by manufacturers. The comment claimed that if a product is provided by a licensed supplier, and not altered by the distributor, the distributor should likewise be relieved of liability.

(Response) FCLAA provides a very limited exemption for retailers and we do not agree that it is appropriate to broaden the exemption to distributors. Nor do we agree that it is appropriate to adopt a broad enforcement discretion policy for retailers and distributors. By choosing to distribute and sell cigarettes, distributors are under an obligation to make sure that the products they receive from manufacturers, importers, and other distributors and subsequently distribute or sell comply with the law, including checking to see whether the packages include a required warning on the front and rear panel. Retailers, however, are not in violation if they display or sell a cigarette package that includes a health warning, even if it is not one of the nine required warnings, as long as other

statutory requirements are met (*see* 15 U.S.C. 1333(a)(4)). The preamble to the proposed rule made clear that manufacturers, importers, and distributors have the primary responsibility for ensuring that the required warnings on cigarette packages comply with all the provisions of part 1141.

(Comment 135) One comment expressed concern regarding the exemption of retailers from an obligation to ensure packages depict required warnings. This comment claimed that the exemption hampers enforcement, because an inspector needs to be able to seize noncompliant packaging at retail.

(Response) We decline to revise the language of proposed § 1141.1(c). As we explained in the preamble to the proposed rule, the limited retailer exemption is in accordance with section 4(a)(4) of FCLAA. The exemption for retailers is limited to situations where the cigarette package contains a health warning, is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor, and is not altered by the retailer in a way that is material to the requirements of section 4(a) of FCLAA. We note, however, that § 1141.1(c) describes situations where a retailer is not considered in violation of part 1141; this exemption does not apply to manufacturers, importers, or distributors that provide retailers with noncompliant cigarette packages. Thus, although a retailer would not be held liable for selling or offering for sale a cigarette package that is not in full compliance with the requirements of part 1141, so long as the retailer fits within the exemption set forth in § 1141.1(c), the manufacturer, importer, or distributor that provided the noncompliant packages would be liable for violating FCLAA and these regulations. Furthermore, the misbranding provisions in § 1141.14 apply to the cigarettes themselves. Therefore, if we discover misbranded cigarette packages in a retail establishment, but the retailer fits within the exemption set forth in § 1141.1(c), we could still initiate a seizure action under section 304 of the FD&C Act (21 U.S.C. 334).

(Comment 136) One comment requested that FDA revise its 2010 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (75 FR 13225, March 19, 2010) (''reissued 1996 rule'') to ensure that the Agency does not exceed the scope of the Tobacco Control Act by imposing liability on retailers and distributors for labeling or advertising in specific situations. This comment contended that the Tobacco Control Act provides specific situations in which retailers should not be held liable for labeling or advertising and those situations are not recognized in the reissued 1996 rule.

(Response) Section 201 of the Tobacco Control Act, amending section 4 of FCLAA to require graphic warnings, does contain a specific exemption for retailers in certain circumstances, and proposed § 1141.1(c) and (d) recognized this exemption. Section 102 of the Tobacco Control Act required FDA to reissue the 1996 Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (61 FR 44396, August 28, 1996) with certain specified exceptions. We have complied with this requirement (75 FR 13225). However, section 102 of the Tobacco Control Act did not specify that the reissued 1996 rule contain an exemption for retailers or distributors. Consequently, this graphic warning rulemaking did not propose any revisions to the reissued 1996 rule (currently codified at 21 CFR part 1140).

(Comment 137) Multiple comments advocated for the placement of graphic warnings on all tobacco products, including smokeless tobacco products.

(Response) We decline to require warnings on other tobacco products in this rulemaking. In section 4(d) of FCLAA, Congress directed FDA to issue regulations to require color graphic images to accompany the warnings statements required by section 4(a)(1) of FCLAA. This section of FCLAA requires that the statements be included on cigarette advertisements and cigarette packages. While we may be able to require warnings on other tobacco products under other authority, such action is outside the scope of this rulemaking.

2. Section 1141.3—Definitions

Proposed § 1141.3 included definitions for the following terms:

- Cigarette
- Commerce
- Distributor
- Front panel and rear panel
- Importer
- Manufacturer
- Package
- Person
- Required warning
- Retailer
- United States

We received only a few comments regarding definitions described in the proposed rule. In light of these comments, we are revising the definition of ''importer.''

As explained in the preamble to the proposed rule, proposed § 1141.3 defined ''importer,'' for purposes of part 1141, as any person who introduces into commerce any cigarette that: (1) Was not manufactured in the United States and (2) is intended for sale or distribution to consumers in the United States. Proposed § 1141.3 defined ''retailer'' as any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted (75 FR 69524 at 69536).

(Comment 138) One comment asked that FDA expand the definition of importer to include persons who introduce into commerce cigarettes manufactured in the United States, exported from the United States, and subsequently imported. According to this comment, legislation in 2000 substantially curtailed this practice, but it is still possible.

(Response) We agree that any person who introduces into commerce cigarettes that were imported into the United States, regardless of where those cigarettes were manufactured, should be considered an importer. We are revising the definition of importer to clarify this point.

(Comment 139) With respect to the definition of retailer, one comment requested that FDA revise the definition to clarify that Internet sellers are included in this definition. The comment noted that it appears the retailer definition is broad enough to cover Internet sellers, but clarification would avoid any arguments to the contrary.

(Response) We have determined that revisions to the definition of retailer are not needed. The definition is clear that any person, including an Internet seller, who sells cigarettes to individuals for personal consumption is a retailer. The comment provided no examples of possible arguments for why an Internet seller would not meet the definition of retailer and provided no alternate language for the definition. It may be possible that an Internet seller would not be considered a retailer because it is not selling cigarettes to individuals for personal consumption. In that case, however, the Internet seller would likely meet the definition of distributor and, if so, would be responsible for complying with all responsibilities of distributors under part 1141 and section 4 of FCLAA.

3. Section 1141.10—Required Warnings

The Tobacco Control Act directs FDA to require that color graphic images depicting the negative health

consequences of smoking accompany each of the textual warning statements that must be randomly displayed on cigarette packages (*i.e.,* in each 12-month period, all of the different warnings must appear in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed) and rotated quarterly in cigarette advertisements under FCLAA. Accordingly, in proposed § 1141.10, we proposed that cigarette packages and advertisements contain such a combination graphic-textual warning.

Proposed § 1141.10 provided that the warnings required by this section be obtained from two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements.'' ''Cigarette Required Warnings—English and Spanish'' was proposed to contain the required warnings that must be included on all cigarette packages, and in cigarette advertisements in which the text of the required warning must be set forth in the English language or the Spanish language. ''Cigarette Required Warnings—Other Foreign Language Advertisements'' was proposed to contain the electronic files that were to be used to generate the required warnings for advertisements in which the text of the required warning must be set forth in a foreign language (other than Spanish).

The material that was proposed to be contained in the two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'' is now contained in a single document entitled ''Cigarette Required Warnings.'' We have provided this information in a single document because each of the electronic files for use in advertisements contained in ''Cigarette Required Warnings'' allows users to select an English or Spanish textual warning statement or to remove the textual warning statement and insert a true and accurate foreign language (other than Spanish) translation of the warning statement into the file. It is thus unnecessary to provide separate documents with electronic files for English and Spanish language advertisements and for advertisements in which the text of the required warning must be set forth in a foreign language (other than Spanish). Section 1141.10 has been updated to reference this single document, ''Cigarette Required Warnings,'' rather than the two proposed documents (''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'').

Section 1141.10(a) sets forth the requirement specific to cigarette packages, explaining that the new required warning must comprise at least the top 50 percent of the front and rear panels of the package, except for cartons where the warnings shall comprise 50 percent of the left side of the front and rear panels. This regulation implements section 4(a)(2) of FCLAA and is in line with the provisions of the Framework Convention on Tobacco Control (FCTC) (Ref. 60). Section 1141.10(a)(3) specifically provides that the ''required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.'' Section 1141.10(b) sets forth the requirements for advertisements, including the requirement that the warnings comprise at least 20 percent of the area of the advertisements. Section 1141.10(c) provides that the required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. For the final rule, we have deleted the language from § 1141.10(a)(2) and (b)(3) that specified that the electronic images must be adapted as necessary to meet the requirements of section 4 of FCLAA and part 1141. As explained in the NPRM (75 FR 69524 at 69536 through 69538), this language was used to indicate that regulated entities should modify the size of the required warnings to ensure they are the required size and occupy the required area of the cigarette package or advertisement. However, § 1141.10(a)(4) and (b)(5) set forth the size and placement requirements for required warnings on packages and advertisements, so this language in proposed § 1141.10(a)(2) and (b)(3) was not necessary. In addition, § 1141.10(a)(1) and (b)(1) make clear that the required warnings on cigarette packages and in cigarette advertisements must be ''in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act.''

We also have made minimal changes to § 1141.10(b)(4), which used similar language. Specifically, proposed § 1141.10(b)(4) indicated that the required warnings for foreign language advertisements (other than Spanish) must be adapted as necessary to meet the requirements of section 4 of FCLAA and part 1141. For clarity, we have modified this language to indicate that the textual warning statement that is inserted into the electronic images must comply with the requirements of section 4(b)(2) of FCLAA. As explained in the NPRM (75 FR 69524 at 69538), proposed § 1141.10(b)(4) would have required regulated entities to obtain color graphics for foreign language required warnings, other than Spanish language warnings, from the electronic files contained in ''Cigarette Required Warnings—Other Foreign Language Advertisements,'' and regulated entities would have to insert a true and accurate foreign language translation of the textual warning required by FCLAA into the electronic file to generate the required warning (as explained previously, these electronic files are now contained in the document entitled ''Cigarette Required Warnings''). While the electronic file obtained from ''Cigarette Required Warnings'' contains some of the elements required by FCLAA (*e.g.,* a rectangular border to enclose the required warnings and the color graphic to accompany the label statement), the textual warning statement that regulated entities insert into the electronic file in accordance with § 1141.10(b)(4) must comply with the requirements of section 4(b)(2) of FCLAA. This section provides, among other things, format specifications related to the textual warning statements in cigarette advertising, including required type sizes and color specifications (*i.e.,* the text of the label statement shall be black if the background is white and white if the background is black), and requires that the statements appear in conspicuous and legible type.

In addition, we wish to clarify our intent regarding whether the same warning statement must appear on both the front and rear panels of an individual cigarette package. We believe that section 4(a)(1) of FCLAA is ambiguous as to whether it mandates the use of the same required warning on both the front and rear panels of an individual cigarette package or allows two different required warnings to be used, one on the front panel and the other on the rear panel. We believe that the latter interpretation is reasonable. It is consistent with Congress' intent that all of the required warnings, each of which conveys somewhat different health information, are required to be displayed in the marketplace at the same time (*see* section 4(c)(1) and (c)(3) of FCLAA). While it is possible that two copies of the same statement on a single package might increase the likelihood of the warning being noticed and remembered, we also note that different statements on a single package could lead to greater consumer exposure as well as delay the wear out of the required warnings. Proposed

§ 1141.10(a)(1), along with the description of this provision in the preamble to the proposed rule (75 FR 69524 at 69536), however, implied that the same required warning must appear on both the front and the back of the package. Therefore, we are revising § 1141.10(a)(1) to state, ''It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import * * * any cigarettes the package of which fails to bear * * * one of the required warnings on the front and the rear panels.''

We received comments regarding the format of required warnings on packages and advertisements, the applicability of the requirements to cigarette cartons, and the need for the warnings to remain clearly visible and permanently affixed to packages. A summary of these comments and our responses is provided in the following paragraphs.

(Comment 140) Many comments, including those from health institutions, nonprofit organizations, academics, and consumers, agreed that the significant enhancements to the cigarette health warnings required by § 1141.10 will make them considerably more noticeable and memorable than warnings that currently appear on cigarette packages and in cigarette advertisements. However, many comments also noted that the FCTC Article 11 Guidelines urge parties to cover as much of the principal display areas as possible and that evidence suggests that warnings larger than 50 percent of the principal display areas may be even more effective (*citing* Ref. 41). The comments noted that researchers also have found that smokers correlate the size of the warning label to the importance of the message—the larger the message, the greater magnitude of the risk (*citing* Ref. 61). Accordingly, these comments requested that FDA consider increasing the size of the graphic warnings such that they occupy more than 50 percent of the front and rear panels of cigarette packages.

(Response) We decline to revise the 50 percent area requirement at this time. We have currently determined that this requirement is sufficient to achieve our goals, and this requirement is consistent with the specification set forth by Congress in section 4(a)(2) of FCLAA.

(Comment 141) A few comments expressed the belief that there was no adequate justification for the amount of space mandated for the new required warnings (*i.e.,* 50 percent of the front and back panels of packages and the top 20 percent of the area of advertisements). One comment noted that Congress enacted the 50 percent requirement without committee testimony or other fact-finding as to whether a smaller-sized warning would be effective. The comments asserted that the current size and placement of the warnings on cigarette packages and advertising have contributed to ''complete awareness levels of the dangers of cigarettes.''

(Response) We disagree. As we stated in the preamble to the proposed rule, our assessment of the literature and our experience as a public health agency supports the requirement that the new warnings comprise the top 50 percent of the area of each of the front and rear panels of cigarette packages and the top 20 percent of the area of cigarette advertisements in the United States (75 FR 69524 at 69533). For example, researchers have found that larger graphic warnings are likely to have the greatest impact and that ''larger (label) size means higher visibility and better ability to compete with other package elements'' (Ref. 40 at p. 30). Smokers are more likely to recall larger warnings, and have been found to correlate the size of the warning with the seriousness of the risk (Ref. 61). One Canadian study found that smokers judged warnings that covered 80 percent of the package to be most effective (Ref. 11). In a New Zealand study gauging responses to different sized graphic health warnings (one sized 50 percent of the front of the pack, and another sized 30 percent of the front of the pack), participants strongly preferred the larger sized warning (Ref. 40 at p. 31). Participants felt that the larger sized warning was more prominent, more likely to stand out from product branding, and that some of the messages on the front of the pack remained visible when the pack was open (*Id.* at p. 30). The 50 percent requirement also is consistent with the FCTC (*i.e.,* the required warnings should occupy 50 percent or more of the principal display areas of packages), which was among the substantial evidence considered by Congress when enacting the Tobacco Control Act (FCTC art. 11.1(b)). ''Congress also informed its warning requirements by looking at the use of a nearly identical warning requirement in Canada.'' *Commonwealth Brands* v. *United States,* 678 F. Supp. 2d 512, 531 (W.D. Ky. 2010), *appeal pending sub nom., Discount Tobacco City & Lottery, Inc.* v. *United States,* Nos. 10–5234 & 10–5235 (6th Cir.).

In addition, as described more fully in section II.C of this document, the existing warnings have not been effective in communicating the health risks of smoking, resulting in significant portions of the population that misunderstand or underestimate the health risks of smoking. The new size and placement requirements are needed to increase the salience of cigarette health warnings, which are now considered ''invisible,'' in order to educate the public about the health risks of smoking, which in turn, can positively impact smoking intentions and behaviors (Ref. 3 at p. 291).

(Comment 142) Some comments suggested that the regulation include a font size requirement.

(Response) We note that the proposal included a requirement related to font size and this is retained in the final rule. The final rule mandates that the required warnings be accurately reproduced from the document incorporated by reference entitled ''Cigarette Required Warnings.'' The required font style and font size already will be included in the options within the downloadable files that allow the user to select English and Spanish language warning statements.

For advertisements in foreign languages other than Spanish, companies must comply with the font size requirements in section 4(b)(2) of FCLAA and any format requirements included in the document incorporated by reference (*see* section V.B.4 of this document). In all situations, the textual statements must be conspicuous and legible as required by section 4 of FCLAA.

(Comment 143) One comment from an industry group took issue with FDA's authority to require the new graphic warnings on cigarette cartons, claiming that Congress' intent was to require the new graphic warnings on individual cigarette packs only, not cartons. The submitter recommended that FDA expressly exempt cartons from this requirement.

(Response) We disagree with this comment. FCLAA defines the term ''package'' to mean a ''pack, box, *carton,* or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.'' (section 3(4) of FCLAA (15 U.S.C. 1332(4)) (emphasis added)). Similarly, section 900(13) of the FD&C Act defines the term ''package'' to mean a ''pack, box, *carton,* or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.'' (21 U.S.C. 387(13) (emphasis added)). Given these definitions, it is clear that when Congress decided to require graphic warnings that occupy 50 percent of the front and back panels of cigarette ''packages,'' it intended for this requirement to apply to both individual

packs and cartons. Therefore, § 1141.10(a)(4) continues to mandate that the required warnings must constitute 50 percent of the left side of the front and rear panels of cigarette cartons.

(Comment 144) One comment recommended that FDA require the nine new textual warning statements, included in section 4(a) of FCLAA, to be displayed in the same manner as the display of the existing warnings, because that format has contributed to the public being fully informed about the health risks of smoking.

(Response) We disagree. First, as explained in section II.C of this document, the public is not adequately informed about the health risks of smoking and frequently underestimates those risks. Second, Congress mandated that the format of the new health warnings change from the small warning on the side panel of the pack, covering only 4 percent of the pack, to health warnings that ''comprise the top 50 percent of the front and rear panels of the package'' and ''at least 20 percent of the area of the advertisement.'' (15 U.S.C. 1333(a)(2) and (b)(2)). This is consistent with the FCTC (FCTC art. 11.1(b)). Therefore, we decline to change the format of the required warnings from that included in the proposed rule.

(Comment 145) One comment suggested that the required warnings on cigarette advertisements cover at least 50 percent of the advertisement's principal surface and match the advertisement's primary language.

(Response) As stated in the preamble to the proposed rule and as required by section 4 of FCLAA, § 1141.10(b)(5) mandates that the required warnings comprise *at least* the top 20 percent of the area of the advertisement. Section 4 of FCLAA also requires that the warning statement appear in conspicuous and legible type. At this time, we conclude these requirements are sufficient to ensure that the required warnings are appropriately clear, conspicuous, and legible by consumers.

Moreover, as stated in the preamble to the proposed rule and as indicated in section IV.C of this document, while the textual portion of the required warning in a cigarette advertisement must generally be in English, if an advertisement is presented in a language other than English, the textual portion of the required warning must be presented in the language principally used in the advertisement (*see* § 1141.10(b)(2)(ii)). Therefore, we have determined that modifications to the codified text are not necessary.

(Comment 146) Proposed § 1141.10(a)(5) provided that the ''required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.'' One comment expressed concern that this provision could be problematic if a manufacturer places the brand name and other information vertically on the front and/or back of the cigarette package. The comment believed that this provision would require the warning, or the text of the warning, to appear sideways on the cigarette package.

(Response) The intent of this provision is to ensure that the textual statement in the required warning and other information on the front and rear panels of the package have the same orientation. As explained in the NPRM, this will in turn ensure that the warnings are noticed and read by consumers that are reading the other information found on the package (75 FR 69524 at 69537). Therefore, in the unusual circumstance where a manufacturer chooses to place its brand name or other information such that viewers do not read along the horizontal axis (*i.e.,* from left to right) to read this information, the manufacturer must place the required warning in the same orientation.

(Comment 147) Two comments suggested that the FDA require health warnings on 100 percent of only the front or the rear panel of the cigarette package.

(Response) We disagree. First, section 4(a)(2) of FCLAA specifically requires that the cigarette health warnings ''comprise the top 50 percent of the front and rear panels of the package.'' Second, Article 11 of the FCTC states that the health warnings ''should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas'' (Ref. 60). FDA's new warnings implement Congress' directive and are consistent with the FCTC.

(Comment 148) A few comments suggested that FDA require health warning statements on cigarette papers and/or filters.

(Response) We decline to require warnings on cigarette papers and/or filters. In section 4(d) of FCLAA, Congress directed FDA to issue regulations to require color graphic images to accompany the warnings statements required by section 4(a)(1) of FCLAA. FCLAA requires that the statements be included on advertisements and cigarette packages, not individual cigarette papers or filters. While we may be able to require warnings on papers or filters under other authority, that is outside the scope of this rulemaking.

(Comment 149) One comment suggested that FDA amend the regulation to prohibit distributors from obscuring any portion of the warning label with revenue stamps.

(Response) As written, the proposed rule would prohibit distributors from obscuring any portion of the required warning with revenue stamps. Cigarette packages must comply with the requirement in § 1141.10(a)(3) that the new required warnings be clearly visible. Moreover, in order for the required warnings to appear conspicuously and legibly as mandated by section 4 of FCLAA, the warnings must not be obscured. Thus, if the placement of revenue stamps by a distributor causes the required warnings to not be clearly visible or legible, the distributor would be in violation of these regulations. Therefore, we do not agree that any revisions to § 1141.10 are necessary.

(Comment 150) One comment suggested that FDA require the use of onserts affixed to cigarette packages in addition to the new required warnings, stating that they would enhance the effectiveness of the new health warnings. Similarly, another comment stated that, in addition to the new required warnings, FDA should require that cigarette packages contain inserts with animated warnings containing supplementary or distinct warning messages to enhance the overall warning impression and further engage individuals.

(Response) A requirement to add onserts or inserts is beyond the scope of this rulemaking and, therefore, we decline to require them here.

(Comment 151) One comment stated that there is no empirical basis for concluding that the nine warning statements required under section 4 of FCLAA should be written in large text on the front and back panels of packages in order to convey the health risk information.

(Response) We disagree with this comment and conclude that there is a sufficient empirical basis for concluding that the warning statements should be in large text that is conspicuous and legible. Research has shown that increasing the salience of warnings increases the likelihood of consumers reading warnings and that the salience of a visual warning can be enhanced by using large, bold print (Ref. 62). In addition, after Australia changed their health warnings to six rotated textual warnings with a cessation resource and additional explanatory text in 1995,

researchers found that the increased text size was the most salient feature (Ref. 63). Furthermore, the IOM Report, which provides a summary of the available research on the efficacy of graphic warnings, found that larger, graphic health warnings (including large text and a large graphic) would promote greater public knowledge of the health risks and would help reduce consumption of tobacco products (Ref. 3). The placement of the large text and graphic image on the front and back panels of cigarette packages is consistent with the FCTC, *i.e.,* that health warnings should occupy 50 percent or more of the principal display areas of packages (FCTC art. 11.1(b)).

(Comment 152) One comment claimed that the format of the new required warnings is inconsistent with FDA's drug warning label regime. For example, the comment stated that even for very severe risks, the drug regulations do not require warning information to appear in large text or to occupy a large portion of the packaging. The comment also noted that, in drug advertising, the FDA requires important risk information to be included in a section of the advertisement entitled ''Brief Summary.''

(Response) We have acknowledged that the warning requirements for cigarettes are, and should be, different than the warnings for other FDA-regulated products. As we explained in the preamble to the proposed rule, ''(1) The warning information for cigarettes is different in its applicability than the warning information for other products, (2) the disclosure requirements for other products have a different purpose than the cigarette warnings, and (3) the mechanisms for exposure to warning information are different for tobacco products than for other products FDA regulates'' (75 FR 69524 at 69539). In contrast to medical products regulated by FDA, there is no population that cigarettes are medically appropriate for, and there is no safe method of using cigarettes; the required warnings for these products thus have an inherently different purpose than medical product warning information. The different warning schemes that apply to tobacco products versus medical products are necessary to most effectively communicate the health risks for tobacco products and for other FDA-regulated products.

(Comment 153) One comment claimed that FDA did not provide an adequate justification for requiring the same health warning messages in multiple media, including print advertisements, point-of-sale displays, cartons, and the front and back of individual cigarette packs. This comment claimed that the publication of health warning messages in multiple media will not foster awareness of the information (because it is already known) or belief in it (because it is already believed).

(Response) We disagree. As explained in section II.D of this document, despite existing warning requirements on packages and in advertisements, consumers lack knowledge of the health risks and underestimate the health risks of smoking. It is critical that the negative health consequences of cigarette smoking, which is the leading cause of preventable death and disease in the United States, be clearly, accurately, and effectively conveyed in *all* advertisements and on *all* cigarette packages sold or distributed in the United States.

This is consistent with the requirements of FCLAA. As explained more fully in response to Comment 143, FCLAA's requirements apply to cigarette packages (including cartons), and to advertisements generally.

Further, with its passage of the Tobacco Control Act, Congress noted the pervasiveness of tobacco advertising and how it impacts use, especially promotions directed to attract youths to tobacco products, and found that comprehensive advertising restrictions will have a positive effect on the smoking rates of young people (section 2(15) and 2(25) of the Tobacco Control Act). Therefore, the requirement that the warnings appear in all advertisements, regardless of the medium used for the advertisement, is also consistent with Congress' intent.

(Comment 154) One comment noted that the Federal government warnings on alcoholic beverages are mandated on packages only, presented in small font, and not required on the prominent faces of containers or packaging. According to the comment, this suggests that Congress believes a configuration like the one for alcoholic beverages also would be sufficient for cigarette warnings, particularly given the more widespread use of alcoholic beverages in this country.

(Response) We disagree. Congress clearly intended for the warnings for cigarettes and alcoholic beverages to be different, as evidenced by the different statutory schemes that govern the warning requirements for cigarettes and alcohol products. For cigarettes, Congress clearly set out the location of the health warnings for cigarette packages and advertisements, the area of the package or advertisement that must be covered by the warnings and the requirements for text and background color of the warnings. In addition, Congress provided specific font size requirements for the cigarette warnings (while also affording FDA the authority to initiate a rulemaking proceeding to adjust the format, type sizes, and certain other aspects of the health warnings under sections 4(b)(4) and (d) of FCLAA and section 202(b) of the Tobacco Control Act. In contrast, Congress' health warning requirements for alcoholic beverages, published at 27 U.S.C. 215, do not set forth area, location, and color requirements with as much specificity.

(Comment 155) One comment from an individual consumer expressed concerns that manufacturers may alter their packaging to subvert § 1141.10(c), which mandates that the required warnings on packages and advertisements must be irremovable or permanent.

(Response) The regulation, as drafted, should address the comment's concern. Section 1141.10(c) of the final rule, which is unchanged from what appeared in the proposed rule, states that the ''required warnings shall be indelibly printed on or permanently affixed to the package or advertisement.'' Therefore, regardless of the type of packaging used by manufacturers, all cigarette packages must contain required warnings that are irremovable or permanently affixed to the cigarette packages.

4. Section 1141.12—Incorporation by Reference of Required Warnings

Proposed § 1141.12 proposed that two documents, ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements,'' be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Draft versions of both documents were made available in the docket with the NPRM.

We did not receive comments regarding the use of the incorporated by reference mechanism provided in 5 U.S.C. 552(a) and 1 CFR part 51 and the proposed codified language, or regarding the two draft documents proposed for incorporation by reference. However, as explained in section V.B.3 of this document, the material that was proposed to be contained in the two documents entitled ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements'' is now contained in a single document entitled ''Cigarette Required Warnings.'' As a result, we have made nonsubstantive changes to the language used in § 1141.12 to indicate that we are

incorporating ''Cigarette Required Warnings'' by reference (rather than ''Cigarette Required Warnings—English and Spanish'' and ''Cigarette Required Warnings—Other Foreign Language Advertisements''). In addition, we also have updated the incorporation by reference document to include the final electronic files [5] for the required warnings and to add additional formats and instructions for regulated entities to use to place the required warnings on various sizes of cigarette packages (including cartons) and in different sizes and shapes of advertisements, as is discussed in more detail in section VI of this document.

''Cigarette Required Warnings,'' including the electronic files for all of the required warnings and the instructions for their use, is available from a variety of sources. For example, this material is available on a Web site located at *http://www.fda.gov/cigarettewarningfiles.* In addition, regulated entities can request a copy of ''Cigarette Required Warnings'' by submitting a request to FDA at the following e-mail address—*cigarettewarningfiles@fda.hhs.gov*—or by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373.

5. Section 1141.14—Misbranding of Cigarettes

Proposed § 1141.14(a) provided that a cigarette shall be deemed to be misbranded unless its labeling and advertising bear one of the required warnings. Under section 903(a)(1) and (a)(7)(A) of the FD&C Act (21 U.S.C. 387c(a)(1) and (a)(7)(A)), a tobacco product, including a cigarette, is deemed misbranded if its labeling or advertising is false or misleading in any particular. Under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), in determining whether something is misleading, it: ''Shall be taken into account * * * not only representations made or suggested * * * but also the extent to which the labeling or advertising fails to reveal facts * * * material with respect to consequences which may result from the use of the article to which the labeling or advertising relates * * * under such conditions of use as are customary or usual.'' As explained in the NPRM (75 FR 69524 at 69539), the required warnings are clearly material with respect to consequences that may result from the use of cigarettes.

Proposed § 1141.14(b) provided that a cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act if it bears one of the required warnings. It also proposed that a cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the FD&C Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings. We received two comments on the issue, which we have summarized and responded to in the following paragraphs.

(Comment 156) One comment from a tobacco product manufacturer stated that FDA should replace the word ''labeling'' with the word ''packages'' in § 1141.14(a). The comment indicated that FDA should avoid using the word ''labeling'' because that term has a broader meaning under the FD&C Act than it does under FCLAA, and therefore its use in the regulation could create unnecessary ambiguity. The comment also stated that FCLAA only requires warnings on cigarette packages and advertisements.

(Response) We agree that the requirements for inclusion of health warnings set forth in FCLAA apply to each package (*i.e.,* pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers) and each advertisement of cigarettes. The package warnings required by FCLAA are one part of a product's ''labeling,'' as the term ''labeling'' encompasses the package label. We have revised § 1141.14(a) to replace the word ''labeling'' with the word ''packages'' for clarity. We note, however, that section 903 of the FD&C Act, ''Misbranded Tobacco Products,'' provides other ways that tobacco products can be misbranded that extend to tobacco product labeling as well as package labels and advertising. Therefore, in addition to complying with the requirements of FCLAA and this rule, regulated entities must comply with the requirements of section 903 of the FD&C Act to avoid misbranding their tobacco products.

(Comment 157) One comment from a public health advocacy group stated that clarifying changes should be made to the language in § 1141.14 to ensure the regulation accomplishes its intended purpose. Specifically, the comment stated that cigarettes can be deemed misbranded under the FD&C Act unless they meet a number of criteria, and that not all of the criteria relate to health warning requirements. Thus, a regulated entity could comply with the warning requirements, but its cigarette product could still be deemed misbranded under the FD&C Act if it failed to meet other criteria in section 903 of the FD&C Act. The comment suggested the language in section § 1141.14 should clarify this point.

(Response) We agree that cigarettes can be deemed misbranded under the FD&C Act for a number of reasons. We also agree that, although compliance with the requirements of part 1141 is necessary to comply with certain provisions of section 903 of the FD&C Act, this does not guarantee that a cigarette product satisfies all the provisions of section 903 of the FD&C Act. However, we do not agree that changes to the codified text at § 1141.14 are necessary, as the text does not indicate that cigarettes will not be deemed misbranded for any reason if they include required warnings, but rather that cigarettes will be deemed misbranded if they fail to include required warnings.

6. Section 1141.16—Disclosures Regarding Cessation

Section 1141.16 of the NPRM proposed that one or more of the required warnings include specified information about an appropriate smoking cessation resource. As explained in the NPRM, the goal is to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering current, unbiased, and evidence-based information, advice, and support. The NPRM identified a number of possible alternatives for a cessation resource, including use of an existing or new quitline or Web site.

[5] As described in section VI.A of this document, the final electronic files for the required warnings are built as Encapsulated PostScript (.eps) files, which is a format that is commonly used by professional printers. Because members of the public may not have software that can easily view these files, we are placing in the docket Ref. 64, which is composed of .pdf versions of each of the formats for each of the English and Spanish language required warnings, as well as the instructions contained in ''Cigarette Required Warnings.'' We note, however, that these .pdf files do not have the same functionality as the .eps files. Unlike .pdf files, .eps files have separate layers for text and images and the use of these layers can be manipulated by users. In addition, .pdf files are not included for foreign language advertisement warnings (other than Spanish) because regulated entities are responsible for generating a true and accurate translation of the textual warning statement in the required language for such warnings, and thus the final versions of such warnings are not contained in ''Cigarette Required Warnings.''

Although we did not include a specific cessation resource on the proposed images published with the NPRM, we proposed that the final rule would include one or more required warnings containing a cessation resource. We proposed that the resource must meet specific criteria designed to ensure that the cessation information, advice, and support provided are unbiased and evidence-based.

As explained more fully in the following paragraphs, we have decided, based on our authority in section 906(d) of the FD&C Act, to require that all nine required warnings refer to a cessation resource, and we have included this resource in the nine graphic warnings in ''Cigarette Required Warnings,'' which is incorporated by reference (IBR document) as described in section V.B.4 of this document. This final rule specifies the criteria that will be required of any responsible entity providing services through the chosen cessation resource. The resource we have selected is the existing National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1–800–QUIT–NOW. This telephone portal, provided by the National Cancer Institute (NCI), routes calls to the appropriate State quitline, based on the area code of the caller. The Network includes a designated quitline run by or on behalf of each of the 50 states as well as the District of Columbia, Puerto Rico, and Guam (hereinafter referred to as ''State quitlines'' or ''State-run quitlines'').[6] We conclude that this resource will provide the broadest access for smokers throughout the United States to unbiased, evidence-based cessation information, advice, and support. The Centers for Disease Control and Prevention (CDC) already provides significant support and oversight to these State-run quitlines. Beginning with the effective date of this rule, CDC's cooperative agreements with State health departments will specify that the State quitlines must meet the criteria described in § 1141.16(b) to qualify for cessation funding under the cooperative agreement. HHS will monitor the quitlines for compliance with the criteria, and if it determines that a State quitline does not meet the criteria, it will take appropriate steps to bring the State quitline into compliance. What is appropriate will depend on the circumstances of the particular situation. For example, it might involve CDC working with the State quitline to ensure staff are adequately trained. If warranted, it could also include more serious measures such as CDC working with NCI to re-route calls to another resource. Because the record indicates that quitlines that are members of the Network generally comply with the criteria already, we anticipate that any measures to bring quitlines into compliance will be rare.

a. *Rationale and authority for requiring inclusion of a cessation resource.* The NPRM explained that reducing the number of Americans who smoke by increasing the likelihood that smokers will quit smoking would provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use. The NPRM also cited studies finding that health warnings are more effective if they are combined with cessation-related information. Consequently, FDA proposed requiring information about an appropriate smoking cessation resource under section 906(d) of the FD&C Act as appropriate for the protection of the public health (75 FR 69524 at 69540 through 69541). We received a number of comments regarding our rationale and authority to require a cessation resource on the graphic health warnings, which we summarized and responded to in the following paragraphs.

(Comment 158) A large majority of comments that addressed the issue strongly supported inclusion of a cessation resource on all the required warnings. These include comments from public health advocacy groups, medical organizations, academics, State and local public health agencies, and representatives of quitlines. The comments provided a variety of reasons supporting inclusion of a cessation resource on the required warnings. Many comments asserted that a majority of smokers want to quit, and referring smokers to a smoking cessation resource will help them to quit. Some comments cited statistics regarding the number of smokers who actually attempt to quit—about 40 percent of smokers try to quit in a calendar year—and the very low percentage of smokers who are successful—95 percent of those who try to quit on their own relapse (*citing, e.g.,* Ref. 65 and Ref. 66). One comment from a State public health agency asserted that smokers contemplating quitting are motivated by smoking cessation messages to call a State tobacco quitline.

Many comments argued that including a cessation resource is consistent with the guidelines for implementing Article 11 of the FCTC. One comment also stated that including a cessation resource would be consistent with Article 14 and Article 12 of the FCTC. In addition, numerous comments cited evidence from other countries, particularly Australia, New Zealand, the Netherlands, Brazil, Singapore, and the United Kingdom, where adding a smoking cessation quitline number to cigarette warnings significantly increased calls to the quitline (*citing, e.g.,* Refs. 67, 68, 69, 70, 71, 72, and 73). As one comment noted, these results show, consistent with behavior change theory, that providing a quitline number may be a critical component of the required warning that facilitates behavioral action. According to one comment from an academic institution, an evaluation of the impact of including a supportive cessation message accompanied by quitline numbers and Web-based cessation information in seven European countries (Denmark, France, Iceland, The Netherlands, Norway, Poland, and Sweden) found a significant increase in quitline call volume in all countries except Norway. One comment from a submitter representing quitlines stated that it is feasible for the cigarette industry to include a cessation resource on every package of cigarettes, noting that approximately 20 nations currently require a quitline number on their tobacco packages and advertisements.

Many comments cited statistics that smokers who use evidence-based services of telephone quitlines have a two to three times higher rate of success in quitting than smokers making unassisted quit attempts (*citing, e.g.,* Ref. 66). One comment from a local public health agency asserted that media campaigns and educational efforts, while effective, still do not reach all smokers. According to this comment, after extensive outreach, about 25 percent of smokers in that city had never heard of the quitline being promoted and 25 percent of smokers reported that it is not easy for a person interested in quitting smoking to obtain information about ways to quit.

Several comments noted that the purpose of graphic warnings is to inform smokers about the risks of smoking and motivate smokers to want to quit, but this message will be more effective if there is information in the graphic warnings on how smokers can obtain help quitting. Some comments argued that health warnings should not just inform smokers about the dangers of tobacco use, but also provide assurance that quitting is possible and assistance is available. One comment cited research that shocking, fear-arousing images can be more effective when combined with encouragement or

[6] Calls to 1–800–QUIT–NOW from U.S. territories that do not currently have a quitline (*e.g.*, the U.S. Virgin Islands or American Samoa) are routed to a quitline that is run by NCI.

empowering messages (*citing, e.g.,* Ref. 74). Another comment from an academic institution claimed that when people perceive that there is a strategy for them to take positive action to reduce the threat in a fear message, fear appeals successfully changed health-related attitudes and behaviors (*citing, e.g.,* Refs. 75, 76, 77, and 78). However, if people do not believe they have an effective means of avoiding a threat, they may suppress thoughts about the risk, and, as a result, not process the threat information (*citing, e.g.,* Refs. 79, 80, and 81). As one comment from an academic institution explained, under fear appraisal theory, a fear communication message will cause aversive anxiety, which individuals will try to ameliorate through behaviors that reduce the perceived threat. This comment asserted that the positive effects of a fear message depend upon the existence of an available coping option that is perceived to be potentially effective at reducing the threat. In addition, comments cited research that smokers may be more likely to attempt to quit when they know a quitline is available (Ref. 82).

One comment from a submitter representing a State quitline claimed that health care providers are more likely to address tobacco use in their patients when they know of an effective program to which they can refer their patients, and that adding a cessation resource to the required warnings will dramatically increase awareness of this resource. Several comments from submitters representing State quitlines noted that they receive referrals from clinicians via fax referral services.

One comment from an academic researcher submitted results from a study that tested one of the proposed required warnings included in the proposed rule with and without a cessation resource. This study found that when youth and adult participants were asked to rank order six images tested for use with one of the warning statements, based on which image would be most effective for discouraging smoking, the image with the cessation resource was ranked as the most effective by more study participants than any other image.

(Response) We agree with comments that there is strong support for including a smoking cessation resource on the required warnings. As required by section 906(d) of the FD&C Act, we find that addition of a cessation resource is appropriate for the protection of the public health because of the benefits, and lack of risks, to the population as a whole. This is due, in part, to the increased likelihood that existing smokers will become aware of the cessation resource and, consequently, the increased likelihood that existing smokers who want to quit will be successful. It is also due to the likelihood that the reference to a smoking cessation resource will enhance the effectiveness of the warnings required under FCLAA at conveying information about the risks to health from smoking.

As stated in the comments, the majority of smokers want to quit and about 40 percent of smokers attempt to quit each year. In addition, the warnings required under FCLAA and this regulation convey information and promote greater understanding about the significant health risks associated with smoking, which will likely lead additional smokers to decide that they want to quit smoking to address these risks. Also, as discussed in the comments, the vast majority of those attempts are unsuccessful. By including a cessation resource on required warnings, the many smokers who want to quit will receive information about a resource that has been demonstrated to be effective in helping smokers to quit (*see* section V.B.6.c of this document). Media campaigns are helpful in reaching some smokers who want to quit, and can be used in conjunction with the inclusion of a cessation resource on the required warnings. It is important to ensure that this information reaches a broad number of smokers. Inclusion of a cessation resource on the required warnings is likely to have a broader reach than media campaigns alone. The evidence from one comment is that, even after an extensive media campaign, approximately one quarter of smokers surveyed were not aware of the existence of the quitline or that help was available to obtain information about ways to quit. The cessation information will be there each time a consumer looks at a package of cigarettes or a cigarette advertisement; a pack-a-day smoker potentially would be exposed to the cessation information more than 7,000 times per year. This evidence highlights that cigarette packages are useful communication tools for ensuring that smokers are aware of cessation resources.

Based on experience in other countries, we anticipate that including a reference to a cessation resource as part of the required warnings will increase the utilization of that resource. Many foreign countries have included cessation resources on cigarette package warnings. As described in the comments, these countries have generally experienced a large increase in the number of calls to the quitlines following their appearance on cigarette packages. For example, in the Netherlands, the number of callers to the quitline increased more than threefold after a smoking cessation message (''Ask for help with smoking cessation'') and the national quitline number were included on cigarette packages (Ref. 72). Similarly, in Australia, the number of calls to the quitline nearly doubled, compared with the previous 2 years, following the introduction of new color graphic warnings with a prominent quitline number. The increase in call volume persisted in the following year, although it was about 40 percent lower than in the year in which the graphic warnings were first introduced. Although there was a series of mass media campaign activities that accompanied the new graphic warnings, one study concluded it was very unlikely that the mass media campaign alone explained the observed increase in calls because the introduction of the graphic warnings had an independent effect (Ref. 67). In New Zealand, after the introduction of pictorial warnings with a supportive cessation message and quitline information, the average number of new monthly calls increased and the percentage of first-time callers who reported obtaining the quitline number from tobacco product packaging doubled (Ref. 83). In Brazil, there was a progressive increase in calls to a quitline in the 6 months following the requirement for graphic warnings and the inclusion of a quitline number on cigarette packages. Interviews with people who called the quitline showed that over 92 percent knew about the quitline number because it appeared on cigarette packs (Ref. 73). We also note that Canada has recently proposed including a quitline number on the graphic warnings that will appear on its packages.

Although we are not aware of any studies regarding the inclusion of cessation information on graphic warnings in cigarette advertisements, it seems likely that adding a reference to a cessation resource to cigarette advertisements would have a similar effect as including the reference on cigarette packages.

Inclusion of a cessation resource on the required warnings is also consistent with the advice of the FCTC. Although the United States has not yet ratified the FCTC and therefore is not bound by the treaty, the United States is a signatory and the Guidelines for implementation of the Treaty provide further support for the inclusion of a cessation resource. The Guidelines for implementation of

Article 11 of the FCTC (Packaging and labeling of tobacco products) explain that the provision of advice on cessation and specific sources for cessation help on tobacco packaging, such as a Web site address or a toll-free telephone number, can be important in helping tobacco users to change their behavior, and is expected to increase demand for cessation-related services.

In addition to providing information to increase the likelihood that smokers will become aware of the cessation resource and use it to successfully quit, including a cessation resource will also help to make the required warnings more effective at conveying information about the health risks of smoking. As noted in the NPRM, studies have found that health warnings are more effective when they are combined with cessation-related information (75 FR 69524 at 69541). Risk communication research indicates that messages that arouse fear about the health risks of smoking should be combined with information on concrete steps that can be taken to reduce those risks (Ref. 81 (Messages that arouse fear ''appear to be effective when they depict a significant and relevant threat * * * and when they outline effective responses that appear easy to accomplish * * *.''); *see also* Ref. 55 (explaining the importance of giving smokers who are motivated to quit smoking upon seeing a graphic health warning an immediate way to act on this impulse and access cessation assistance)). In addition, the results from one study conducted by an academic researcher and submitted to the docket also suggest that adding a cessation resource to the required warnings is beneficial. When youth and adult participants were asked to rank order six images (including one image with and without a cessation resource) tested for use with one of the warning statements, based on which image would be most effective for discouraging smoking, the image with the cessation resource was ranked as the most effective by more study participants than any other image.

(Comment 159) Several tobacco industry comments claimed that it was difficult to comment on the issue of a cessation resource, because the proposed rule did not identify the resource FDA proposed to reference or suggest alternative resources from among which FDA would choose. Tobacco industry comments also claimed that the NPRM did not indicate how FDA proposed to reference the resource or integrate it into the proposed warning images. For these reasons, some tobacco industry comments contended that the NPRM did not provide adequate notice for requiring inclusion of a cessation resource, and that FDA should not require a cessation resource without providing an additional opportunity to comment on specific proposed cessation resources.

(Response) We disagree. The Administrative Procedure Act requires that a notice of proposed rulemaking include ''either the terms or substance of the proposed rule or a description of the subjects and issues involved'' (5 U.S.C. 553(b)(3)). Consistent with this requirement, the NPRM provided adequate notice that FDA was considering the inclusion of a cessation resource in the required warnings and the factors it would consider in choosing a specific smoking cessation resource. Proposed § 1141.16 specifically stated that one or more of the required warnings ''shall include a reference to a smoking cessation assistance resource'' (75 FR 69524 at 69564). The preamble to the proposed rule explained the goal ''would be to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support'' (75 FR 69524 at 69540). The preamble also explained the range of alternatives available, including use of an existing or new quitline or Web site (75 FR 69524 at 69540; *see Small Refiner Lead Phase-Down Task Force* v. *EPA,* 705 F.2d 506, 549 (DC Cir. 1983) (''Agency notice must describe the range of alternatives being considered with reasonable specificity.'')). In addition, proposed § 1141.16(b) identified specific criteria that any referenced cessation resource would need to meet as well as two additional criteria that the resource would need to meet if the resource was a toll-free telephone number (proposed § 1141.16(d)) and two additional, but different, criteria that the resource would need to meet if it was a Web site (proposed § 1141.16(c)). The NPRM further explained that the reference to a smoking cessation resource was proposed to ''be included as part of one or more of the required warnings and therefore would not appear outside of the areas specified for the required warning'' (75 FR 69524 at 69541). Thus, the ''notice was sufficiently descriptive of the subjects and issues involved so that interested parties [could] offer informed criticism and comments'' (*Air Transport Ass'n of America* v. *Civil Aeronautics Bd.,* 732 F.2d 219, 224 (DC Cir. 1980) (*quoting National Small Shipments Traffic Conference, Inc.* v. *CAB,* 618 F.2d 819, 834 (DC Cir. 1980)) (internal quotations omitted)).

Our choice of a specific smoking cessation resource, 1–800–QUIT–NOW and the State quitlines to which it links, is a logical outgrowth of the proposed rule. We received many comments that discussed whether FDA should use a toll-free telephone number and/or a Web site. We also received a comment advocating that the Agency include information about contacting a physician for help quitting (*see* Comment 170). Numerous comments identified an existing resource (primarily 1–800–QUIT–NOW) as the preferred cessation resource for the required warnings. As discussed in section V.B.6.b of this document, many comments addressed the specific criteria proposed for the cessation resource and several comments provided reasons why 1–800–QUIT–NOW meets the criteria identified in the NPRM. In addition to comments received about whether to include a resource and, if so, what resource, as discussed in section V.B.6.d of this document, the proposed rule was sufficiently detailed for comments to raise issues regarding implementation details, such as the words surrounding the cessation resource.

We are generally adopting the criteria identified in the NPRM, including the criteria specific to a toll-free number. Our changes to the criteria are minor clarifications that were informed by comments. Thus, the requirement that the graphic warnings include a reference to a cessation resource is a logical outgrowth of the proposed rule and further notice and opportunity for comment is not necessary (*Air Transport Ass'n of America,* 732 F.2d at 224 (''An Agency adopting final rules that differ from its proposed rules is required to renotice when the changes are so major that the original notice did not adequately frame the subjects for discussion. * * * The agency need not renotice changes that follow logically from or that reasonably develop the rules it proposed originally'') (*quoting Connecticut Light and Power Co.* v. *NRC,* 673 F.2d 525, 533 (DC Cir. 1982))). An agency is permitted to add specific details to a rule in response to comments even if the proposed rule described the requirement in a more general manner (*Chemical Manufacturers Ass'n* v. *EPA,* 870 F.2d 177, 202 (5th Cir. 1989) (finding that EPA provided adequate notice for final rule appendices, one of which established limits for the discharge of certain metals, even though the appendices were not included in the

proposed rule, because there was adequate notice that the agency was considering establishing limitations ''and this was all the APA demands''); *Trans-Pacific Freight Conference of Japan/Korea* v. *Federal Maritime Comm'n,* 650 F.2d 1235, 1248–49 (DC Cir. 1980) (finding that the final rule merely enumerates more specifically the type of information which the Commission sought, but parties were on notice that a requirement of more detailed reports was under consideration)).

b. *Criteria for cessation resource.* The NPRM included three paragraphs in proposed § 1141.16 detailing criteria that would apply, on an ongoing basis, to any cessation resource chosen in the final rule. The purpose of these proposed criteria was to ensure that the cessation information, advice, and support provided by the cessation resource are unbiased and evidence based (75 FR 69524 at 69540). Proposed § 1141.16(b) described 10 criteria that would be applied to any cessation resource chosen. Proposed § 1141.16(c) described two additional criteria that would apply if the cessation resource chosen were a Web site, and proposed § 1141.16(d) described two additional criteria that would apply if the cessation resource chosen were a toll-free telephone number. In addition, the preamble to the proposed rule provided examples and additional explanation to help clarify the proposed criteria (75 FR 69524 at 69540).

As discussed more fully in section V.B.6.c of this document, we have decided that the appropriate cessation resource is a toll-free telephone number (1–800–QUIT–NOW). Therefore, our final rule does not include the criteria proposed for a cessation resource that is a Web site. We have incorporated the two criteria proposed for a cessation resource that is a toll-free telephone number into § 1141.16(b) as paragraphs 11 and 12, deleted the proposed criteria for a Web site, and added a paragraph clarifying an issue raised in the comments.

In the following paragraphs, we summarize and respond to comments regarding our general criteria for a cessation resource, as well as criteria relating to a cessation resource that is a telephone quitline. However, because we are not choosing a Web site as the cessation resource, we do not respond to specific suggestions regarding the criteria in proposed § 1141.16(c) and other comments about criteria for a cessation resource that is a Web site.

(Comment 160) One comment suggested that the rule does not need to specify criteria for the cessation resource. Instead, this comment proposed that FDA rely on the most recent version of the Public Health Service Guideline on Treating Tobacco Use and Dependence (2008 PHS Guideline) (Ref. 66). The rationale for this suggestion was that this guideline is regularly updated to reflect new effective treatments for tobacco dependence and, therefore, the criteria would not become out-of-date. In addition, the comment asserted that the 2008 PHS Guideline is the gold standard for tobacco cessation in the United States, because it is produced by leading cessation experts, updated on a regular basis, and published by HHS.

(Response) We agree with the comment that the 2008 PHS Guideline is a valuable resource for evidence-based smoking cessation treatments. However, the purpose of FDA's criteria is not to reference particular treatment strategies. Rather, these criteria are designed to ensure that the resource's information, advice, and support are unbiased and evidence-based. By setting forth a requirement that the cessation resource provide evidence-based treatment strategies, the resource will be able to employ newer strategies as more research is done on the most effective approaches to smoking cessation treatments.

(Comment 161) Comments representing tobacco product manufacturers claimed that the criteria set forth in proposed § 1141.16 are unspecific or that this section uses vague terminology. One comment argued that the terminology is subject to conflicting interpretations.

(Response) We disagree. The criteria in the proposed rule, and generally adopted in this final rule, are extensive and detailed. In addition, the notice and comment process gave the public an opportunity to raise questions about our use and interpretation of specific terms. The proposed rule provided adequate detail for a number of comments to request revisions and clarifications. We have responded to the significant issues raised in the comments. As explained more fully in response to Comments 163 and 164, in the final rule, we revised the criteria to clarify that quitlines may tailor their services to meet the needs of individual callers and added more explanation and examples to the preamble to further clarify issues raised by comments. The criteria we are adopting will ensure that smokers using the referenced cessation resource receive unbiased and evidence-based services suited to their individual needs.

(Comment 162) Several comments that supported the choice of 1–800–QUIT–NOW as the cessation resource expressed concern that State quitlines would be subject to two sets of potentially inconsistent requirements because the CDC already maintains standards for these quitlines. These comments proposed that FDA specify that quitlines authorized by CDC for connection to the 1–800–QUIT–NOW network are qualified to be the cessation resource included on the required warnings.

(Response) We believe that it is important to establish criteria for the cessation resource as part of this rule to ensure that the standards reflected in these criteria will be followed for as long as the rule is in effect. We do not believe there will be any conflict between these criteria and CDC's requirements for State quitlines that are associated with our chosen resource (1–800–QUIT–NOW). We have worked closely with CDC regarding the choice of the cessation resource and the criteria that will be required. Moreover, CDC will include the criteria in this rule in its State grantee funding requirements, and will work with leading quitline experts to review, and where necessary, update existing scripting such as to accurately reflect current FDA-approved cessation medications.

(Comment 163) Many comments from public health advocacy groups and representatives of quitlines expressed concern about the criterion in proposed § 1141.16(b)(7) regarding providing information, advice, and support that is evidence-based, unbiased, and relevant to tobacco cessation. In particular, comments were concerned about the sentence in the preamble to the proposed rule that states that a cessation resource cannot include derogatory statements regarding cigarette manufacturers, importers, distributors, or retailers, or advocate public policy changes (75 FR 69524 at 69540). These comments asserted that the term ''derogatory statements'' is vague and could lead to challenges from industry. The comments asserted that the tobacco industry has made similar challenges in the context of interpreting the Master Settlement Agreement of 1998.

(Response) We disagree that the term ''derogatory statements'' is vague. Moreover, neither the proposed nor the final version of § 1141.16(b) or (c) includes that term. Instead, § 1141.16(b)(7) states a cessation resource must ''[p]rovide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.'' The focus of the cessation resource should be about changing a

smoker's behavior by providing factual information and evidence-based advice and support about tobacco cessation. Our purpose in adding to the preamble the example about derogatory statements was to emphasize that our chosen cessation resource must not provide biased information about, for example, tobacco companies. The preamble to the proposed rule contrasted derogatory statements as well as statements advocating public policy changes with factual information relevant to tobacco cessation. We conclude that this distinction should be retained in the final rule. Nonetheless, as discussed in the response to Comment 164, the final rule clarifies the distinction between providing factual information, advice, and support and providing biased opinions or advice.

(Comment 164) One comment representing quitlines expressed concern that many of the cessation resource criteria described in proposed § 1141.16(b) and the preamble to the proposed rule may interfere with the ability of counselors at a telephone quitline to tailor information to a specific caller. Specifically, this comment requested that FDA delete many of the criteria or clarify that they refer to the capacity of the quitline overall, and not to each interaction with a caller. Also, this comment requested that FDA either delete the term ''unbiased'' in proposed § 1141.16(b)(7), or define that term to include the concept of tailoring a call to the needs of an individual caller. In addition, this comment asked that FDA remove the word ''unbiased'' from proposed § 1141.16(d)(1) regarding staff training for a telephone quitline.

(Response) We agree that this issue needs to be clarified. It was not our intent that the criteria described in proposed § 1141.16 would limit the ability of the cessation resource to tailor an interaction to the needs of the individual smoker seeking help. In fact, as discussed below, we believe that one of the many benefits of choosing a telephone quitline as the cessation resource is the ability of the resource to tailor counseling sessions to individual callers. Although we do not agree that it is appropriate to delete any of the general criteria or the word ''unbiased'' from § 1141.16(b)(7), we have revised the rule to reorganize the criteria described in proposed § 1141.16(b) and (d). The final rule includes a paragraph (b) describing the types of services that a cessation resource must provide generally. The criteria in § 1141.16(b)(1) through (b)(7) were previously described in proposed § 1141.16(b)(1) through (b)(7), however, we revised the introductory language to clarify that a quitline may tailor individual calls as appropriate to meet the smoking cessation needs of individual callers. Thus, for example, if a caller says that he or she has attempted to quit many times and knows what to expect, the quitline does not need to provide factual information about what smokers can expect when trying to quit. Instead, the quitline might focus the counseling on practical advice about how to deal with common issues faced by users trying to quit or evidence-based information about effective relapse prevention strategies. In addition, we changed ''users'' to ''smokers'' in § 1141.16(b)(3) for consistent terminology with the rest of the paragraph.

The final rule also contains a paragraph (c) in § 1141.16 that addresses general requirements for the cessation resource, rather than the types of information to be provided to consumers seeking information or assistance. Section 1141.16(c) is primarily composed of the criteria in proposed § 1141.16(b)(8) through (b)(10) and (d). Except for the requirements regarding staff training and the maintenance of appropriate controls, this paragraph lists prohibitions for the cessation resource. For example, the cessation resource must not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation. As described more fully in the response to Comment 166, we have clarified that the cessation resource may tailor information about cessation products to meet the particularized needs of an individual caller and may provide particular FDA-approved cessation products to callers, based on availability of those products to the resource. With respect to the comment expressing concern about the use of the term ''unbiased'' in the staff training criterion precluding the ability to tailor information, the revisions to paragraph (b) address concerns about the ability of cessation resource staff to tailor information to the needs of an individual caller. The criterion in paragraph (c) about staff training, when read in conjunction with paragraph (b), does not preclude tailoring of information during individual calls. Therefore, it is unnecessary to delete the term ''unbiased'' from § 1141.16(c)(8) to address this concern. We conclude that the revised criteria in paragraphs (b) and (c) of § 1141.16 will ensure that the cessation resource has the flexibility to provide counseling about smoking cessation that is appropriate to the needs of an individual caller while still ensuring that the resource does not provide opinions, advice, or support that are biased or not supported by appropriate evidence.

(Comment 165) One comment representing quitlines suggested that FDA either delete the criterion described in proposed § 1141.16(b)(10) that prohibits the cessation resource from encouraging ''the use of any non-evidence-based smoking cessation practices,'' or replace the word ''practices'' with ''treatment.'' This comment explained that practices such as coping strategies for dealing with cravings have not been as rigorously tested as medications and may not be considered evidence-based. This comment asserted that the criterion in proposed § 1141.16(b)(3), requiring a cessation resource to provide practical advice about how to deal with common issues faced by users trying to quit, adequately addresses this issue.

(Response) We understand the concerns expressed by this comment and agree that a cessation resource should be permitted to discuss coping strategies for dealing with cravings (*e.g.,* chewing gum) that may not have been rigorously tested in a scientific manner. However, because the distinction between treatment and practices is unclear, we conclude that a broad term such as ''practices'' is appropriate in order to ensure that evidence-based research is being used to provide callers with effective services. Using the broader term ''practices'' also avoids the possibility that definitional questions about whether something is a treatment will interfere with the ability of the cessation resource to provide effective cessation services to smokers. Deleting proposed § 1141.16(b)(10) completely, or replacing the word ''practices'' with ''treatment,'' may result in cessation resources encouraging non-evidence-based practices even though evidence-based practices are available. Section 1141.16(b)(3) permits the cessation resource to provide practical advice, and the practices described in the comment would be considered ''practical advice'' rather than ''non-evidence-based practices.'' In addition, as discussed in the comment, a cessation resource is permitted to tailor each counseling session to the needs of the individual caller.

(Comment 166) FDA received several comments relating to the cessation resource providing or discussing particular smoking cessation drug products. One comment representing a manufacturer of smoking cessation drug products suggested that the Agency permit the resource to provide one or more FDA-approved over-the-counter

cessation products, but not include language in the rule that prohibits the cessation resource from ''advertising or promoting a particular product.'' This comment claimed that there is evidence that recognizable brands of smoking cessation products can be important tools to promote cessation (Ref. 84). Comments representing telephone quitlines and a public health advocacy group requested that FDA clarify that simply mentioning a particular cessation product does not constitute advertising or promoting a particular product, so long as the resource makes clear it does not recommend the use of one cessation product or brand over another.

(Response) The final rule has been revised to clarify that a cessation resource may tailor a discussion of cessation medications for an individual caller. As noted in the preamble to the proposed rule, under the criteria the cessation resource may provide one or more FDA-approved over-the-counter cessation products, provided that it does so in a manner that does not advertise or promote a particular product (75 FR 69524 at 69540). We agree that, in the context of individual counseling, one medication may be suggested over another, based on an individual smoker's health needs and prior experience with cessation medications. For example, a quitline counselor may take into account warnings, precautions, and contraindications identified in the labeling of a specific drug product in relation to an individual caller. Also, a quitline counselor may suggest a particular medication based on the caller's prior experience with cessation medications (*e.g.,* not recommend a medication that previously caused significant side effects or did not work; recommend a medication that worked well in the past). In addition, a cessation resource may provide one or more FDA-approved over-the-counter cessation products, based on availability of the product(s) to the resource. A cessation resource may also mention the availability of free medication, provided it does so in a manner that does not advertise or promote a particular product. However, the resource must not advocate or promote a cessation product, such as by recommending the use of particular cessation products or brands over others to callers generally. All products that have been approved with smoking cessation claims have been found by FDA to be safe and effective for the approved indication. Even if there might be benefits associated with brand recognition for a smoking cessation drug product, we do not believe that it is appropriate for the cessation resource that we include in a required warning to promote any particular product.

(Comment 167) Several comments proposed that additional criteria be added to the criteria proposed in the NPRM. One comment suggested adding an additional criterion that the cessation resource must provide evidence-based advice regarding the protection of children and other nonsmokers from secondhand smoke. This comment reasoned that two of the warning statements address the dangers of secondhand smoke and the cessation resource should be prepared to counsel smokers who seek assistance after seeing these messages. Another comment recommended adding a criterion to prohibit the cessation resource from promoting a tobacco industry cessation program. This comment claimed that research has demonstrated that tobacco industry sponsored cessation resources either have no effect on smoking prevalence or actually cause increased smoking (Refs. 85 and 86). One comment from a submitter representing quitlines recommended the addition of a new criterion that would require the cessation resource to provide proactive, multi-call counseling services. The comment claimed that there is evidence these types of services are effective.

(Response) We recognize that there could be additional criteria for a cessation resource that would require the resource to provide broader services. However, we have designed the criteria in this final rule to focus on the minimum services that must be provided by an effective cessation resource and the minimum standards the resource must meet. We are mindful that existing cessation resources have varied budgets and do not want to require additional standards that, while possibly beneficial, would disqualify some effective treatment programs that do not have the resources to provide these services. We note, however, that the criteria described in § 1141.16 (b) and (c) do not preclude any cessation resource from providing additional unbiased, evidence-based cessation information, advice, and support. With respect to prohibiting the promotion of a tobacco industry cessation program on the basis that they are not effective, we conclude that the addition of a separate criterion is unnecessary. The cessation resource that will appear in the required warnings—1–800–QUIT–NOW—is run by government entities, and the criteria are designed to ensure that the resource provides cessation information, advice, and support that are unbiased and evidence-based.

(Comment 168) One comment recommended that an additional role of a cessation resource should be to direct smokers (who request it) to local specialist face-to-face treatment services and to provide accessible information on Medicaid, Medicare, and other large insurers' coverage for tobacco dependence treatment.

(Response) Our primary objective in requiring that referenced cessation resources comply with the criteria is to ensure that the cessation resource chosen provides evidence-based counseling to help smokers quit. Our criteria are designed to ensure that the cessation resource will continue to meet certain minimum standards. While not required by the criteria in this regulation, a referenced cessation resource is not precluded from providing additional relevant factual information, such as information about reimbursement for tobacco dependence treatments.

c. *Choice of cessation resource.* The NPRM did not specify a particular cessation resource. Rather, it noted that there are a number of possible alternatives, including use of an existing or new quitline or Web site, where smokers and other members of the public can obtain current unbiased, factual smoking cessation information (75 FR 69524 at 69540). Based on the information before the Agency, including the information provided in the comments, we have chosen the Network, which uses the toll-free telephone number 1–800–QUIT–NOW (1–800–784–8669), as the cessation resource to include on all nine required warnings. The Network is the single point of access to reach State-based quitlines in all 50 states, the District of Columbia, Puerto Rico, and Guam. Since 2005, CDC and NCI have partnered with States to create the Network. NCI manages the 1–800–QUIT–NOW telephone number, along with appropriate telecommunications and routing infrastructure, to ensure that calls are transferred to the appropriate State or territory quitline based on the area code of the caller. Calls from U.S. territories that do not have a quitline are routed to an NCI-run quitline. CDC and individual States or territories provide the funding for the quitlines. CDC provides funding through cooperative agreements as part of the National Tobacco Control Program.

As discussed more fully in the context of comments and responses in the following paragraphs, we find that this cessation resource, which was strongly

favored in many comments, will provide people in the United States with access to unbiased, evidence-based smoking cessation information, advice, and support. We have determined that including this cessation resource as part of the required warnings will increase the likelihood that smokers will quit smoking and thereby provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use. Therefore, we conclude that including a reference to 1–800–QUIT–NOW as part of all the required warnings is appropriate for the protection of the public health.

(Comment 169) Comments favoring inclusion of a cessation resource generally preferred the use of a telephone quitline. In particular, most of these comments advocated the use of 1–800–QUIT–NOW. The comments pointed to a robust body of evidence showing that proactive telephone counseling is effective in helping smokers to quit successfully. Several comments cited statistics from individual State quitlines about the types of services provided and success rates. In addition, several comments asserted that quitlines associated with 1–800–QUIT–NOW generally meet the criteria for a cessation resource specified in the NPRM.

Many comments discussed the advantages of choosing 1–800–QUIT–NOW. In support of the choice of a telephone quitline over a Web-based cessation resource, several comments noted the broad penetration of telephone access, including among low income and minority populations. These comments noted that Internet access has much lower penetration among the American public, particularly in many groups with high rates of smoking (*e.g.,* low income, low level of education). Many comments that advocated the use of 1–800–QUIT–NOW noted that it has an existing infrastructure that is available in all 50 states, the District of Columbia, Puerto Rico, and Guam. One comment stated that all quitlines associated with 1–800–QUIT–NOW are at least several years old.

Several comments argued that inclusion of 1–800–QUIT–NOW on cigarette packages could address issues relating to poorer smoking cessation outcomes among racial and ethnic minorities, as well as populations with low income and/or low education. One academic noted that smokers in these groups try to quit as often as other smokers but are less likely to use effective treatments (*citing* Ref. 87). The comment claimed that adding 1–800–QUIT–NOW to the required warnings holds unprecedented potential to close the gaps and disparities in treatment awareness and use. One comment representing a State quitline argued that quitlines can help address racial or ethnic disparities in access to effective tobacco treatment. For example, African-Americans have been significantly overrepresented among quitline callers in California, relative to the proportion of African-American tobacco users in that State. Several comments stated that quitlines provide services in languages other than English, particularly Spanish, and provide materials to important population groups (*e.g.,* youth, pregnant women, racial/ethnic populations). One comment representing a State quitline asserted that quitlines can help address disparities related to socioeconomic status. In California, utilization of quitline service is highest among low socioeconomic status tobacco users. This comment also claimed that the attractiveness of quitlines to tobacco users with low socioeconomic status is related to the fact that services are provided without a charge and are accessible by telephone, eliminating the need to arrange for transportation or child care. According to this comment, these factors can be significant barriers for individuals with modest resources. Another quitline provider stated that quitlines are disproportionately used by the chronically ill and those who are socially and economically stressed. This comment claimed that, arguably, these groups have the greatest need for support because they have a higher prevalence of smoking and are disproportionately affected by tobacco-related health concerns.

One comment representing a public health advocacy group pointed out that designation of a single quitline number would avoid the difficulty of manufacturers having to print different dialing information depending on where the cigarette package will be sold.

(Response) We agree with comments that a telephone quitline is the most effective means of ensuring that all Americans have access to unbiased, evidence-based smoking cessation information, advice, and support. We have decided to use the Network as the cessation resource and its portal number, 1–800–QUIT–NOW, will be included as part of electronic files for the required warnings that are available in the IBR document described in section V.B.4 of this document.

A key factor in our decision is that the evidence regarding the effectiveness of telephone quitlines is well documented. The 2008 PHS Guideline found that quitlines significantly increase abstinence rates compared to minimal or no counseling interventions. The 2008 PHS Guideline also found that use of quitline counseling in conjunction with cessation medication significantly improves abstinence rates compared to the use of medication with minimal or no counseling (Ref. 66 at pp. 91–92; *see also* Ref. 88). Consequently, quitlines are an important part of the HHS Tobacco Control Strategic Action Plan (Ref. 89).

In addition, there is evidence that knowing about the availability of a quitline increases quit attempts and successful cessation even among smokers who do not call the quitline (Ref. 88 (finding ''[t]elephone quitlines provide an important route of access to support for smokers, and call-back counselling enhances their usefulness'')). For example, one study of the effect of a smokers' hotline as an adjunct to self-help manuals found ''it is unlikely that higher abstinence rates among users [of the hotline] accounted for the total differences in outcome between hotline and manual only counties. It is possible that simply knowing that telephone help was there if needed enhanced abstinence even among nonusers'' (Ref. 82). A CDC report hypothesized that a possible explanation is that ''knowledge of cessation services, engendered through promotion, increases tobacco users' belief in the normalcy of quitting, which may lead to increased quit attempts among people who have access to the services, even those who do not use them'' (Ref. 90).

Another factor that we considered in choosing a telephone quitline is that telephone access within the United States is nearly universal. According to a 2010 Federal Communications Commission statistical report, household telephone subscribership in the United States was 96 percent in March 2010. This report shows that, even among households with annual incomes as low as $25,000, telephone penetration was over 90 percent in 2009, including among African-Americans and Hispanics (Ref. 91). Currently, Internet use and broadband penetration is much lower than telephone penetration in the United States, particularly among low income groups, certain racial and ethnic minorities, and households with low education levels (Ref. 92).

Beyond their wide accessibility, quitlines are also successful in helping certain high risk populations and other important demographic groups. One comment asserted that low income and uninsured smokers, those with the

lowest levels of formal education, and those in racial/ethnic populations with the highest smoking rates try to quit as often as other smokers, but are far less likely to use effective treatments. For example, smokers in several racial and ethnic groups attempt to quit as often as or more often than nonminority smokers but use effective treatments less often and have lower success rates (Ref. 66 at p. 156). Similarly, low socioeconomic status smokers or those with limited education express significant interest in quitting and appear to benefit from treatment. However, these smokers are less likely to receive cessation assistance (*Id.* at p. 151). One study concluded that non-Hispanic black and Hispanic smokers who attempted to quit smoking were significantly less likely to use cessation aids, and that this has implications for successful quitting among minority smokers (Ref. 87). Several comments, however, explained that at least some quitlines receive a disproportionate numbers of calls from certain minority or disadvantaged populations (*see, e.g.,* Ref. 93). In light of the overall low rates of calls to quitlines (approximately 1 percent of smokers call quitlines, although this percentage varies by State and how much the State promotes its quitline), even a disproportionately high volume of calls from important demographic groups is not enough to alter the overall quit rates for these groups. However, as discussed in section V.B.6.a of this document, there is strong evidence that there will be an increase in call volume to quitlines after the required warnings appear on cigarette packages and in cigarette advertising. This increase in use of quitlines could have an important impact on high risk and other important demographic groups if they continue to constitute a significant percentage of calls to quitlines.

In addition, a telephone quitline provides an excellent opportunity to tailor counseling sessions and provide additional materials for specific populations. The 2008 PHS Guideline also found that individually tailoring materials to address smoker-specific variables (*e.g.,* support sources available, time lapse since quitting, concerns about quitting) has been shown to be effective and have broad reach (Ref. 66 at p. 92). Several comments noted that virtually all State quitlines associated with 1–800–QUIT–NOW provide specialized materials to special populations, including pregnant women, racial and ethnic populations, and youth. Quitlines can also provide information (*e.g.,* about the negative health consequences of smoking or the health benefits of quitting) to smokers who are not ready to quit but who want additional information.

With respect to our choice of the Network and its telephone number, 1–800–QUIT–NOW, for the quitline cessation resource, we have determined that this resource will fulfill the goal to provide a place where smokers and other members of the public can obtain smoking cessation information from staffed trained specifically to help smokers quit by delivering current, unbiased, and evidence-based information, advice, and support. The quitlines that compose the Network, the telecommunications infrastructure supporting the Network, and the telephone number, 1–800–QUIT–NOW, are already well established and provide smoking cessation services to people throughout the United States. Comments that advocated the use of a specific quitline referred to 1–800–QUIT–NOW as the preferred cessation resource. By using an existing resource, infrastructure, and telephone number, we can leverage the Network's established structure and experience providing cessation services. This choice also avoids the costs associated with establishing a new quitline.

In addition, we agree with comments that the individual State and territory quitlines that are associated with 1–800–QUIT–NOW generally meet the criteria specified in § 1141.16(b). We understand, however, that these quitlines have some differences in funding resources and consequently provide differing levels of service. For example, some State quitlines provide longer hours of service than others. Based on the statistics provided in some comments, it is possible that not all of the individual State and territory quitlines associated with 1–800–QUIT–NOW meet all of the criteria we are adopting in § 1141.16(b). To assure that these criteria are met, CDC will include these criteria beginning with its 2013 National Tobacco Control Program funding opportunity announcement and HHS will monitor the quitlines for compliance with the criteria on an ongoing basis and will take appropriate steps to address any noncompliance.

(Comment 170) One medical organization suggested that the reference to the smoking cessation resource in the required warnings should also include a message encouraging smokers to contact their physician or health care provider. This comment cited studies to support the proposition that physician advice is effective in encouraging smoking cessation (*citing, e.g.,* Ref. 94). This comment also noted that both Australian and European Union graphic warnings recognize the role that physicians play in assisting patients' cessation efforts.

(Response) We agree that physicians, particularly primary care physicians, and other health care providers are a very helpful resource for encouraging smokers to quit (Ref. 66 at p. 35). However, we decline to include language on the required warnings encouraging smokers to see their doctor.

Many Americans do not have an ongoing relationship with a physician. Recent evidence indicates that the United States may be suffering from a shortage of primary care physicians, making it less likely that they would be available to provide cessation information to smokers (*see* Ref. 95 for statistics on decreasing numbers of U.S. medical school graduates selecting a family medicine career). In addition, unlike the selected quitline, we would not have a practical means to monitor health care provider compliance with the criteria the Agency is establishing in § 1141.16(b). Studies indicate that rates of physician adherence to similar practice guidelines for smoking cessation advice vary widely (*see* Ref. 96). For these reasons, it is preferable to include a reference to 1–800–QUIT–NOW on the required warnings. We note, however, that quitlines frequently refer people to their primary care physicians (*e.g.,* if a caller has further questions about the use of medications).

In addition, there is limited space available for including information about a cessation resource. The size of the required warnings is relatively small and the textual warning statement and color graphic image included in each warning must be clear, conspicuous, and legible as required by section 4 of FCLAA. In light of the limited space available, we have determined that including an additional message encouraging smokers to contact their physician or health care provider is not appropriate at this time.

(Comment 171) Some comments urged FDA to include a Web site as a cessation resource. Generally these comments suggested that a Web site would be a useful cessation resource in addition to a telephone quitline. For example, one public health advocacy group noted that there are advantages to utilizing both quitlines and Internet resources. According to this comment, while quitlines provide individualized telephone counseling, a Web site provides support 24 hours per day. One comment from a public health advocacy group claimed that about 10 million smokers search online for smoking cessation assistance every year, and it is

particularly important for the required warnings to include Web-based resources because there are a large number of Internet sites that ostensibly offer quitting assistance but do not offer evidence-based cessation help. Several comments acknowledged that the 2008 PHS Guideline did not find enough evidence to recommend computer-based interventions, but noted that the 2008 PHS Guideline also concluded that these interventions remain promising. Some comments also noted that Internet use is low in many groups with high rates of smoking (*e.g.,* low income, racial and ethnic minority groups). However, several comments advocating inclusion of a Web site resource noted that many cessation services, including many quitlines and health plans, are utilizing the Internet to provide combined telephone counseling and Web-based cessation treatment. One comment suggested that as American culture adopts different forms of communication, it will be important to assess the effectiveness of using new technologies and approaches. This comment encouraged FDA to fund research to learn which approaches will encourage the most people to quit smoking.

One comment from the tobacco industry claimed that reference to a smoking cessation Web site may raise additional implementation issues and requested an opportunity to comment in advance of such a requirement. This comment did not identify any specific issues associated with reference to a smoking cessation Web site.

(Response) We recognize that Web sites are another important source of smoking cessation information and interventions. Although the 2008 PHS Guideline did not recommend the use of Web-based interventions, it concluded that ''[g]iven the potential reach and low costs of such interventions * * * they remain a highly promising delivery system for [treating] tobacco dependence'' (Ref. 66 at p. 94). We also recognize that Internet use is highest among younger populations, and thus might be a useful tool to intervene with young smokers, given that maximum cessation benefits are gained by quitting at a younger age. Furthermore, Web sites can provide information to smokers who are not ready to quit but who are seeking additional information about cessation.

However, we have decided not to include a Web site as the cessation resource incorporated in the required warnings. For the reasons explained more fully above, we find that a telephone quitline is a better overall cessation resource than a Web site. There is stronger scientific support that telephone quitlines are effective, they are more widely available to a broader cross section of Americans, particularly groups with higher rates of smoking and lower access to cessation services, and there is a strong national quitline infrastructure in place. In light of the limited space available on the required warnings and the need to ensure that the graphic images and textual warning statements are clear, conspicuous, and legible, we do not think it is appropriate at this time to include both a telephone quitline and a Web site address on all required warnings. We intend to evaluate this possibility in the future when we are designing and testing revised versions of the required warnings.

d. *Implementation issues.* Proposed § 1141.16(a) stated that a required warning must include a reference to a smoking cessation assistance resource as specified in the IBR document. The preamble to the proposed rule explained that the smoking cessation information would be included as part of the required warning and would not appear outside of the areas specified for the required warning. In other words, the cessation resource would be within the top 50 percent of the front and rear panels of cigarette packages and within the 20 percent of the area of advertisements occupied by the required warning (75 FR 69524 at 69541). We received several comments regarding how a cessation resource should appear in the required warning and other implementation issues relating to inclusion of a cessation resource in the required warning. These comments and our responses are summarized in the following paragraphs.

(Comment 172) A comment representing small tobacco product manufacturers expressed confusion about whether FDA would add the reference to a cessation resource to the required warnings or whether a manufacturer would have to select the cessation resource and incorporate it into the required warning. The comment noted a preference that FDA provide the specific language for the cessation resource. However, one small tobacco product manufacturer asked that FDA provide a variety of options for cessation resources and include those options in the electronic files for the required warnings provided by the Agency.

(Response) We have selected 1–800–QUIT–NOW as the cessation resource that must appear on the required warnings. The required warnings in the IBR document include the reference to the cessation resource, 1–800–QUIT–NOW. We disagree with the request that we provide a variety of options for cessation resources and include those options in the electronic files for the required warnings. Such an approach could be confusing to consumers, because the required warnings would appear with a different cessation resource on different packages of cigarettes and in different advertisements. Also, it would be difficult to monitor many cessation resources to ensure that each one meets the criteria established in § 1141.16(b) and (c). By choosing one, existing toll-free telephone number that is under the control of NCI, provides access to consumers throughout the country, and includes State quitlines that have cooperative agreements with CDC, we have assurances that our cessation resource criteria will be followed.

(Comment 173) Several comments mentioned that an increase in the volume of calls to State quitlines may increase funding needs. These comments suggested that additional resources should be provided to State quitlines.

(Response) We expect that inclusion of 1–800–QUIT–NOW on the required warnings will increase the volume of calls to State quitlines. While some quitlines may currently have some additional capacity, there will likely be need for additional resources. In the fiscal year 2012 President's Budget, there is $25 million from the Prevention and Public Health Fund allocated for CDC to spend on the National Network of Tobacco Cessation Quitlines. Additionally, the Centers for Medicare and Medicaid Services is working with the State Medicaid Directors to permit tobacco quitlines as an allowable Medicaid administrative activity.

(Comment 174) One comment encouraged FDA to require that the cessation resource be displayed as a telephone number (1–800–784–8669) in addition to 1–800–QUIT–NOW because some wireless phones do not have letters on the keypad. However, another comment representing a quitline expressed the view that it is important to use the letters in 1–800–QUIT–NOW rather than the telephone number because it is itself a cogent cessation message.

(Response) We agree there would be benefits to identifying the cessation resource using 1–800–QUIT–NOW as well as the telephone number 1–800–784–8669. However, as explained previously, there is very limited space for identifying the cessation resource. The use of 1–800–QUIT–NOW is a way to provide the number for people to call

while in the same space providing information about what the number is for. Using less space for the cessation resource helps ensure the required warning remains clear, conspicuous, and legible and appears within the specified area. Moreover, the use of letters is likely to be easier for people to remember. The Agency also believes most telephones in use still include letters on keypads and that toll-free telephone numbers are frequently identified using these letters. As stated previously, we will also conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy, including elements related to identifying cessation resources.

(Comment 175) Several comments addressed the words that would signal the appearance of a cessation resource. These comments described experience from New Zealand that showed increases in both quitline number recognition and the number of callers reporting cigarette packages as the source for learning the quitline number after the introduction of new graphic warnings with a redesigned reference to a cessation resource (*i.e.,* ''You CAN quit smoking. Call Quitline 0800 778 778, or talk to a quit smoking provider''). The prior warning said ''For more information call'' next to a telephone number. According to one study, there was a 24 percent increase in reported recognition of the quitline number after this change (Ref. 69). Also, in the first full year after the introduction of the new graphic warnings, the volume of calls to the quitline increased significantly and 26 percent of callers reported cigarette packages as the source of the number (compared to 7.5 percent the prior year) (*Id.,* Wilson 10/10). One academic researcher suggested a short, direct ''call to action'' phrase to motivate cessation behavior. Similarly, another comment from an academic institution suggested that the warnings provide the smoker with avenues to take in order to quit and simultaneously instill confidence in the user that he or she can take action.

(Response) As stated previously, there is limited space for the cessation resource on the required warnings. Therefore, we have determined that the cessation resource will be identified solely by the telephone number 1–800–QUIT–NOW. In the limited space available, we have determined that this telephone number and its context provide sufficient information such that viewers will understand that a call to the telephone number will provide information, advice, and support regarding smoking cessation.

(Comment 176) One comment from an academic institution encouraged FDA to require, in addition to a quitline number, clear encouragement of action steps for quitting. This comment recognized that space on the required warnings is limited and suggested that package inserts and onserts are one way of accomplishing this without compromising the visual impact of the graphic warnings.

(Response) A requirement to add onserts or inserts is beyond the scope of this rulemaking and, therefore, we decline to require them here.

VI. Comments Regarding Implementation Issues

A. Technical Issues Regarding Compliance

Section 1141.12 refers to ''Cigarette Required Warnings,'' which is incorporated by reference (IBR) in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The IBR document includes electronic files of images that must be included on all cigarette packages, and in all cigarette advertisements.

In response to the proposed rule, some comments, including comments from cigarette manufacturers and tobacco industry trade associations, raised issues relating to the electronic files and the implementation of the graphic warnings on cigarette packages and in cigarette advertisements. Those comments, and FDA's responses, are discussed in the following paragraphs.

(Comment 177) Comments from two tobacco product manufacturers stated that they would need to make certain technical adjustments to the single sized graphic warnings published with the proposed rule in order to ensure that the warning fits packaging of varying sizes and shapes. According to the comments, if FDA provided only the single warning format published with the proposed rule, the company would need to adjust the height-to-width ratio (*i.e.,* aspect ratio) of that warning in order to cover 50 percent of the front and rear panels of various package configurations. However, adjusting the aspect ratio, such as by elongating or compressing the warning, could distort the graphic image and/or textual warning statement. These comments recommended that FDA ensure that manufacturers are able to adapt the graphic warnings to fit cigarette packages of varying sizes and shapes and provide guidance about how to adapt the warnings.

(Response) We agree that the size and shape of certain packages might require companies to adapt the electronic files provided in the IBR document. To help prevent distortion of the image and text and to minimize the need for adaptation, we are providing electronic files in different formats designed to fit packaging of various sizes and shapes. We are adding language to the IBR document that provides instructions as to when each of the formats must be used. The instructions are based on the aspect ratio of the display area where the required warning must appear. This language also describes the requirements companies must follow when adapting the electronic files provided in the IBR document. For example, the requirements state that each of the different elements of the warning (*i.e.,* the image, the textual warning statement and reference to the cessation resource) must, to the extent possible, maintain the relative scale and proportions of the elements as displayed in the relevant electronic file, and the positions of each of these elements must be maintained relative to each other.

(Comment 178) Two comments from cigarette manufacturers requested clarification concerning how companies should incorporate the required warnings on packages with hinged lids. These comments stated that the content of warnings printed on the hinged lids can shift up or down by about 1 mm at the point where the lid meets the front of the pack due to normal variations in production of the packaging. These comments recommended that FDA design the warnings with all text located either above or below the hinged lid, or allow for minor variations in how the graphic warnings appear on cigarette packs due to this manufacturing variability.

(Response) We agree that the integrity of the warning must be maintained on packages to ensure that the warning is clear and legible. To clarify the requirements that companies must follow when they adapt the electronic files for hinged lid packages, we have added language to the IBR document that permits companies to separate two lines of text within the textual warning statement so that the line at the location where the lid is to open cuts across the background space between two lines rather than through a line of text. This provision will allow companies to adapt the electronic files provided in the IBR document to ensure that the textual warning statement is not severed when the package is opened and is clear, conspicuous, and legible in accordance with section 4 of FCLAA. According to this language in the IBR document, companies are specifically prohibited from severing any word in the textual

statement and are required to ensure that the integrity of the warning will be restored when the package is closed. We note that product packages with hinged lids are widely prevalent in countries that already require graphic warnings and, based on that experience, we conclude that this new provision should provide companies with the flexibility that they need for displaying the warnings on packages with hinged lids.

(Comment 179) Two comments, from a cigarette manufacturer and a tobacco company trade association, raised a concern about incorporating the required warnings on ''soft pack'' style packaging. These comments stated that ''soft pack'' style packaging is manufactured through a process in which the top of the package is folded down after cigarettes are inserted and held together by a small overwrap closure, or ''stamp.'' Historically, the closure is made of opaque paper and applied with glue to hold the package in place. According to these comments, the closure hangs down approximately 0.375 inches over the top center of the front and back panels of the package. The closure would obstruct any text or image appearing under it. According to these comments, it is not technically feasible to make a clear or transparent closure that will adhere to the package. One comment recommended that FDA amend the proposed rule to permit that graphic warnings for soft packs appear at the bottom of the individual pack, or to specifically allow the closures at the top center of the pack. The other comment recommended that FDA use enforcement discretion to permit the closure on soft packs until a technologically feasible solution is developed.

(Response) We recognize the technological difficulty of incorporating the required warnings on ''soft pack'' style packaging. Given the paramount need to incorporate the warning without obstructing any of the discrete elements of the warning (*i.e.,* the image and the textual warning statement) or the reference to a cessation resource, the final rule permits companies to adapt the warnings on ''soft pack'' style packaging by moving the warning below the closure in accordance with the requirements included in the IBR document. The IBR document states that this is only permitted when it is not technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the warning as set out in the electronic files provided in the IBR document. The requirements included in the IBR document allow companies using ''soft pack'' style packaging only to move the upper boundary of the display area of the warning so that it runs along a line that is parallel to and not more than 0.375 inches from the top edge of the package. The companies compress the vertical size of the image and then shift it down (so that it stays within the top 50 percent of the package). This language also requires companies who do this to ensure that, to the extent the file must be adapted to fit the dimensions of the warning area below the closure, the proportions of the required warning must be maintained. In addition, the instructions in the IBR document specify that the closure and the portion of the packaging that appears between the top edge of the package and the upper boundary of the display area of the required warning must be either solid black or solid white. This will allow companies to continue to produce ''soft pack'' style packaging with closures at the top center of the pack without obstructing the required warning. However, if we determine that it would be technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the warning as set out in the electronic files provided in the IBR document, we plan to notify the regulated companies and the public of this conclusion and give regulated companies a reasonable amount of time to modify their packaging before any regulatory action is taken under this rule. We decline to change the final regulation to permit graphic warnings on ''soft pack'' style packaging to appear at the bottom 50 percent of the packaging. We have determined that requiring that the warnings appear in the upper portion of the package, as specified by the Tobacco Control Act, will result in warnings that are more prominent, more salient, and more effective than warnings appearing at the bottom of the package.

(Comment 180) Two comments, from a cigarette manufacturer and a tobacco company trade association, noted that cigarette packages are typically wrapped in clear cellophane with a tear tape located in the upper 50 percent of the package. The tear tape permits an individual to open the package, and usually is removed once the package is opened for the first time. One comment stated that the cellophane tear tape will obstruct the required warning when the cigarette package has not yet been opened for the first time, and recommended that FDA expressly permit the use of tear tapes and require that warnings for ''soft pack'' style packaging appear at the bottom of the packaging. The other comment recommended that FDA permit the use of tear tapes and that the Agency use enforcement discretion to allow companies to potentially obstruct the required warning before the package is opened for the first time.

(Response) We have determined that companies can use cellophane tear tapes, and the final regulation does not prohibit such use on cigarette packaging. We further have determined that it is technologically feasible to use clear tear tape in a manner that does not obstruct the required warning before the cigarette package is opened for the first time, and note that clear tear tape is widely used on product packaging in other countries that require graphic warnings. We are not aware that this has created any substantial technical difficulty in the production of cigarette packages, nor are we aware that clear tear tape has led to any significant obstruction of the graphic warnings. If a company has a unique problem with regard to its packaging, it should raise this issue with us, and the difficulty can be addressed on an individual basis. We decline to change the final regulation to allow the required warnings to appear on the bottom 50 percent of the packaging. We have determined that requiring that the warnings appear in the upper portion of the package, as specified by the Tobacco Control Act, will result in warnings that are more prominent, more salient, and more effective than warnings appearing at the bottom of the package.

(Comment 181) Comments from two companies raised concerns about their ability to incorporate the required warnings in advertisements of varying sizes and shapes. These comments noted that the proposed FDA rule requires that companies maintain the aspect ratio of the warnings as set forth in the electronic files. The comments stated that it would not be possible to maintain the clarity of the warning in certain advertisements if companies are required to use the 4:3 aspect ratio set out in the advertisement format published with the proposed rule. One company recommended that FDA provide warnings with different aspect ratios (1:1, 1.5:1, 1:2, 2:1, and 2.5:1) to address this concern. The other company recommended that FDA either eliminate the requirement that companies maintain the aspect ratios set out in the electronic files or allow companies to adjust the layout of the warnings so long as the manufacturer includes both the image and the textual warning statement.

(Response) We have revised the proposed IBR document and the

electronic files provided in the final IBR document include warnings designed with a variety of different aspect ratios. Specifically, the files are designed with aspect ratios of 1:1, 1.5:1, 1:2, 2:1, and 2.5:1. As provided in § 1141.10, the required warnings must be accurately reproduced in advertisements. Therefore, companies should choose an aspect ratio that is appropriate for the dimensions of their advertisement such that the required warning can be reproduced accurately once it is sized (*i.e.,* expanded or compressed) to occupy the required area of the advertisement. These files will permit companies to incorporate the required warnings into their advertisements without significant distortion or loss of clarity.

(Comment 182) One comment from a tobacco product manufacturer recommended that FDA provide 5.5 inch wide and 27 inch wide formats for advertisements. The comment stated that expanding a required warning more than 150 percent or compressing it down to less than 30 percent of the original image will result in a loss of image clarity. The comment stated that providing required warnings in the 5.5 inch and 27 inch sizes will allow it to incorporate the warnings into the range of advertisements it uses without any loss of clarity.

(Response) The electronic files provided in the IBR document include formats for advertisements in 5.5 inch wide and 27 inch wide sizes.

(Comment 183) One comment from a tobacco product manufacturer noted that FCLAA requires advertising warnings to have a rectangular border that is the width of the first down stroke of the capital ''W'' of the word ''WARNING'' in the textual warning statements. The comment went on to state that FDA's various proposed required warnings have different-sized ''W's'' in the word ''WARNING,'' and requested that FDA permit manufacturers to apply a uniform border width across the nine required warnings for consistency.

(Response) The electronic files provided in the IBR document have a uniform border built into the formats for required warnings to be used in advertisements. We have exercised our authority under section 201 of the Tobacco Control Act to adjust the statutory requirement that the border of the warning be the width of the first down stroke of the letter ''W'' in the word ''WARNING'' in the textual warning statement. A uniform border requirement for all advertisements will ensure that the warnings are clear, conspicuous, and legible, and appear within the specified areas, especially given the variety of font styles included in the nine selected warnings.

(Comment 184) Several comments requested that FDA provide fonts for the textual warning statements in each of the required warnings.

(Response) For English and Spanish language warnings, the font size and font style is built into the electronic files provided in the IBR document. For advertisements in foreign languages other than Spanish, companies must comply with the font size requirements in section 4(b)(2) of FCLAA and any format requirements included in the IBR document. In all situations, it is the advertiser's responsibility to ensure that the textual statements appear in conspicuous and legible type and that the required warning complies with the format specifications set forth in section 4 of FCLAA.

(Comment 185) One comment requested that FDA provide instructions on how companies should combine and display the images developed for use in small advertisements less than 12 square inches with the required textual warning statements.

(Response) We recognize that the small size of these advertisements presents additional challenges. We are providing an electronic file of the graphic that must be used for warnings appearing in advertisements that are less than 12 square inches. Companies may combine the graphic and the textual warning statement or otherwise adjust the layout of the warning so long as each warning includes the specified graphic and an appropriate textual warning statement. It is the advertiser's responsibility to ensure that the textual warning statement appears in conspicuous and legible type and that the combined warning complies with the format specifications set out in section 4 of FCLAA.

(Comment 186) Several comments recommended that FDA require that companies reproduce the color graphics in the industry standard four-color (CMYK) printing process.

(Response) The electronic files provided in the IBR document were built with CMYK printing standards. The directions in the IBR document specify the use of CMYK printing standards.

(Comment 187) One comment requested that FDA make available ''printers proofs'' for each of the required warnings in order to ensure optimal clarity.

(Response) We have determined that the electronic files provided in the IBR document will be adequate to ensure necessary clarity. Thus, we do not believe it is necessary to provide ''printers proofs'' for the warnings.

(Comment 188) One comment requested that FDA adopt required warnings with consistent dimensions to allow for accurate incorporation into manufacturers' packages and advertisements.

(Response) We decline to adopt this recommendation. As discussed previously, our selection of the nine final required warnings was based in part on our desire for a diverse set of warnings in a variety of different styles (*e.g.,* photographic and illustrative, different fonts and font sizes) and diversity of human images (*e.g.,* race, gender, age) in order to reach the broadest range of target audiences. We have determined that this variety will enhance the effectiveness of the warnings and help to delay potential wear out of the warnings. Because of the diversity of styles and images, some warnings have slightly different dimensions than others.

(Comment 189) One comment recommended that FDA provide layered high resolution .tif or .eps files, with text supplied as a separate layer. Another comment recommended that FDA provide images as .jpeg files.

(Response) The electronic files included in the IBR document are built as .eps files, with separate layers for text and images. Companies will be able to convert the files into .jpeg files if needed.

B. Textual Statement Color Formats

In the document entitled ''Proposed Required Warning Images'' included in the docket for the NPRM, FDA provided two formats for each proposed required warning; one with the warning statement in white text on a black background and one with the warning statement in black text on a white background, under section 4(a)(2) and (b)(2) of FCLAA. Several comments offered suggestions regarding the use of the color combinations, which we have summarized and responded to in the following paragraphs.

(Comment 190) A few comments suggested that FDA specify that the required warnings on cigarette packages and advertisements contain required warnings in *either* the white text on black background format or the black text on white background format, whichever the Agency chooses to most effectively communicate the warnings.

(Response) We disagree. Section 4(a)(2) of FCLAA states that for cigarette packages, the ''text shall be black on a white background, or white on a black background.'' Similarly, for advertisements, section 4(b)(2) of

FCLAA states that the text of the statement in the required warning ''shall be black if the background is white and white if the background is black.'' We interpret these statutory requirements to mean that companies can use either of these two text/background color combinations on the package or in the advertisement.

(Comment 191) One comment recommended that the word ''CANCER'' always appear in red as part of the health warnings on cigarette packages and advertisements.

(Response) We disagree. As stated previously, section 4(a)(2) and (b)(2) of FCLAA prescribe the colors for the textual statements on packages and advertisements (*e.g.,* white text on black background or black text on white background). FDA has the authority to change the format of the textual statements if such a change would promote greater understanding of the health risks associated with cigarette smoking. If we determine at a later date, that requiring the word ''CANCER'' to appear in red font will promote a greater understanding of smoking's risks, we may propose new iterations of the required warnings in future rulemakings.

C. Random Display and Rotation of Warnings

The proposed rule did not specifically address the statutory requirements for the warnings on cigarette packages to be randomly displayed in each 12-month period and for quarterly rotation of warnings in advertisements, under section 4 of FCLAA. However, FDA received several comments on this issue. These comments, and FDA's responses, are included in the following paragraphs.

(Comment 192) One comment expressed concern that cigarette manufacturers may only use some of the nine new required warnings on their cigarette packages and requested that FDA require companies to use all the required warnings in equal numbers.

(Response) We agree that all cigarette manufacturers must use all of the nine required warnings on their cigarette packages. Section 4(c)(1) and (c)(3)(B) of FCLAA expressly requires that the nine required warnings must be randomly displayed in as equal a number of times as possible on each brand of cigarette product and be randomly distributed in all areas of the United States so that all of the required warnings appear in the marketplace at the same time.

(Comment 193) One comment recommended that retailers be exempted from any requirement to rotate the required warnings for each brand they sell in stores.

(Response) We decline to address this issue here, as it is beyond the scope of the current rulemaking.

(Comment 194) Several comments recommended that FDA rotate the graphic warnings to prevent overexposure. The comments also noted that different warnings will have different impacts on the various segments of the population, further emphasizing the need to rotate the warnings.

(Response) It is unclear whether these comments were referring to the quarterly rotation of the required warnings in advertisements or the need to refresh the warnings on a regular basis. We agree that rotation of the warnings is important to delay wear out and to ensure that all population segments are exposed to the different warnings in as equal a number of times as is possible. In accordance with section 4(c)(2) of FCLAA, the required warnings must be rotated quarterly in cigarette advertisements. See section II.E of this document for additional information regarding FDA's efforts to delay or prevent wear out.

(Comment 195) One comment recommended that FDA monitor the rotation of required warnings in cigarette advertisements to ensure compliance by all manufacturers, distributors, importers, and retailers.

(Response) We agree with this comment. We will monitor rotation and ensure compliance, which will include the review and approval of warning plans submitted to the Agency in accordance with section 4(c) of FCLAA.

(Comment 196) One comment suggested that manufacturers be given broad discretion in complying with the requirements that they include the required warnings on all cigarette packages such that in each 12-month period all of the different warnings appear in as equal a number of times as is possible on each brand of the product (*see* 15 U.S.C. 1333(c)). The comment stated that its printing machines, and in particular the print cylinders, used to produce ''soft pack'' style packaging only allows the company to print five images per roll and does not allow for warnings to be die cut and collated. Because ''soft pack'' style packaging only accounts for about 10 percent of all packages distributed and sold, this style of packaging frequently is printed in small batches and for some, is printed only once per year. The comment stated that in light of these production constraints, it would be impossible to apply and distribute ''soft pack'' style packages displaying the nine required warnings randomly and in approximately equal numbers. The comment recommended that, for ''soft pack'' style packages, FDA apply a policy of enforcement discretion that relieves companies of the obligation to display the nine required warnings randomly and equally as long as companies have taken reasonable steps to distribute the warnings as randomly and equally as possible. Another comment expressed general concerns about a manufacturer's ability to comply with the requirement that the warnings be randomly displayed in as equal a number of times as possible.

Several comments requested additional guidance on the filing of warning plans, including how to hold parties responsible for meeting FCLAA and the Tobacco Control Act's rotation and random display requirements.

In addition, one comment asked that FDA adopt a formal process for approval of required warnings on packages and warning plans. Some comments from manufacturers suggested that, to add predictability for companies on the transition to the new warnings, FDA should consider adopting a procedure to allow pre-approval or pre-submission review of cigarette packaging and advise manufacturers of any deficiencies so the manufacturer can remedy them before production. One comment requested that FDA use Federal Trade Commission (FTC) procedures for pre-approval review of packaging.

(Response) We have opted not to address these issues as part of this rulemaking proceeding. Under section 4(c) of FCLAA, warning plans must be submitted to FDA for approval. As noted in the NPRM, we intend to separately address the requirements of section 4(c) of FCLAA related to the submission of plans regarding the random display of warnings on packages and rotation in advertisements (75 FR 69524 at 69538). This is still our plan, and we believe the issues raised in these comments would be better addressed in that context.

(Comment 197) One comment suggested that FDA provide sample pre-approved layouts for required warnings on cigarette packages.

(Response) By providing the electronic files of the required warnings, we are providing formats that the companies must use for their packages. The final rule includes a document incorporated by reference, entitled ''Cigarette Required Warnings,'' which contains the final images to be required on cigarette packages. Cigarette manufacturers also should refer to § 1141.10(a), which mandates that the required warnings be on the top 50

percent of both the front and back of the cigarette packages.

(Comment 198) One comment requested that FDA issue a tobacco product advertising guide for industry. This comment noted that while product labeling and advertising present some similar issues, there are specific issues that relate solely to advertising communications with consumers. Another comment suggested that FDA should issue separate advertising guidance for industry that includes recommendations for display of required warnings in each common advertising form.

One comment stated that FDA should require that cigarettes displayed at the point of sale should be required to be displayed in a manner so that the graphic warnings are visible.

One comment submitted on behalf of several nonprofit organizations suggested that FDA modify proposed § 1141.10 to include two paragraphs regarding the use of images of cigarette packs in advertisements and in other communications. They requested that FDA add one paragraph to state that any image of a cigarette pack in an advertisement must include a required warning on the cigarette pack image. In addition, they requested that FDA add a paragraph to state that no manufacturer, importer, distributor, or retailer may alter any image used to depict cigarette packs as legally distributed or sold to consumers in any public communication (including, but not limited to, movies, Web sites, and television programs) so that the required warning on the cigarette pack image is removed or obscured in any way.

(Response) We recognize that the range of advertising materials covered by the new graphic warning rules may create additional complexities. As stated previously, we intend to issue separate regulatory documents to provide information on compliance with the random display and rotation requirements. We will consider whether any other actions that are within the scope of our authority under the Tobacco Control Act may be warranted, such as addressing requests for additional guidance regarding advertising or suggested regulatory changes.

VII. Legal Authority and Responses to Comments

A. FDA's Legal Authority

As set forth in the preamble to the proposed rule (75 FR 69524 at 69524 through 69525), the Tobacco Control Act provided FDA with the authority to regulate tobacco products, and section 201 of the Tobacco Control Act modifies section 4 of FCLAA to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements and to require that ''the Secretary [of Health and Human Services] shall issue regulations that require color graphics depicting the negative health consequences of smoking'' to accompany the nine new health warning statements.

Under section 4(d) of FCLAA (as amended by section 201(a) of the Tobacco Control Act), FDA may adjust the type size, text, and format of the required warnings as FDA determines appropriate so that both the textual warning statements and the accompanying graphics are clear, conspicuous, and legible and appear within the specified area. Furthermore, section 202(b) of the Tobacco Control Act amends section 4 of FCLAA to permit FDA to, after notice and an opportunity for the public to comment, adjust the format, type size, color graphics, and text of any health warning statement if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In addition, provisions of the FD&C Act provide authority to require disclosures. For example, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)) authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products, including restrictions on the advertising and promotion of such products, if FDA determines the restriction is appropriate for protecting the public health.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product advertising and labeling include proper warnings (*see* 21 U.S.C. 321(n); 387c(a)(1), (a)(7)(A), (a)(7)(B), and (a)(8)(B)). In addition, under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has authority to issue regulations for the efficient enforcement of the FD&C Act.

While we did not receive comments regarding our authority to issue these regulations under the provisions referenced in the previous paragraphs, we did receive comments regarding the constitutionality of the warning requirements, which are summarized and responded to in sections VII.B and VII.C of this document.

B. First Amendment Commercial Speech Issues

FDA received several comments related to First Amendment commercial speech issues. These comments are summarized and responded to in the following paragraphs.

(Comment 199) Several comments from the tobacco industry, advertising industry associations, and private citizens expressed concern that the graphic warning requirements proposed by FDA violate the First Amendment of the United States Constitution. Specifically, comments alleged that the proposed required warnings are unconstitutional because, rather than conveying factual information to consumers, they contain ''disturbing,'' ''lurid'' images that are designed to elicit emotions, such as ''loathing, disgust, and repulsion.'' Thus, the comments state, they force tobacco companies to ''stigmatize their own products'' and compel them to convey the government's ''ideological message'' that ''the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them'' and that no one should use these lawful products. The comments also asserted that the warning requirements are unjustified because the health risks of smoking are already well known, and that they are unduly burdensome because the size and positioning requirements for the warnings on packages and advertisements would effectively rule out the companies own attempts to convey information about their products. For these reasons, the comments asserted that the graphic warning requirements constitute compelled speech regulation that is content-based and presumptively invalid and that the requirements can only be upheld if they satisfy strict scrutiny, *i.e.,* if they further a compelling government interest by the least restrictive means available. The comments stated that the graphic warning requirements cannot satisfy this standard because they will have no material impact on consumers' beliefs about the health risks of smoking or on smoking behavior and because the government bypassed less speech-restrictive alternatives in favor of the requirements.

The comments from the tobacco industry also stated that the warning requirements violate the First Amendment because they restrict tobacco companies' speech. They stated that requiring the warnings to occupy the top 50 percent of the front and back display panels of cigarette packages and the top 20 percent of cigarette advertisements impairs the communication value of the tobacco product manufacturers' trademarks and trade dress and narrows their avenues of communications with adult smokers, which are already limited because of the

Master Settlement Agreement and the other requirements of the Tobacco Control Act. Indeed, one of the comments argued that relegating tobacco companies' message to the bottom half of cigarette packages would render their speech on packaging ''wholly ineffective'' and that the collective requirements with respect to packaging and advertisements would ''effectively rule out'' the companies' attempts to convey information about their products to consumers. The comments asserted that the warning requirements do not satisfy the test governing restrictions on commercial speech articulated by the Supreme Court in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission,* 447 U.S. 557 (1980), which requires that government restrictions on commercial speech directly advance a substantial government interest and be no more extensive than necessary to serve that interest. Similar to their assertions with respect to compelled speech, the comments asserted that, to the extent that the warning requirements restrict speech, they do not pass muster under the First Amendment because they will have no material impact on consumers' beliefs about, or understanding of, the health risks of smoking or on smoking behavior, and because the government bypassed less speech-restrictive alternatives in favor of the requirements.

Other comments, including comments from a law firm, a public health advocacy group, and a private citizen, disagreed that the warning requirements violate the First Amendment. Specifically, two comments noted that the warning requirements have been upheld by a Federal court in *Commonwealth Brands* v. *United States,* 678 F. Supp. 2d 512, 529–32 (W.D. Ky. 2010), *appeal pending sub nom., Discount Tobacco City & Lottery, Inc.* v. *United States,* Nos. 10–5234 & 10–5235 (6th Cir.). One comment noted that the court rejected an argument that the new warnings required under the Tobacco Control Act are too large and too prominent and stated that Congress has made findings with respect to the required size of the warnings, their placement on packages and advertisements, and the text of the warnings based on a substantial record. The comment also stated that Congress' findings are supported by the voluminous authority cited in FDA's NPRM. Another comment stated that, although tobacco companies will have to redesign their packages as a result of the warning requirements, they will still be able to communicate with their customers through packaging, advertising, and other channels. In addition, the comment stated that the warning requirements do not offend manufacturers' First Amendment rights because the required warnings are factual disclosures that accurately depict the real consequences of smoking cigarettes and the benefits and importance of quitting. The comment asserted that the warning requirements support the public interest by providing consumers with truthful information that is helpful in making informed purchasing decisions. The comment also stated that the government constitutionally regulates the advertising and labeling for a wide variety of industries in the interest of providing consumers with accurate information about products that affect their health and that no product affects consumers' health more than cigarettes. Finally, one comment stated that requiring warnings for cigarettes is well established legally and that the addition of graphic images to the warnings represents a difference in form that will not change the fundamental message content of the warnings. As a result, the comment concluded that there is no constitutional basis to delay the implementation of the warning requirements.

(Response) We have carefully considered these comments and we disagree that the warning requirements violate the First Amendment under either of the theories set forth in the comments. To the extent that the warning requirements compel commercial speech, they are permissible under *Zauderer* v. *Office of Disciplinary Counsel of Supreme Court of Ohio,* 471 U.S. 626 (1985), and to the extent that they restrict commercial speech, they satisfy the *Central Hudson* requirements.

The Warning Requirements Permissibly Compel Disclosure of Factual Information. The comments do not dispute that required warnings and other disclosure requirements ''trench much more narrowly on an advertiser's interests than do flat prohibitions on speech'' and may appropriately be required ''in order to dissipate the possibility of consumer confusion or deception'' (*Zauderer,* 471 U.S. at 651 (citation omitted)). Accordingly, regulations that compel ''purely factual and uncontroversial'' commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech and will be sustained if they are ''reasonably related'' to the government's asserted interest (*Id.; see also Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 130 S. Ct. 1324, 1339 (2010) (disclosure requirements are subject to ''less exacting scrutiny'' than affirmative limitations on speech)). ''Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests'' (*Nat'l Electric Manufacturers Ass'n* v. *Sorrell,* 272 F.3d 104, 113–14 (2d Cir. 2001), *cert. denied,* 536 U.S. 905 (2002)). Instead, such disclosure advances ''the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas' '' (*Id.* at 114). ''Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech'' (*Id.*).

The nine new health warning statements and the accompanying graphic images selected by FDA convey information that is factual and uncontroversial. Therefore, the warning requirements are subject to the ''reasonable relationship'' test in *Zauderer,* rather than strict scrutiny as suggested by some of the comments.

The comments do not dispute that the warning statements are true. Indeed, as detailed in the NPRM and in section II.A.2 of this final rule, there is substantial scientific evidence to support the information conveyed in the new required warnings. The NPRM summarizes a large body of scientific evidence showing that cigarettes cause a wide range of negative health consequences, including various types of cancer; all the major cardiovascular diseases, including heart disease and stroke; COPD and other respiratory diseases; and a variety of negative health effects in infants born to women who smoke and in nonsmokers exposed to secondhand smoke (75 FR 69524 at 69527 through 69529). The NPRM also sets forth scientific evidence describing the negative effects of nicotine addiction and the major and immediate health benefits of smoking cessation (75 FR 69524 at 69528 through 69529). As the court in *Commonwealth Brands* correctly observed, the content of the warnings ''is objective and has not been controversial for many decades'' (*Commonwealth Brands,* 678 F. Supp. 2d at 531).

The images we have selected to accompany the nine warning statements also convey information that is factual and uncontroversial regarding the negative health consequences of smoking. These images are consistent with the information conveyed in the

accompanying textual warning statements; each image depicts themes and subjects that provide visual context for the textual warning statements. The images also play a crucial role in the communication of the textual warning information; as discussed extensively in the NPRM, the addition of graphic images to health warning messages causes consumers to notice and attend to the warning information in the first instance, and increases recall of the warning message and the depth of cognitive processing of the message (75 FR 69524 at 69531).

The comments did not dispute that the images proposed to accompany the warning statements accurately depict the negative health consequences of smoking. Rather, they faulted our proposed images for being ''disturbing'' or eliciting emotions. For example, one of the comments cited as disturbing several of the images selected by FDA in this rule, including the images entitled ''hole in throat,'' depicting a man smoking through a tracheostomy opening; ''healthy/diseased lungs,'' depicting healthy lungs juxtaposed with lungs damaged by smoking; ''cancerous lesion on lip,'' depicting a lesion consistent with that caused by oral cancer; and ''man with chest staples,'' depicting a man with an autopsy scar. The comment did not assert, however, that the effects shown in the images are false, *i.e.,* that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death. The fact that the images are disturbing or evoke emotion does not mean that they are not factual representations of the effects of smoking. In fact, the severe, life-threatening and sometimes disfiguring health effects of smoking conveyed in the required warnings *are* disturbing and the images we have selected appropriately reflect this fact. As such, it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen. If the required warnings failed to elicit emotional reactions, they would also fail to communicate the described negative health consequences of smoking in a truthful, forthright manner.

Some comments also stated that ''non-factual cartoon images'' proposed by FDA remove any doubt that the proposed warnings convey an ideological message. For this final rule, one of the images we have selected is, indeed, a graphic illustration. That image shows a ''baby in incubator'' and accompanies the warning statement, ''Smoking during pregnancy can harm your baby.'' As set forth in the NPRM, there is ample evidence to show that smoking during pregnancy has negative effects, including increasing rates of preterm delivery and shortened gestation and increasing the likelihood of low birth weight infants, among other things (75 FR 69524 at 69528). Thus, the image ''baby in incubator'' accurately depicts the health consequences smoking during pregnancy can have for infants born to mothers who smoke. The style of the depiction—here, a graphic illustration—does not make it less factual. The style is just a means to convey the information.

The remaining images we have selected also factually depict the negative health consequences of smoking when viewed in context with their accompanying warning statements. As explained in section III of this document, the image ''smoke approaching baby'' accompanying the statement ''WARNING: Tobacco smoke can harm your children'' effectively conveys the factual message that exposure to tobacco smoke is harmful for children by realistically showing a baby being exposed to secondhand smoke. The image ''oxygen mask on man's face,'' which accompanies the statement ''WARNING: Cigarettes cause strokes and heart disease,'' accurately depicts a typical intervention for a patient suffering acute cardiac distress or stroke. The image ''woman crying,'' which is paired with the statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers,'' is a realistic portrayal of the emotional suffering experienced as a result of disease caused by secondhand smoke exposure. Finally, the image ''man I Quit t-shirt,'' which is paired with the statement ''WARNING: Quitting smoking now greatly reduces serious risks to your health,'' realistically portrays an image of a man that is consistent with and supportive of this factual warning statement, although, unlike the other required warnings, this warning is framed in a positive manner (*i.e.,* it conveys factual information about the negative health consequences of smoking by educating consumers about the positive health consequences of refraining from smoking).

The comments also asserted that some of the proposed images, including some now selected by FDA in this final rule, appear to use technologically-enhanced photographs to emphasize the effects of sickness and disease. While we acknowledge that some of the photographs were technologically modified to depict the negative health consequences of smoking, the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking, and the comments did not dispute this fact.

As one of the comments noted, the addition of graphics to warnings for cigarettes is a difference in form only and does not change the fundamental content of the messages, which convey factual information about the health consequences of smoking. The court in *Commonwealth Brands* was correct when it stated that it ''does not believe that the addition of a graphic image will alter the substance of such [warning] messages, at least as a general rule'' (*Commonwealth Brands,* 678 F. Supp. 2d at 532). Rather, these images alter the effectiveness of the warnings by enhancing their ability to communicate factual information to consumers.

Despite the factual nature of the messages conveyed by the required warnings as described previously, some comments asserted that the government's goal is to force cigarette companies to stigmatize their products by including the government's ideological, antismoking message on their packages and advertisements. These comments claimed that the size of the warnings and the FDA study endpoints assessing consumers' emotional and cognitive reactions to the required warnings and whether the warnings were ''difficult to look at,'' belie any suggestion that they are purely factual.

We disagree with these comments. The size of the warnings and their ability to evoke cognitive and emotional responses are consistent with the government's interest in ensuring that the required warnings effectively communicate factual information about the negative health consequences of smoking to consumers. The NPRM (75 FR 69524 at 69531 through 69534) and section II.D of this final rule summarize the significant research literature supporting FDA's conclusion that larger, graphic warnings more effectively communicate health risks to consumers than the existing smaller, text-only warnings on cigarette packages and in advertisements.

Likewise, our decision to use images that elicit strong cognitive and emotional responses is consistent with established models of risk communication. Our research study included three measures to assess the salience (*i.e.,* noticeability and readability) of the proposed required warnings: Emotional reactions, cognitive reactions, and whether the warning was difficult to look at. Use of

these measures is well-established in the scientific literature. As discussed in the study report (Ref. 49, study report) and in comments discussed in section III of this document, risk information is most readily conveyed by warnings that elicit strong responses on these measures—eliciting strong emotional and cognitive reactions to graphic warnings enhances recall and information processing, which helps to ensure that the warnings are better understood and remembered. These responses in turn influence short-term outcomes, such as later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke, and eventually lead to long-term changes in behavior. Thus, contrary to the comments discussed previously, our use of these reaction measurements does not demonstrate the Agency's intent to stigmatize tobacco products. Rather, these measures are appropriate indicators of how effectively health warning messages are communicated, and were used in FDA's research study to provide valuable information regarding the relative ability of the 36 proposed required warnings to effectively convey the very real adverse health consequences of smoking to the public.

Indeed, the court in *Commonwealth Brands* rejected an argument that the purpose of the new, larger warnings with their graphic image component is to ''browbeat potential tobacco consumers'' with the government's antismoking message. The court stated that ''the government's goal is not to stigmatize the use of tobacco products on the industry's dime; it is to ensure that the health risk message is actually *seen* by consumers in the first instance'' (*Commonwealth Brands,* 678 F. Supp. 2d at 530 (emphasis in original)). We agree with these findings of the district court.

Because the warning requirements compel the disclosure of information that is purely factual and noncontroversial, they are permissible under *Zauderer* if they are reasonably related to the government's asserted interest. As stated repeatedly in the NPRM and this rule (*see, e.g.,* section II.D of this document), the Agency's primary interest is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements, a necessary part of which, as the court in *Commonwealth Brands* recognized, is ''to ensure that the health risk message is actually *seen* by consumers in the first instance.'' The warning requirements are clearly reasonably related to this interest.

Both the research literature and FDA's study of the proposed required warnings indicate that the required warnings are effective at communicating the health consequences of smoking to consumers. We have cited extensive literature in the NPRM and in section II.D of this final rule discussing the greater effectiveness of larger, graphic warnings over the current warnings at getting consumers' attention (*see* 75 FR 69524 at 69531 through 69532). For example, in one study in which students were shown images of the Canadian graphic warnings and the current warnings in use in the United States, the Canadian graphic warnings significantly increased aided recall of the warnings, increased depth of message processing, and increased the perceived strength of the message (75 FR 69524 at 69531, *citing* Ref. 97). In addition, as discussed in section III of this document, FDA's study report (Ref. 49) demonstrates that eight of the nine required warnings selected for the final rule showed highly significant effects relative to the text-only control on all the salience measures (emotional reaction scale, cognitive reaction scale, and difficult to look at measure) across all of the target audiences (youth, young adults, and adults). The ninth warning, which communicates the message that ''Quitting smoking now greatly reduces serious risks to your health,'' also showed strong effects relative to the text-only control, with significant effects in at least some audiences on the emotional and cognitive reaction scales. Again, these results with respect to the salience measures are important because they have been shown to enhance recall and information processing, which helps to ensure that warnings are better understood and remembered.

As set forth previously, to the extent that the warning requirements compel speech, they are permissible under *Zauderer* because they require disclosure of factual information and are reasonably related to FDA's goal of effectively communicating the health consequences of smoking to consumers. Accordingly, it is not necessary to address the strict scrutiny analyses set forth in the comments.

We are not persuaded to the contrary by the comments' assertions that the warning requirements are unjustified and unduly burdensome. The industry comments discussed previously contended that the warnings are unjustified because the health risks of smoking are already universally known and overestimated and the FDA study results show that the required warnings will have no impact on smoking beliefs or behavior. To support their argument, they cite *Ibanez* v. *Florida Department of Business and Professional Regulation,* 512 U.S. 136 (1994), and *International Dairy Foods Ass'n* v. *Boggs,* 622 F.3d 628 (6th Cir. 2010), for the proposition that courts have found disclosure requirements to be unjustified where the possibility that disclosure will prevent consumer confusion is only speculative.

We disagree with these comments. As discussed in section II.C of this document, there is significant evidence to show that consumers lack knowledge about or underestimate the health risks of smoking. Examples of such evidence include: A 2007 survey that found that two in three smokers underestimate the chance of developing lung cancer; several studies in which only a minority of smokers surveyed believed that they were at increased risk for cancer and heart disease; various studies indicating that Americans who are aware of certain risks, such as cancer, are unaware of the many other health risks associated with smoking; surveys showing that young adults do not appreciate the addictive nature of cigarettes; studies showing that knowledge of smoking risks is even lower among certain demographic groups, such as people with lower incomes and fewer years of education; and research demonstrating that Americans grossly underestimate the effects of secondhand smoke on nonsmokers (*see* section II.C of this document for more extensive discussion of this research).

In addition, we included in the NPRM an extensive discussion of how the current cigarette warnings have gone unnoticed and fail to appropriately convey crucial information to consumers about the health risks of smoking (75 FR 69524 at 69525 and 69529 through 69531). For example, in 1994, the Surgeon General reported that the current warnings, which have been required on cigarette packages and in cigarette advertisements for many years, are given little attention or consideration by viewers (75 FR 69524 at 69525). The same report found that warnings on billboard advertisements were so small that passing motorists could read them only with ''great difficulty'' (*see also* the discussion of billboard advertisements at 75 FR 69524 at 69525). Likewise, as noted in section I.A of this document, a major study into tobacco policy in the United States by the IOM in 2007 concluded that U.S. package warnings are both ''unnoticed and stale'' and found that they fail to communicate relevant information in an effective way (Ref. 3 at 291). The Chair of the IOM's Committee on Reducing Tobacco Use described the warnings on cigarette packs as ''invisible'' in

testimony in 2007 on a precursor to what was enacted as the Tobacco Control Act (75 FR 69524 at 69530). Research regarding warning statements in cigarette advertisements has shown similar results (*Id.,* and studies cited therein). As discussed in the NPRM, the IOM expressed concern about the ability of consumers with less education to recall the information included in text-based messages. The IOM further explained that smokers are more likely to recall larger warnings as well as warnings that appear on the front of packages instead of the side, as is the case for the current warnings (75 FR 69524 at 69531). As the court in *Commonwealth Brands* likewise concluded, the evidence before Congress clearly demonstrates that the new warning requirements are justified (678 F. Supp. 2d at 530–31).

Substantial evidence showing consumer ignorance regarding the health risks of smoking and the ineffectiveness of the current warnings at communicating such risks clearly supports the need for the required warnings. The results of our research study showing significant effects on salience measures for all of the required warnings, along with the substantial international evidence showing that larger, graphic warnings effectively communicate health risks, demonstrate that, unlike the disclosures in the cases cited in the comments, the required warnings will have more than a speculative effect on consumer confusion about the risks of smoking.[7]

Equally unavailing is the assertion that the warning requirements are unduly burdensome because the required size and positioning of warnings on packages and in advertisements effectively rule out tobacco companies' own attempts to convey information. Because this part of the compelled speech argument overlaps with the assertion that the warning requirements restrict speech in violation of the First Amendment, it is addressed in the following paragraphs.

The Warning Requirements Are Permissible Under Central Hudson. To the extent that the challenged provisions restrict commercial speech, the restrictions are analyzed under the framework established in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission,* 447 U.S. 557 (1980). ''The First Amendment's concern for commercial speech is based on the informational function of advertising'' (*Id.* at 563). Consequently, there is no protection for ''commercial messages that do not accurately inform the public about lawful activity'' or that are ''related to illegal activity'' (*Id.* at 563–64). If the communication is neither misleading nor related to unlawful activity, the government may impose restrictions that directly advance a substantial government interest and are not more extensive than is necessary to serve that interest (*Id.* at 566). That standard does not require the legislature to employ ''the least restrictive means'' of regulation or to achieve a perfect fit between means and ends (*Board of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). It is sufficient that the legislature achieve a ''reasonable'' fit by adopting regulations '''in proportion to the interest served''' (*Id., quoting In re R.M.J.,* 455 U.S. 191, 203 (1982); *accord Pagan* v. *Fruchey,* 492 F.3d 766, 771 (6th Cir. 2007) (en banc)).

The Supreme Court has emphasized that ''[t]he Constitution gives to Congress the role of weighing conflicting evidence in the legislative process'' (*Turner Broadcasting System, Inc.* v. *FCC,* 520 U.S. 180, 199 (1997)). ''Even in the realm of First Amendment questions where Congress must base its conclusions upon substantial evidence, deference must be accorded to its findings as to the harm to be avoided and to the remedial measures adopted for that end, lest [a court] infringe on traditional legislative authority to make predictive judgments when enacting nationwide regulatory policy'' (*Id.* at 196). Thus, ''the question is not whether Congress, as an objective matter, was correct'' in its determinations (*Id.* at 211). ''Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record before Congress'' (*Id.*).

Comments from tobacco product manufacturers argued that the warning requirements restrict tobacco companies' speech because the warnings must occupy the top 50 percent of the front and back display panels of cigarette packages and 20 percent of the area of cigarette advertisements. They stated that these size and positioning requirements are unduly burdensome and will significantly impair their ability to convey information about their products to adult consumers. In essence, their argument is that the new warnings are too large and too prominent, which, as recognized by some of the comments discussed previously, has already been rejected by the court in *Commonwealth Brands* (*see Commonwealth Brands,* 678 F. Supp. 2d at 531).

It is important to note that the comments did not identify *any* specific statements that will be restricted by the warning requirements. Nonetheless, we will assume for the purpose of argument that any speech that possibly could be restricted as a result of this rule would be nonmisleading and relate to lawful activity and, thus, would be commercial speech protected by the First Amendment.

The comments did not dispute that the government has a substantial interest in effectively communicating the health risks of smoking to the public or, as the court in *Commonwealth Brands* characterized it, in ''ensur[ing] that the health risk message is actually *seen* by consumers in the first instance'' (*Id.* at 530). This substantial interest satisfies the first step of the *Central Hudson* analysis.

With respect to the second step, we have repeatedly discussed in the NPRM and this final rule evidence demonstrating that the required warnings will directly advance that interest. Such evidence includes the FDA study results showing significant effects on salience measures for all of the nine required warnings (*see* section III of this document) and the international experience demonstrating the enhanced communication value of larger, graphic warnings (*see* 75 FR 69524 at 69531 through 69533). It also

[7] In *Zauderer,* the asserted government interest was preventing consumers from being misled by a legal advertisement, and thus, the Court noted that warnings or disclaimers could be appropriately required ''in order to dissipate the possibility of consumer confusion or deception'' (*Zauderer,* 471 U.S. at 651 (citations omitted)). In articulating the applicable level of First Amendment scrutiny for disclosure requirements, the Court stated that such requirements must be ''reasonably related to the State's interest in preventing deception of consumers'' (*Id.*). However, appellate courts have held that *Zauderer*'s holding was not limited to disclosure requirements that addressed potentially deceptive advertising, but rather applied to disclosures aimed at better informing consumers about the products that they purchase (*see Sorrell,* 272 F.3d at 115 (applying the *Zauderer* standard and upholding a disclosure statute aimed at increasing consumer awareness of the presence of mercury in various products because the statute's goal was consistent with the policies underlying First Amendment protection of commercial speech and the distinction between compelled and restricted commercial speech); *see also New York State Restaurant Assoc.* v. *New York City Board of Health,* 556 F.3d 114, 133–36 (2d Cir. 2009) (upholding under *Zauderer* a requirement that restaurants disclose calorie content on menus because it was reasonably related to the city's goal of reducing obesity); *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F. 3d 294, 310 n. 8 (1st Cir. 2005) (stating that the court did not find any cases limiting *Zauderer* to ''potentially deceptive advertising directed at consumers'')).

Thus, even if there were no consumer confusion regarding the health risks of smoking that needed to be addressed by the required warnings, the government would still have an interest in updating the warnings and better informing consumers about the effects of the products that they purchase—particularly products such as cigarettes, which have such a significant impact on health. Accordingly, the *Zauderer* standard would still apply.

includes studies showing the improved effectiveness of Canada's larger, graphic warnings at communicating health risks. For example, national surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information (*see* Ref. 3 at p. 294). In another study of adult smokers, more than half of the study participants reported that the pictorial warnings made them think about the health risks of smoking (Ref. 44). A study comparing Canadian and United States warnings found that while ''83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,'' only ''7 percent of U.S. students'' did the same (*see* Ref. 3 at C–3 to C–4).

The comments that argued that the warning requirements are unconstitutionally restrictive ignored this evidence. Instead, they suggested that, to satisfy this step, FDA's research study would have to have shown a material impact on consumers' beliefs about, or understanding of, the health risks of smoking or smoking behavior.

We disagree. The evidence showing that the required warnings will directly advance the government's primary goal of effectively communicating the negative health consequences of smoking by first ensuring that the warnings will be seen and processed by consumers is sufficient to satisfy the second step of *Central Hudson*. A showing with respect to other goals, such as impacts on consumer beliefs or smoking behavior, is not necessary for purpose of this analysis. However, we note that there is significant evidence that these goals will also be advanced by the warning requirements.

The comments repeatedly cited to FDA's study report to support the proposition that the required warnings will have no effect on consumer beliefs or behavior. However, such an assertion fails to take into account the study design and the extensive evidence in the literature indicating that the required warnings will positively impact beliefs and behavior. As we note in section III of this document, it is not surprising that the proposed required warnings, as a whole, did not elicit strong responses on the beliefs and intentions measures because study participants had only a single exposure to one warning; the study was not designed to show long-term effects on behavior. However, the study cannot be viewed in isolation from the overall body of scientific evidence regarding the positive effects of larger, graphic health warnings on smoking beliefs and behavior, which we summarized in the NPRM (75 FR 69524 at 69531 through 69534).

Finally, the comments stated that the warning requirements do not satisfy the third step of the *Central Hudson* test because the mandated size and positioning of the warnings on packages and advertisements will effectively rule out tobacco companies' ability to convey information about their products. They stated that the requirements are more extensive than necessary to achieve the government's interests and suggested that less-speech restrictive alternatives, including alternatives to the warning size and positioning requirements included by Congress in the Tobacco Control Act, would be equally as effective.

The comments provided no basis for setting aside Congress' judgment as to the appropriate specifications. As the court in *Commonwealth Brands* explained, Congress considered extensive evidence, starting with the 1994 Surgeon General's Report and ending with the 2007 IOM Report, which is discussed in the NPRM (75 FR 69524 at 69530), demonstrating that the existing warnings are ''unnoticed'' and ''stale'' and decided that the content and format of the warnings needed to be revised (*Commonwealth Brands,* 678 F. Supp. 2d at 530–31). In so doing, Congress chose specifications for the warnings that accord with FCTC, which calls for warnings that ''shall be rotating,'' ''shall be large, clear, visible and legible,'' ''should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,'' and ''may be in the form of or include pictures or pictograms'' (FCTC art. 11.1(b)). The FCTC has been signed by the United States and ratified by 167 countries. As the *Commonwealth Brands* court correctly found, ''Congress also informed its warning requirements by looking at the use of a nearly identical warning requirement in Canada'' (*Commonwealth Brands,* 678 F. Supp. 2d at 531). Like the required warnings, the Canadian warnings occupy the top half of the two main panels of cigarette packages.

Thus, Congress based its legislative decision to revise the warnings in the first instance and to mandate certain size and placement specifications for the warnings on substantial evidence in the record. At this time, we do not intend to change those specifications. Although comments from tobacco companies asserted that the larger size leaves inadequate room for their own commercial messages, they identified no information that is suppressed by virtue of the larger warnings, even though they have complied with similar requirements in other countries for years. The tobacco companies retain more than half of their cigarette packaging and 80 percent of their advertisements for their own commercial speech.

Moreover, extensive disclosure requirements are by no means unique to cigarettes. For example, for products such as pain relievers, certain allergy medications, and products to treat a variety of cold symptoms, the required warnings together with other FDA-required information typically encompass more than 50 percent of the product packaging.[8]

For these reasons, ''the warning requirement is sufficiently tailored to advance the government's substantial interest under *Central Hudson''* (*Id.* at 532).

The reliance by two comments on the Seventh Circuit's decision in *Entertainment Software Association* v. *Blagojevich,* 469 F.3d 641 (7th Cir. 2006), does not persuade us to the contrary. In that case, the court invalidated a State law requiring video-game retailers to place a four-square-inch label with the numerals ''18'' on any ''sexually explicit'' video game. Unlike here, the court concluded that the sticker ''communicates a subjective and highly controversial message—that the game's content is sexually explicit,'' a term capable of multiple definitions, and expressly rejected the comparison to the ''surgeon general's warning of the carcinogenic properties of cigarettes, the analogy the State attempts to draw'' (*Id.* at 652). ''Applying strict scrutiny,'' the court noted that ''[t]he State has failed to even explain why a smaller sticker would not suffice'' (*Id.*). Here, by contrast, Congress has required accurate and objective warnings in a format that accords with the provisions of the FCTC, to which the United States is a signatory, and whose effectiveness has been demonstrated by international experience, after concluding existing, yet smaller, warnings were ineffective at conveying important health information.

We also disagree with the assertion in the comments that the warning requirements fail to meet the third step of *Central Hudson* because the government failed to consider numerous less speech-restrictive alternatives. One of the comments suggested that the government disseminate information

[8] See 21 CFR 201.66; see also *http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022032s003lbl.pdf* (example of packaging for OTC heartburn medication).

about health risks as one alternative for communicating health risks to consumers. However, government dissemination of the message already occurs—for example, HHS currently has several hundred tobacco-related Web sites, which provide informative messages regarding, for example, the harmful effects of tobacco use (Ref. 89), and CDC's Office on Smoking and Health funds health departments in all 50 states, the District of Columbia, and seven U.S. territories for comprehensive tobacco prevention and control and provides access to tobacco control advertising material for use in this comprehensive effort (*see* Ref. 98). However, as discussed in section II.C of this document, evidence shows that the health risks are still misunderstood or underestimated by consumers. Moreover, government advertising cannot take the place of displaying effective warnings on product packaging, which ''can provide a clear, visible vehicle to communicate risk at the most crucial time for smokers and potential smokers''—the very instant that they are deciding whether to purchase or consume a cigarette (75 FR 69524 at 69529). Indeed, ''[p]ack-a-day smokers are potentially exposed to warnings more than 7,000 times per year'' (*Id.;* Refs. 11, 99, and 100).

To the extent that the comments discussed other suggested alternatives (*e.g.,* increased enforcement of sales to minors, increased funding for tobacco control programs, increased taxes) in the context of their ability to reduce youth smoking, the suggestions provided are misplaced in an analysis of requirements whose primary purpose is effective communication of health risks. These suggested alternatives were not aimed at communicating health risks and were not effective at doing so. In any event, *all* of these alternatives have been implemented by the government in one form or another and have been insufficient. This is reflected in the findings of the *Commonwealth Brands* court:

> Plaintiffs' argument is premised on the idea that ''[b]efore a government may resort to suppressing speech to address a policy problem, it must show that regulating conduct has not done the trick or that as a matter of common sense it could not do the trick.'' (Plaintiffs' Brief, p. 26) (quoting *BellSouth,* 542 F.3d at 508); see also *Western States,* 535 U.S. at 373. However, that is precisely what Congress has done here. Contrary to Plaintiffs' contention, this is not a case where Congress went ''straight to [their] speech.'' (Plaintiffs' Brief, p. 19). This is a case where Congress, after decades of implementing various measures that did not affect Plaintiffs' speech, decided to add label and advertising restrictions to its comprehensive regulation of the tobacco industry. That decision seems eminently reasonable, too, since every other tool in the government's arsenal is made less effective and more costly by Plaintiffs' use of advertising ''to stimulate underage demand.'' (Government's Response, p. 40). Accordingly, the Court rejects Plaintiffs' contention that the existence of ''numerous obvious non-speech-restrictive alternatives'' renders the Act's speech restrictions unconstitutional for lack of tailoring. (678 F. Supp. 2d at 538).

For all of the reasons set forth in the previous paragraphs, we conclude that the warning requirements do not violate the First Amendment.

(Comment 200) One tobacco industry comment also claimed that requiring a reference to a cessation resource in the required warnings would violate the First Amendment because it is compelled speech that does not convey factual information about the product that is being sold. This comment claimed that requiring a cessation resource communicates a subjective policy message that consumers should not buy or use the product.

(Response) We disagree. As explained previously, the requirement in this rule for graphic warnings on cigarette packages and advertisements is consistent with the First Amendment. Contrary to the comment, the reference to a cessation resource, when considered in context with the rest of the required warnings, conveys factual information to consumers and is permissible under the *Zauderer* standard for compelled disclosures because it is reasonably related to our interest in increasing the likelihood that existing smokers will become aware of the cessation resource and, consequently, increasing the likelihood that those who want to quit will be successful. It is also reasonably related to our interest in effectively communicating the health risks of smoking to consumers.

As discussed in detail in section V.B.6 of this document, the rule requires each required warning to include a reference to the existing National Network of Tobacco Cessation Quitlines (Network), which uses the telephone portal 1–800–QUIT–NOW. This rule will require that the cessation resource be displayed on the required warning images: ''1–800–QUIT–NOW''.

The NPRM cited evidence that more than 70 percent of smokers in the United States report that they want to quit, and approximately 44 percent report that they try to quit each year (75 FR 69524 at 69529; Ref. 66 at p. 15). However, as a result of nicotine addiction, only a very small percentage of these smokers achieve success (75 FR 69524 at 69528 through 69529).

Instead of advocating a subjective policy message as suggested by the comment, including a cessation resource on required warnings will provide factual information for the many smokers who have already developed a desire to quit, either prior to or after viewing the health risk information in the required warnings. The reference is designed to inform such smokers and others that a resource exists that can help smokers to quit and to inform them how they can access that resource. The factual nature of this information is underscored by our explanation in the NPRM that the Agency's goal is ''to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering *unbiased and evidence-based information, advice, and support''* (75 FR 69524 at 69540 (emphasis added)). In addition, our adoption of detailed criteria designed to ensure that the resource's information, advice, and support are unbiased and evidence-based further emphasizes that the required reference to a cessation resource is factual in nature.

We disagree that a reference to a cessation resource does not convey information about the product being sold. The reference must be considered in context with the rest of the required warnings, which consist of textual statements and accompanying graphic images conveying to consumers factual information regarding the negative health consequences of smoking and the benefits of quitting. The reference to a smoking cessation resource naturally complements this information; instead of leaving consumers who are motivated to quit by the health risk information unassisted, it provides them with a concrete step to take action on this information.

Because the reference to a smoking cessation resource conveys factual information, it is permissible under *Zauderer* if it is reasonably related to the government's asserted interest. Here, the reference is reasonably related to FDA's interest in increasing the likelihood that existing smokers will become aware of the cessation resource and, consequently, increasing the likelihood that they will successfully quit smoking. As set forth in the discussion of the comments in section V.B.6 of this document, foreign countries that have included cessation resources on cigarette package warnings have generally experienced large increases in volume of calls to quitlines following their appearance on cigarette packages. In addition, as also discussed

in section V.B.6 of this document, the effectiveness of telephone quitlines is well documented; there is evidence that significant numbers of smokers are unaware of such assistance, even after extensive media campaigns; and there is evidence that knowing about the availability of a quitline increases quit attempts and successful cessation even among smokers who do not call the quitline.

Moreover, requiring a smoking cessation resource is also reasonably related to FDA's interest in effectively communicating the health risks of smoking to consumers. As noted in the NPRM (75 FR 69524 at 69541) and in section V.B.6 of this final rule, there is evidence to show that including a reference to a smoking cessation resource in graphic warnings can enhance the effectiveness of graphic warnings at conveying health risk information to the public. We have determined that it is also important to inform smokers about a specific tool they can use to help them to quit smoking at the time they are looking at the warnings and thinking about the health consequences of smoking and the positive health benefits of quitting. Risk communication research indicates that messages that arouse fear about the health risks of smoking should be combined with information on concrete steps that can be taken to reduce those risks (Ref. 81 (Messages that arouse fear ''appear to be effective when they depict a significant and relevant threat * * * and when they outline effective responses that appear easy to accomplish * * *.'')). As one comment stated, providing information about how to reduce a risk that arouses fear helps to prevent consumers from suppressing thoughts about such risks, and thereby, failing to process the risk information. For this reason, too, we do not agree that the requirement to refer to a smoking cessation resource on cigarette packages and advertisements violates the First Amendment.

C. Takings Under the Fifth Amendment

We received a comment related to the Takings Clause of the Fifth Amendment. That comment is summarized and responded to in the following paragraphs.

(Comment 201) One comment submitted by several tobacco companies argued that the new health warning requirements unconstitutionally deprive them of their property rights in violation of the Takings Clause of the Fifth Amendment. The tobacco companies asserted that the new required warnings constitute a *per se* physical taking of their packaging and advertising space, as well as a regulatory taking of their property interests in their trademarks.

(Response) We disagree that the rule effects a taking under either theory. The Takings Clause provides that ''private property [shall not] be taken for public use, without just compensation.'' A takings analysis begins with a threshold determination of what interest a person has in the thing that is allegedly taken (*see Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1001 (1984)). In order to assert a taking, a person must first identify a specific, concrete property interest that has been invaded or destroyed by the government (*Penn Central Transp. Co.* v. *New York City,* 438 U.S. 104, 124–25 (1978)). Once a concrete property interest is identified, it is necessary to determine whether the government's action constitutes a taking of that interest.

The graphic warning requirements do not effect a *per se* taking. To conclude that a categorical, or *per se,* taking has occurred when the government directly appropriates or physically invades property is another way of saying that the government action so onerously burdens an important property right that the inquiry ends there. As the Supreme Court has explained: ''A permanent physical invasion, however minimal the economic cost it entails, eviscerates the owner's right to exclude others from entering and using her property—perhaps the most fundamental of all property interests'' (*Lingle* v. *Chevron U.S.A. Inc.,* 544 U.S. 528, 539 (2005); *see also Loretto* v. *Teleprompter Manhattan CATV Corp.,* 458 U.S. 419, 433 (1982) (citation omitted) (''[T]he land-owner's right to exclude [is] 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.' '')).

Viewed in this light, a requirement that tobacco companies display graphic health warnings as part of the package label on their products cannot be equivalent to the ''physical invasion'' of real property in the cases that the comment cites to support its *per se* takings argument (*see Loretto,* 458 U.S. at 441 (''Our holding today is very narrow.'')). The warnings involve personal property of a type that is already subject to extensive government regulation. Indeed, given the ubiquitous nature of government-mandated warnings on all kinds of consumer products, manufacturers of inherently dangerous products such as cigarettes cannot be said to have a categorical right to exclude health warnings from their products' labels.[9] Therefore, the tobacco companies have failed to identify the sort of property right the destruction of which would result in a *per se* taking.

Furthermore, as the Supreme Court has explained, the Takings Clause exists ''to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole'' (*Armstrong* v. *United States,* 364 U.S. 40, 49 (1960); *see Monongahela Nav. Co.* v. *United States,* 148 U.S. 312, 325 (1893)). The tobacco companies' argument amounts to an assertion that they must be compensated because they have been required to allow health warnings on their property. The point of the warnings is to protect the public health by informing consumers about the many harmful effects of the companies' products, which kill an estimated 443,000 Americans every year. Therefore, the proposition that the public must pay for the cost of the warnings on tobacco products is simply not compatible with how ''the burden of common citizenship'' is proportioned in our system of modern government (*see Keystone Bituminous Coal Ass'n* v. *DeBenedictis,* 480 U.S. 470, 488–91 (1987); *Pennsylvania Coal Co.* v. *Mahon,* 260 U.S. 393, 413 (1922) (''Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'')).

In addition, the graphic warning requirements do not effect a regulatory taking. The tobacco companies also argue that the warnings constitute a regulatory taking because they have a reasonable expectation that their property rights will be protected based on statutory and common law protections provided to trademarks and trade dress. The tobacco companies do not identify the specific statutory or common law protections that led to their expectation that their property would be protected. Also lacking is an explanation of how the rule would interfere with such expectations. In any event, we do not agree that the rule effects a regulatory taking of the tobacco companies' property.

The Supreme Court has declined to prescribe a ''set formula'' for identifying takings and instead has characterized a takings analysis as an ''essentially ad hoc, factual'' inquiry (*Penn Central,* 438 U.S. at 124). Nonetheless, the Court has identified three factors for consideration in assessing whether a regulatory taking has occurred: (1) The character of the

[9] For example, for products such as pain relievers, certain allergy medications, and products to treat a variety of cold symptoms, the required warnings together with other FDA-required information typically encompass more than 50 percent of the product packaging (*see* 21 CFR 201.66).

governmental action; (2) the regulation's economic impact; and (3) the extent to which the regulation interferes with reasonable investment-backed expectations (*Ruckelshaus,* 467 U.S. at 1005). The force of any one of these factors may be ''so overwhelming * * * that it disposes of the taking question'' (*Id.*).

With respect to the first *Penn Central* factor, the character of the government action, the government is ''given the greatest leeway to act without the need to compensate those affected by their actions'' when the government has acted for ''the protection of health and safety'' (*Rose Acre Farms, Inc.* v. *United States,* 559 F.3d 1260, 1281 (Fed. Cir. 2009)). Indeed, the Supreme Court has rejected takings claims arising out of health and safety legislation even where a property interest has been destroyed (*see Penn Central,* 438 U.S. at 125–27 (citing cases)). Thus, as explained previously, this factor of the analysis weighs strongly in favor of finding that no taking will occur as a result of this rule.

The second factor to consider is the economic impact of the government action. The analysis involves looking not just at what has been lost, but at the nature and extent of the interference with rights in the property as a whole (*see Penn Central,* 438 U.S. at 130–31). Thus, it is necessary to assess the impact of the rule on tobacco companies' trademarks, packages, and advertisements as a whole. In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the ''economically viable'' use of its property. Mere denial of the most profitable or beneficial use of property does not require a finding that a taking has occurred (*see, e.g., Keystone,* 480 U.S. at 498–99). Here, tobacco companies have not shown how the rule deprives them of the use of their intellectual property or packaging to such a severe extent to effect a taking (*see Village of Euclid* v. *Ambler Realty Co.,* 272 U.S. 365, 384 (1926) (75 percent diminution in value insufficient to prove taking); *Hadacheck* v. *Sebastian,* 239 U.S. 394, 405 (1915) (92.5 percent diminution insufficient to prove taking)). Manufacturers, importers, distributors, and retailers will still be able to use packages and advertisements to sell cigarettes. Indeed, manufacturers still have use of 50 percent of the front and rear panels of cigarette packages, as well as the side panels and the top and bottom panels, to use their trademarks and otherwise promote their products. Eighty percent of the area of each advertisement will likewise be available. Accordingly, the second factor of the analysis also supports the conclusion that no taking will occur as a result of the rule.

The vague suggestion that the rule interferes with tobacco companies' ''reasonable investment-backed expectations'' is similarly unpersuasive. To be reasonable, expectations must take into account the power of the State to regulate in the public interest (*Pace Resources, Inc.* v. *Shrewsbury Township,* 808 F.2d 1023, 1033 (3d Cir.), *cert. denied,* 482 U.S. 906 (1987)). The nature of the property, and whether it has historically been, or potentially could be, subject to regulation also aids in determining whether any expectation in remaining free from regulation is reasonable. ''[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * *.'' (*Lucas* v. *South Carolina Coastal Council,* 505 U.S. 1003, 1027–28 (1992)). This is particularly true with respect to cigarettes, which are lethal and addictive—features the industry masked for decades while stimulating underage demand (*see United States* v. *Philip Morris USA, Inc.,* 566 F.3d 1095, 1124 (DC Cir. 2009); *United States* v. *Philip Morris USA, Inc.,* 449 F. Supp. 2d 1, 580 (Finding 2717) (D.D.C. 2006); Ref. 54 at p. 211). Commerce in tobacco products has been regulated for decades, subject to increasingly more restrictive Federal, State, and local measures over time. Indeed, Congress has mandated warnings on cigarette packs since 1965 (*see* Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA), Pub. L. 89–92, 79 Stat. 282). Congress later amended FCLAA to update the text of the cigarette warnings and mandate them in cigarette advertisements as well (*see* Comprehensive Smoking Education Act of 1984, Pub. L. 98–474, 98 Stat. 2200). In light of this long history of regulation, companies that package and advertise cigarettes lack a reasonable investment-backed expectation that they will be able to continue to use their property without modification of the regulatory requirements that protect the public health. Any expectation that the industry would escape comprehensive regulation, such as the Tobacco Control Act, was eminently unreasonable.

For these reasons, the third factor of the takings analysis, like the first two factors, compels the conclusion that the rule does not amount to a regulatory taking of property that requires compensation under the Fifth Amendment.

VIII. Implementation Date

In the preamble to the proposed rule, FDA stated that the final rule would become effective 15 months after the date the final rule publishes in the **Federal Register**. This time period is consistent with section 201(b) of the Tobacco Control Act, which specifies that the requirements for health warnings on cigarette packages and in advertisements are effective 15 months after the issuance of the regulations that FDA issues in this rulemaking.

In particular, we proposed that as of the effective date, no manufacturer, importer, distributor, or retailer of cigarettes may advertise or cause to be advertised within the United States any cigarette product unless the advertising complies with the final rule. With respect to cigarette packages, we explained that cigarettes must not be manufactured after the effective date unless their packages comply with the regulation. If any packaged cigarette product was manufactured prior to the effective date and does not comply with the final rule, a manufacturer may continue to introduce that package into commerce in the United States for an additional 30 days after the effective date of the final rule. After 30 days following the effective date, a manufacturer may not introduce into domestic commerce any cigarette the package of which does not meet the requirements of the final rule (75 FR 69524 at 69541). We noted that this limitation applied only to manufacturers and requested comments regarding mechanisms for enforcing this rule and its effective date, including ways to differentiate cigarette packages sold from inventory manufactured prior to the effective date rather than from inventory manufactured after the effective date.

We received several comments about the effective date, particularly requesting clarification regarding its application to manufacturers, distributors, and retailers after the 30-day period in which manufacturers may continue to sell noncompliant packages. Based on the comments and our review of the language in section 201(b) of the Tobacco Control Act, we find:

- The effective date should be 15 months after the date of publication in the **Federal Register** of this final rule;
- No manufacturer, importer, distributor, or retailer may advertise any cigarette product after the effective date if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any cigarette

the package of which does not comply with this rule;

- Beginning 30 days after the effective date of this rule, a manufacturer may not introduce into domestic commerce any cigarette, irrespective of the date of manufacture, if its package does not comply with the requirements of this rule;
- After the effective date, an importer, distributor, or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette the package of which does not comply with this regulation, unless the cigarette was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell cigarettes the packages of which do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in § 1141.1(c).

In the following paragraphs, we describe the individual comments concerning the effective date and respond to these comments.

(Comment 202) Several comments expressed the view that 15 months is an excessive amount of time to allow the tobacco industry before it must comply with the new requirements of this rulemaking. For example, some comments contended that tobacco companies have employed marketing and advertising experts and are continuously changing cigarette packaging and advertisements. These comments also noted that the tobacco industry has known that they will need to update packaging and advertising to comply with this regulation since the passage of the Tobacco Control Act. Some comments estimated the number of Americans that will become new smokers or die due to smoking during the 15 months prior to the effective date. Other comments recognized that the statute specifies a 15-month effective date, but requested that FDA make clear that cigarette packages manufactured after the effective date must comply with the requirements of the regulation.

(Response) The Tobacco Control Act specifies a 15-month implementation period for cigarette manufacturers to include required warnings on their packages and for all cigarette advertisements to comply with this rule. We agree this is an appropriate amount of time for implementation of the rule.

(Comment 203) One tobacco product manufacturer indicated in its comment that all manufacturers should be required to implement the same warning requirements within the same time periods, and that there should not be a separate implementation period for small manufacturers.

(Response) As in the proposed rule, the implementation date in the final rule is the same for all manufacturers, regardless of size.

(Comment 204) One comment requested that FDA delay implementation of the rule until Constitutional issues raised in the comment are resolved either administratively or through litigation.

(Response) We disagree that the effective date of this rule should be delayed beyond the 15 months proposed in the NPRM. As explained in section VII of this document, we disagree that there are any Constitutional deficiencies associated with this rule and, therefore, there is no need to revise the rule or issue a new proposed rule to address these alleged deficiencies. Furthermore, section 201(b) of the Tobacco Control Act specifies that the requirements for health warnings on cigarette packages and in advertisements for cigarettes are effective 15 months after the issuance of this final rule.

(Comment 205) Several comments addressed the 30-day period for manufacturers to sell noncompliant packages that were manufactured prior to the effective date. One comment asserted that it is unnecessary to permit this 30-day sell-off period if there is adequate time for manufacturers to make necessary changes to cigarette packages prior to the effective date. The comment cited the United Kingdom as an example of a jurisdiction where tobacco product manufacturers had adequate lead time (1 year to implement changes to cigarette packages and 2 years to introduce picture warnings on other tobacco products) to meet implementation deadlines so that only compliant packages were sold after the compliance deadline. Other comments recognized that the statute grants manufacturers 30 days to sell noncompliant cigarette packages; however, these comments emphasized that FDA does not have the discretion to lengthen the 30-day period. Comments also stressed that any additional delay of implementation would needlessly delay the important public health benefits of the rule.

(Response) As explained previously, section 201(b) of the Tobacco Control Act specifies that manufacturers have an additional 30 days to sell cigarette packages that do not meet the requirements of the regulation if those packages were manufactured prior to the effective date.

(Comment 206) A small tobacco product manufacturer requested that FDA specify the meaning of the term ''introduce into domestic commerce.'' The comment asked whether the term means out of the manufacturer's possession. The comment raised this question in the context of expressing concern that distributors and retailers might want to return product to a manufacturer if there is doubt about a distributor or retailer being permitted to sell cigarette packages that do not have a required warning, but were introduced intro domestic commerce by the manufacturer during the 30-day sell through period for manufacturers.

(Response) We agree with this comment that when a cigarette package has been sold by the manufacturer and is in the possession of a distributor or retailer, the product would be considered introduced into domestic commerce. However, we do not agree that a definition of ''introduce into domestic commerce'' is needed at this time. The comment recognized that there was similar language in the context of a statutory prohibition on the use of ''light,'' ''low,'' and ''mild'' descriptors and related FDA guidance for industry, however, that guidance did not define the phrase ''introduce into domestic commerce.'' We are not aware of confusion regarding this phrase in the context of ''light,'' ''low,'' and ''mild'' descriptors and decline to define that phrase here.

(Comment 207) Public health advocacy groups expressed concern that manufacturers will seek to sell a disproportionate number of noncompliant cigarette packages immediately prior to the expiration of the 30-day sell-off period and, therefore, FDA should take steps to ensure that all these sales are fully documented. The comment recommended that FDA impose certain requirements for selling noncompliant cigarette packages, such as a requirement to mark these packages with a statement that the product was manufactured prior to September 22, 2012, or with a readily identifiable symbol. This comment also recommended that each manufacturer be required to certify that all cigarettes so marked were manufactured before that date and submit an accounting of the number of packages on hand as of the effective date, the number of cigarette packages introduced into commerce during the 30-day period, and the number of packages on hand as of the expiration of the 30-day period. This comment also suggested that FDA not permit manufacturers to introduce into commerce in any calendar month a number of noncomplying cigarette packages that exceeds 10 percent of the average total number of cigarette packages introduced per month during the preceding year.

(Response) We disagree that such specific requirements are necessary to address a one-time sell-off period of 30 days. We recognize that some manufacturers may try to increase their sales of cigarette packages prior to the effective date and prior to the expiration of the sell-off period. However, there will be some limit to the demand for these cigarette packages. Manufacturers may increase manufacturing prior to the effective date at their own risk. After the 30-day sell-off period, a manufacturer may not sell noncompliant cigarette packages and would need to repackage or destroy any noncompliant cigarettes packages intended to be sold in the United States.

(Comment 208) One comment requested that importers be required to comply with all requirements applicable to manufacturers. According to this comment, importers should be prohibited from introducing noncomplying cigarettes imported after the effective date and should be required to meet the same requirements as manufacturers with respect to cigarettes manufactured prior to the effective date and sold after the effective date.

(Response) This comment did not provide a statutory interpretation that would justify this approach. Section 201(b) of the Tobacco Control Act states the effective date ''shall be with respect to the date of manufacture'' and that 30 days after the effective date, a manufacturer is precluded from introducing into domestic commerce any product that is not in conformance with section 4 of FCLAA. No similar statutory provision applies to importers or distributors.

(Comment 209) Public health advocacy groups requested that FDA clarify that manufacturers are not prohibited from introducing into commerce cigarette packages that comply with the regulation prior to the effective date.

(Response) We agree that manufacturers are not precluded from introducing into commerce cigarette packages that contain required warnings in accordance with the regulation prior to the effective date. We also note that a cigarette manufacturer, importer, or retailer may include a required warning in an advertisement prior to the effective date. However, because the health warning requirements in FCLAA do not change until the effective date of this rule, any manufacturer, importer, or retailer that, prior to the effective date, includes a new required warning on a cigarette package or advertisement must also comply with the warning requirements under the current version of FCLAA and any warning plan approved by the FTC.

(Comment 210) Many comments requested clarification regarding whether there is any limitation on the period during which distributors and retailers may sell cigarettes that were manufactured prior to the effective date that are not compliant with the rule. Several comments submitted by organizations representing manufacturers and retailers asked that FDA clarify that distributors and retailers have an unlimited period to sell cigarette packages that do not comply with the regulation as long as the cigarettes were manufactured prior to the effective date. Several comments noted that this approach would be consistent with FDA's treatment of cigarettes with the descriptors ''light,'' ''low,'' and ''mild.'' One manufacturer commented that any restraint on the ability of distributors or retailers to sell through their lawfully acquired product would unfairly deprive them of the benefit of their investment. Small tobacco product manufacturers noted that small manufacturers cannot afford to have distributors and retailers returning product based on a potential labeling concern. Retailer comments contended that limiting a sell-off period may cause a severe financial burden on small retailers because manufacturers generally do not allow cigarettes to be returned. Retailers also claimed that cigarettes do not have an indefinite shelf life and both distributors and retailers generally turn over their cigarette inventory in a timely manner. One comment suggested that retailers should be allowed to sell noncompliant cigarette packages at least through their ''sell by'' date, as indicated on the cigarette package by the manufacturer.

On the other hand, one comment claimed it is essential that there be a fixed implementation deadline at the retail level or old stock can be expected to remain on retail store shelves for 6 months and more after the effective date.

(Response) As explained in the NPRM, section 201(b) of the Tobacco Control Act describes no limitation on the period during which distributors and retailers may sell cigarette packages that were manufactured prior to the effective date of this rule. In addition, there is no requirement that manufacturers include a ''sell by'' date on all cigarette packages. We note, however, that distributors, importers, and retailers are responsible for complying with this rule. After the rule's effective date, they may not sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette the package of which does not comply with this regulation, unless the cigarette was manufactured prior to the effective date. After the effective date, however, retailers may sell cigarettes the packages of which do not have a required warning if they demonstrate they meet the provisions of § 1141.1(c) and are exempt from the requirements of 21 CFR part 1141 that apply to the display of health warnings on cigarette packages.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' This rule is being issued under section 4 of FCLAA, as amended by the Tobacco Control Act, and sections 701(a), 903, and 906 of the FD&C Act (21 U.S.C. 371(a), 387c, and 387f), as amended by the Tobacco Control Act. Federal law includes an express preemption provision that preempts any requirement, except under the Tobacco Control Act, for a ''statement relating to smoking and health, other than the statement required by section 4 of [FCLAA], * * * on any cigarette package.'' (section 5(a) of FCLAA (15 U.S.C. 1334(a))). It also includes an express preemption provision that preempts any ''requirement or prohibition based on smoking and health * * * imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of [FCLAA],'' which includes section 4 of FCLAA (section 5(b) of FCLAA). However, section 5(b) of FCLAA does not preempt any State or local statutes and regulations ''based on smoking and health, that take effect after [June 22, 2009], imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes'' (section 5(c) of FCLAA).

In addition, section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) expressly preempts any State or local requirement ''which is different from, or in addition to, any requirement under [Chapter IX of the FD&C Act] relating to,'' among other things, misbranding and labeling. This express preemption provision, however, ''does not apply to

requirements relating to'' among other things ''the sale, distribution, * * * access to, [or] the advertising and promotion of * * * tobacco products.''

X. Environmental Impact

FDA has determined under § 25.30(k) (21 CFR 25.30(k)) that this action is of a type that does not individually or cumulatively have an impact on the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. We received one comment on this issue, which we have summarized and responded to in the following paragraphs.

(Comment 211) One comment expressed concern regarding FDA's statement in the proposed rule that this action does not individually or cumulatively have an impact on the human environment. The comment stated that there is an impact on the environment due to the fact that a reduction in the number of cigarettes consumed will result in a reduction of cigarette-related waste. The comment explained that cigarette butts pose a greater health hazard than most other litter, because they contain toxins that can be leached into water systems. The comment requested that this be included in FDA's analysis to understand the large positive impact the required warnings will have on the human environment.

(Response) We have considered this comment, but have concluded that neither an EA nor an EIS is required under § 25.30(k). We have determined that a categorical exclusion applies in this instance, because (1) the action meets the criteria of the exclusion, *i.e.,* there are no increases in existing levels of use or changes in intended use, and (2) there are no extraordinary circumstances.

According to the National Environmental Policy Act of 1969 (NEPA) and the Agency's corresponding regulations, FDA must prepare an EIS for major Federal actions ''significantly affecting the quality of the human environment'' (*see* 40 CFR 1501.4; 21 CFR 25.22). If the action ''may'' have such a significant environmental effect, an agency must prepare an EA to provide sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact (FONSI) (*see* 40 CFR 1501.3; 21 CFR 25.20). Agencies can establish categorical exclusions for categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required (*see* 40 CFR 1508.4). However, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that ''the specific proposed action may significantly affect the quality of the human environment'' (*see* 21 CFR 25.21; 40 CFR 1508.4).

A regulation to modify labeling regulations constitutes a major Federal action under NEPA (*see* 40 CFR 1508.18), and typically requires at least an EA under 21 CFR 25.20(f). However, regulations establishing labeling requirements for marketed articles are categorically excluded, if the action will not result in (1) increases in the existing levels of use of the article or (2) changes in the intended use of the article (§ 25.30(k)). Therefore, FDA would not be required to file an EA if it meets these requirements.

We have determined that this regulation meets the requirements for a categorical exclusion. First, this regulation is clearly not expected to increase cigarette usage. In fact, this regulation is expected to cause a reduction in overall smoking rates and initiation, and we estimate that this rule will reduce the number of smokers by 213,000 in 2013, with smaller additional reductions through 2031. Second, the rule will not affect the way in which cigarettes are used among smokers and it does not change the intended use of cigarettes.

In addition, we have determined that there is no potential for serious harm to the environment resulting from the final rule that would otherwise constitute an extraordinary circumstance (*see* 21 CFR 25.21). Our action to regulate cigarette labeling does not lead to an increase in the level of use of these articles or a change in the intended use of these articles or their substitutes. The primary effect of this regulation will be to reduce smoking initiation and increase cessation efforts. Accordingly, there is no extraordinary circumstance that requires the filing of an EA.

XI. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This rule is an economically significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. This rule will result in a 1-year expenditure that meets or exceeds this amount.

Conducting an impact analysis under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act involves assembling any available information that is relevant to the assessment of a regulation's benefits and costs. It is not uncommon in scientific pursuits for there to be a lack of definitive information on some aspects of the question under investigation, and the impact analysis of this final rule is no exception. In light of this situation, we identify and present a range of possible benefits and costs.

The benefits, costs, and distributional effects of the final rule are summarized in table 1a of this document. As the table shows, the midpoint of the estimates for benefits annualized over 20 years is approximately $630.5 million at a 3-percent discount rate and $221.5 million at a 7-percent discount rate. The midpoint for costs annualized over 20 years is approximately $29.1 million at a 3-percent discount and $37 million at a 7-percent discount rate.

The total benefits and costs of the final rule can also be expressed as present values. The midpoint of the estimates for the present value of benefits over 20 years is approximately $9.4 billion at a 3-percent discount rate and $2.3 billion at a 7-percent discount rate. The midpoint of the estimates for the present value of costs over 20 years is approximately $434 million at a 3-percent discount rate and $392 million

at a 7-percent discount rate. With both discount rates, our midpoint estimates indicate that the benefits of the rule greatly exceed the costs. Executive Order 13563, section 1(b), requires that, to the extent permitted by law, agencies proceed with a regulation "only upon a reasoned determination that its benefits justify its costs." The regulation is consistent with this requirement.

BILLING CODE 4160–01–P

Table 1a.--Summary of Benefits, Costs and Distributional Effects

Economic Data: Costs and Benefits Statement							
Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Benefits							
Annualized Monetized $ millions/year	$221.5	$0	$3,360.7	2009	7%	2012-31	Many of the health benefits included in the totals are realized after 2031 (as far out as 2113), but the smoking preventions that generate these benefits are estimated only for the period from 2012-2031.
	$630.5	$0	$10,916.6	2009	3%	2012-31	
Annualized Quantified					7%		All quantified benefits are also monetized.
					3%		
Qualitative							Reduction in morbidity for dissuaded smokers who do not reach ages 18-24 between 2012 and 2031, reduction in passive smoking, reduction in infant and child health effects due to mothers smoking during pregnancy.
Costs							
Annualized Monetized $ millions/year	$37.0	$34.7	$52.7	2009	7%	2012-31	One-time costs to change cigarette package labels and remove point-of-sale promotions that do not comply with the new restrictions, smaller ongoing costs for equal random display and for government activities.
	$29.1	$27.4	$40.8	2009	3%	2012-31	
Annualized Quantified					7%		
					3%		
Qualitative							Ongoing government costs due to increased traffic to the cessation resource.
Transfers							
Federal Annualized Monetized $ millions/year	$36.6	$0	$237.8	2009	7%	2012-31	Some of the transfers included in the totals occur after 2031 (as far out as 2113), but the smoking preventions that generate these transfers are estimated only for the period from 2012-2031. Numbers reflect the assumption that the Federal cigarette excise tax will rise, on average, at the rate of inflation from 2012-2113. Numbers also include effects on Medicare, Social Security, Medicaid, other government insurance programs and income taxes.
	$76.3	$0	$495.7	2009	3%	2012-31	
From/To	From: Government (more specifically, general taxpayers and recipients of government services)			To: Individuals who would have been smokers in the absence of the rule but will not be smokers in the presence of the rule			
Other	$12.6	$0	$81.7	2009	7%	2012-31	Some of the transfers included in the

Table 1a.--Summary of Benefits, Costs and Distributional Effects

Economic Data: Costs and Benefits Statement							
Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
Annualized Monetized $ millions/year	$23.0	$0	$149.4	2009	3%	2012-31	totals occur after 2031 (as far out as 2113), but the smoking preventions that generate these transfers are estimated only for the period from 2012-2031. Numbers reflect the assumption that State cigarette excise tax rise, on average, at the rate of inflation from 2012-2113. Numbers also include effects on Medicaid, other government insurance programs, income taxes, private insurance, pensions and life insurance programs.
From/To	From: Individuals who would have been smokers in the absence of the rule but will not be smokers in the presence of the rule			To: General public (in some cases, via State government)			
Effects							
State, Local or Tribal Government: Each year, State governments will lose approximately $25.1 million in excise tax revenue. There will be additional changes in Medicaid and other government health insurance receipts and outlays.							
Small Business: The proposed rule would affect small entities in several industries, from tobacco farming to the retail industry. In particular, at least 20 of the 24 domestic cigarette manufacturers are small, and the one-time labeling change cost could be a significant proportion of average annual sales receipts of these firms.							
Wages: No Estimated Effect							
Growth: No Estimated Effect							

BILLING CODE 4160–01–P

Our primary estimate of annualized net benefits equals $601.4 million, with a 3-percent discount rate, or $184.5 million, with a 7-percent discount rate. As shown in table 1b of this document, these net benefits are associated with 16,544 smoking preventions and 5,802 quality-adjusted life-years (QALYs) saved, annualized at a 3-percent discount rate, or 19,687 smoking preventions and 1,749 QALYs saved, annualized at a 7-percent discount rate.

Table 1b.--Annualized Net Benefits, Smoking Preventions and Quality-Adjusted Life-Years Saved

Discount Rate	Net Benefits ($ mil)			Smoking Preventions	Quality-Adjusted Life-Years Saved
	Primary Estimate	Low Estimate	High Estimate	Primary Estimate	Primary Estimate
7%	184.5	-52.7	3,326.0	19,687.1	1,749.4
3%	601.4	-40.8	10,889.2	16,544.3	5,802.5

FDA's estimate of the benefits of the rule is determined by the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from diseases caused by smoking. In the first step of our analysis, we conclude that graphic warnings on cigarette packages will reduce smoking rates (both by encouraging smokers to quit and by deterring nonsmokers from starting). This conclusion is based on an analysis of the experience of Canada, which introduced graphic warnings on cigarette packages in December 2000. By comparing smoking rates in the United States with those in Canada and accounting for other relevant differences between the two countries, we are able to isolate the effect of graphic warnings on smoking rates from the effects of other interventions to reduce smoking in Canada and the United States. This comparison yields an estimate of how the graphic warnings required by this rule will reduce smoking rates in the United States. FDA estimates that this rule will reduce the number of smokers by 213,000 in 2013, with smaller additional reductions through 2031.

This estimated drop in the smoking rate in turn allows us to estimate benefits that will accrue to dissuaded smokers and to other members of society. Some individuals whose smoking status is not affected by the required graphic warning labels will receive benefits from the rule-induced reductions in smoking-related fires and certain financial outlays, such as life insurance premiums that are not actuarially fair,[10] that implicitly subsidize smoking. Individuals who are dissuaded from smoking by the rule receive benefits equal to the value of cessation or avoided initiation. We use two methods of estimating this value, one that extrapolates from the price of actual cessation programs and one that measures the excess value of health improvements, over and above what smokers give up by not engaging in the activity of smoking. Our estimates of health improvements include the monetized value of life extensions, the monetized benefits from improved

[10] The term "actuarially fair" refers to insurance premiums that are exactly equal to expected losses.

health status (avoided nonfatal health consequences or morbidity from smoking), and reductions in medical costs. We do not have direct estimates for the value smokers attach to the activity of smoking, which adds some uncertainty to the second benefits estimation method. We therefore present several benefits estimates for which there is some justification in the literature or in comments on the proposed rule. For each discount rate and value of a statistical life-year (VSLY), our primary benefits result is the midpoint between the lower and upper bound values generated by the multiple estimation methods. Table 2 of this document shows the benefits broken down into the value of gained life-years, improved health status, medical cost reductions, other financial effects, and reduced fire-related losses. Most of the public health benefits from the rule will be realized in the future, perhaps several decades after the rule takes effect.

The estimated totals may understate the full public health benefits of the rule because they fail to quantify reductions in external effects attributable to passive smoking and the reduction in infant and child morbidity and mortality caused by mothers smoking during pregnancy. These benefits are likely to be significant, but FDA has been unable to obtain reliable data with which to quantify them with greater precision than an order-of-magnitude approximation which will be discussed in the ''Benefits'' section of this Analysis of Impacts. In particular, we were not able to project future levels of exposure to secondhand smoke (passive smoking) from historical trends. We were also unable to quantify reductions in the cost of excess cleaning and maintenance costs caused by smoking.

Table 2.--Benefits of Regulation

Impacts of the Rule	Annualized Benefits ($ mil)					
	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Smokers' Life-Years Saved	237.6	465.1	692.7	66.1	132.4	195.9
Health Status Improvements	49.9	97.8	145.6	22.8	45.7	67.6
Medical Expenditure Reduction	28.0	27.7	27.6	22.8	22.8	22.6
Other Financial Effects	27.4	27.5	27.6	15.4	15.4	15.5
Fire Loss Averted	7.1	12.4	17.6	3.2	5.2	7.2
TOTAL	349.9	630.5	911.1	130.3	221.5	308.8

Note: Table entries are annualized over 20 years, but many of the benefits represented will not be realized until well beyond the 20th year of the rule's implementation. (Details of timing appear in Technical Appendix X3.) The ranges in the table are generated by three values of a statistical life-year: $106,308 (low), $212,615 (medium), and $318,923 (high).

The total estimated costs of implementing cigarette graphic warning labels include $319.5 million to $518.4 million in one-time costs and $6.6 to $7.1 million in annual recurring costs. Annualized over 20 years, the total costs range from $27.4 million to $40.8 million with a 3-percent discount rate and from $34.7 million to $52.7 million with a 7-percent discount rate, as shown in table 3 of this document. These totals include the costs to manufacturers of changing cigarette labels, the administrative and recordkeeping costs to manufacturers of ensuring equal and random display of the nine different warning labels over time, the costs to large manufacturers of market-testing new cigarette package labels, and the costs to manufacturers and retailers of removing point-of-sale advertising that does not comply with the rule. There are also costs to the Government of administering and enforcing the rule. FDA could not quantify every regulatory cost. Some commercial sectors will experience costs for short-term dislocations of current business activities, but the costs will be mitigated for those businesses that anticipate the industry's adjustments to the final rule.

In addition to the costs described previously, the rule will lead to private costs in the form of reduced revenues for many firms in the affected sectors. These sector-specific revenue reductions are for the most part distributional effects and cannot be counted as social costs.

Table 3.--Costs of Regulation

Requirements of the Rule	Annualized Costs ($ million)					
	3 percent			7 percent		
	Low	Med	High	Low	Med	High
Private Sector						
Label Change	17.8	19.3	30.3	24.0	26.0	41.0
Market Testing	0.1	0.1	0.5	0.1	0.2	0.7
Point-of-Sale Advertising	3.0	3.0	3.0	4.0	4.0	4.0
Continuing Admin and Recordkeeping	0.4	0.6	0.8	0.3	0.6	0.8
Subtotal	21.2	23.0	34.7	28.5	30.8	46.5
Government						
FDA	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)						
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	27.4	29.1	40.8	34.7	37.0	52.7

As tobacco industry revenues decline, State and Federal tobacco tax revenues will also fall. If excise tax rates on tobacco products remain at current levels, annual State tax revenues will fall by approximately $25.1 million and annual Federal tax revenues by $19.3 million.

In the following section, FDA responds to comments on the economic analysis of the proposed rule. The full economic analysis of the final rule begins in section XI.C of this document.

B. Comments on the Preliminary Regulatory Impact Analysis

1. General

In the Preliminary Regulatory Impact Analysis (PRIA), FDA estimated various benefits, costs and transfers brought about by the graphic warning label rule. We received comments on the PRIA from approximately seven tobacco manufacturers or industry groups, one advertising industry group, four nonprofit organizations, a group of researchers and an individual researcher affiliated with a medical school, two economists submitting on behalf of the tobacco industry, one additional economist, and several private citizens. Two comments related to the scope of the effects that should have been estimated in the PRIA and to a parameter choice that affected several portions of the analysis.

(Comment 212) One comment stated that FDA's use of a 7-percent discount rate is not appropriate.

(Response) The use of both 3-percent and 7-percent discount rates is standard practice in regulatory impact analysis and is required by OMB Circular A–4 (Ref. 103).

(Comment 213) One comment stated that FDA should measure the scope of the following potentially rule-induced phenomena: Increases in the purchase of illicit cigarettes (counterfeits, contraband, cheap whites, *etc.*), increases in the presence of nondomestic products (duty-free, *etc.*), and decreases in the presence of legal domestic products.

(Response) FDA has performed a quantitative analysis of the regulation's effect on domestic cigarette consumption (sections XI.D.1 and Technical Appendix X6) and a qualitative analysis of the international effects of the regulation (section XI.H of this document). FDA agrees that it would be useful to include the effect of the rule on illicit cigarette trading in the regulatory impact analysis. However, due to data limitations, FDA has been unable to quantify this effect.

2. Need for the Rule

In the preliminary impact analysis of the graphic warning label rule, FDA cited our statutory mandate as the primary need for the regulation. We received a comment stating that we had failed to discuss the economic rationale for the rule.

(Comment 214) One comment stated that FDA, in the preliminary Analysis of Impacts, failed to identify the market failure that the regulation is addressing. The comment went on to state that warning labels are a means of disseminating information, and if consumers are already fully informed about a particular product, there can be no increase in consumer welfare due to the addition or revision of a warning label.

(Response) An absence of adequate information is a well-established market failure, one which provides a rationale for disclosure requirements. There is evidence that smokers may not be fully informed of the risks associated with cigarette smoking and that large graphic warning labels can be more effective at providing information than small, text-only warnings. There is also evidence that those who have an accurate understanding of the *statistical* risks may underestimate their *personal* risks; and even where consumers have an accurate understanding, the risk might not be considered at the time of purchase (Ref. 183).

Evidence on some of these points is provided by O'Hegarty *et al.* (Ref. 111), who find that young American consumers are aware of some health consequences of smoking, such as the increased probability of lung cancer, but not of others, such as the increased probability of stroke. Other evidence on this question comes from Khwaja *et al.* (Ref. 112), who find that smokers aged 50 to 65, unlike their nonsmoking counterparts, underestimate their personal probability of dying within the next 10 years. Borland and Hill (Ref. 63, Borland 1997) find that Australia's requirement of larger warning labels increased tobacco consumers' knowledge that smoking causes cancer, heart and circulatory illnesses, and pregnancy-related problems. O'Hegarty *et al.* (Ref. 111) report that American focus group members anticipate that Canadian-style large, graphic warning labels would be more effective at communicating health information than the labels currently required in the United States. Evidence from the International Tobacco Four-Country Survey (Ref. 26, Hammond 2006) supports this conclusion, with Canadian smokers more likely than smokers from the United States, United Kingdom, or Australia—countries that required only text warnings at the time of the survey—to know that smoking causes heart disease, stroke, and impotence and that cigarettes contain such chemicals as carbon monoxide and cyanide.

The U.S. Census indicates that nearly 11 million respondents in the year 2000 did not speak English well or very well (Ref. 102); the non-English-speaking population has likely increased in the intervening years. Moreover, the Department of Education reports that, in 2003, 30 million American adults, aged 16 and over, possessed ''below basic'' prose literacy skills (Ref. 113). Images of smoking's consequences and translation of warnings into Spanish and other languages can provide health information to consumers who lack English literacy.

FDA also notes that the economics and psychology literatures suggest several rationales, other than incomplete or imperfect information, for policy intervention in the realm of smoking. The growing literature on myopia, self-control, and time-inconsistency examines situations in which consumers may overvalue (relatively modest) short-term benefits and undervalue (relatively large) mid-term or long-term harms. The theoretical and empirical evidence suggests the possibility that through their decisions at early stages, smokers may impose significant costs on their future selves, producing net losses in terms of welfare; if so, these costs might legitimately be taken into account for purposes of policy. Helping to inaugurate the modern literature, Thomas Schelling suggests in a series of papers that smoking and similar behaviors characterized by attempts to quit and relapses can be interpreted as a contest between two selves: One self trying to stop smoking for health reasons and the other self wanting to continue to smoke. These alternating preferences violate the assumption of stable preferences and can provide a rationale for policy interventions (Refs. 106, 107, and 108).

Discussing another potential rationale for policy intervention, Gruber and Köszegi (2001) (Ref. 104) state: ''While the rational addiction model implies that the optimal tax on addictive bads should depend only on the externalities that their use imposes on society, the time inconsistent alternative suggests a much higher tax that depends also on the 'internalities' that use imposes on consumers.'' With the graphic warning label rule, FDA is undertaking a policy option that, like a tax, can induce lower cigarette consumption, and we reach a conclusion similar to that of Gruber and

Köszegi; we find that individuals who are dissuaded from smoking are made better off (*i.e.,* they receive a net benefit) as a result of government policy intervention. (We note that Gruber and Mullainathan (Ref. 182), using subjective well-being data, find that one regulatory tool—excise taxation—has a positive effect on the happiness of those with a propensity to smoke, a result consistent with the results we present in this analysis.)

Bernheim and Rangel (Ref. 105) find that the benefits of smoking (realized by smokers themselves) are less than the realized health costs, but chemical reactions in the brain cause the consumer to mistakenly forecast more benefits when making consumption choices than he or she actually realizes from consuming the addictive product. These authors suggest that this overestimation occurs through a flawed hedonic forecasting mechanism in which particular environmental cues lead a smoker to move into a ''hot'' state in which he or she overestimates the pleasure from smoking. This analysis suggests that graphic warning labels may be able to serve as counter-cues that prevent movement into the hot state and allow the addict to continue to exercise self-control.

Laux (Ref. 109) identifies other reasons that smokers may not fully internalize the costs of their addictive behavior, including teen addiction as an intrapersonal (two selves) externality, partially myopic adult behavior, and peer effects.

According to the model developed by Gul and Pesendorfer (Ref. 110), if graphic warning labels reduce the temptation associated with the addictive product, they will reduce smoking and increase social welfare.

3. Benefits

In the preliminary impact analysis, FDA estimated a variety of welfare-enhancing effects of the graphic warning label rule; these included reductions in smoking-related mortality, morbidity, medical expenditures, and fire damage. We received many comments on the methods, assumptions, choice of sources, and results that were reported in the benefits analysis.

(Comment 215) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too low, in that it ignored the rule's effect on initiation, in favor of a cessation-only analysis.

(Response) For both the proposed rule and the final rule, FDA has analyzed the national adult smoking rate (*i.e.,* the nation's smoking population divided by the nation's total population). The smoking rate at any particular moment is a function of all past initiation, cessation, birth, death, and migration of smokers and nonsmokers across national borders. Therefore, our approach includes the effect of the rule on initiation.

(Comment 216) One comment stated that FDA's preliminary estimate, that only 82,000 individuals would be dissuaded from smoking between 2014 and 2031, was too low.

(Response) FDA's estimate that the rule-induced reduction in U.S. smoking population will occur mostly during the first year after implementation of graphic warning labels is a product of the simplicity of our empirical model. We agree that a time trend of the effect of the rule is to be preferred over a single average effect. However, our attempts to estimate linear or quadratic time trends have produced highly implausible results, especially for projections furthest into the future. We are then left with a best estimate of how the rule would decrease the U.S. smoking rate in which the number of dissuaded smokers is smaller for any year from 2014 to 2031 than for 2013. This estimated change is not a decrease from year to year (*e.g.,* 2013 to 2014), but a net decrease for a given year in the presence of the rule compared with the same year in the absence of the rule.

(Comment 217) Two comments stated that FDA's preliminary estimate of smoking rate reduction was too low, in that it ignored the fact that someone who is dissuaded from smoking in 1 year will likely remain a nonsmoker in future years.

(Response) FDA notes that the likelihood that an individual dissuaded from smoking in a particular year will likely continue to be a nonsmoker in subsequent years was accounted for by our preliminary estimate, which had the U.S. smoking rate continuing to be lower than it otherwise would have been in years 2014 through 2031, not just in 2013. The same characterization holds for the estimate in FDA's Final Regulatory Impact Analysis.

(Comment 218) One comment stated that ''Canada has used graphic warnings for years, and in the last decade their smokers dropped from 23% to 22% of the population.''

(Response) Canada's smoking rate has decreased by around seven percentage points, not one, since the implementation of graphic warning labels in late 2000. Even if the one percentage point statistic was correct, a one percentage point decrease in the smoking rate would not be a small change when applied to the large population of the United States; in fact, it would imply that there would be more than 3 million dissuaded American smokers.

(Comment 219) One comment stated that the required label change would have very little impact on smoking rates because minors, who form the bulk of new smokers, obtain their cigarettes from parents rather than from retail establishments.

(Response) Due to lack of data, FDA's estimates of the amount of smoking cessation or avoided initiation brought about by the rule include only adults aged 18 and above, or young persons who reach age 18 by the year 2031. The number of minors dissuaded from smoking by the rule may be substantial. Whether they obtain cigarettes from friends, through theft, or by purchasing them from retail establishments operating in violation of youth access laws, young people will be exposed to new graphic warning labels because the labels are printed directly on cigarette packages.

(Comment 220) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not address potential competitive responses of the cigarette companies to the proposed rule. The comment went on to state that, under the proposed rule, graphic warning labels would take up a substantial portion of the area in packaging and advertising where firms establish brand recognition, thus reducing consumers' ability to distinguish premium from discount brands. This would cause premiums for branded cigarettes to decrease and price competition to intensify, which in turn would likely lead to an increase in cigarette usage.

(Response) FDA believes that, even if well-known brands only have half a package with which to advertise themselves, they still have name recognition. We expect that consumers will continue to be able to find their preferred brands; as a result, any change in prices due to competitive pressures is likely to be small.

The cigarette producers' strategic responses suggested by the comment should have occurred in Canada when that country implemented graphic warning labels. Because FDA's estimate of the effect of graphic warning labels is based on the Canadian experience, we implicitly account for any decrease in the price of cigarettes caused by competition between premium and discount brands. Our point estimate indicates that the net effect of graphic warning labels is a decrease in the national smoking rate in spite of this possible offsetting effect.

(Comment 221) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to recognize or control for other regulatory changes (such as smoking bans) affecting cigarette consumption at the State, provincial, or municipal levels.

(Response) FDA acknowledges that our model does not explicitly allow for many potential confounding factors, but we note that our estimates of the effect of graphic warning labels could as easily be underestimates as overestimates. More specifically, our model will produce an overestimate if: Smoking-reducing phenomena (other than graphic warning labels) were growing in prevalence or effectiveness at a faster rate in Canada after 2000 than before 2001, smoking-reducing phenomena (other than graphic warning labels) were more prevalent or effective in Canada than in the United States after 2000, or smoking-reducing phenomena (other than graphic warning labels) were less prevalent or effective in Canada than in the United States before 2001. In the opposite cases, our model will produce an underestimate. In the absence of extensive high-quality data, we assume that trends in smoking-reducing phenomena (other than graphic warning labels) were about the same before and after the year 2000 and about the same in Canada and the United States.

(Comment 222) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for potential differences in responder bias between United States and Canadian surveys created by different levels of stigma associated with smoking in the two countries.

(Response) FDA generates its estimate not only by comparing Canada with the United States but also by comparing each country with itself. Specifically, we find the difference between each country's actual 1994 through 2009 smoking rates with rates predicted by a pre-2000 trend (which accounts for changes in cigarette taxes), and then calculate how the average difference for 2001 through 2009 compares with the average difference for 1994 through 2000. The trend at least partially controls for any steady change over time in responder bias within a given survey, and the within-country comparison of pre-2001 and post-2000 rates controls for any difference in responder bias between the two countries.

(Comment 223) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for differences in cigarette prices over time in the United States and Canada.

(Response) For the analysis of the final rule, FDA has incorporated changes in Canadian and United States tax rates into its estimates.

This comment suggests elsewhere that graphic warning labels will cause prices to decrease. FDA agrees that this is a possibility. Thus, for the non-tax portion of cigarette prices, we are faced with what economists call an endogeneity problem; it is difficult to determine, in an empirical analysis in which price is used directly as a control variable, the direction and magnitude of causality. However, if the changes in the non-tax portion of prices in the United States and Canada follow the same pattern post-2000 as they did pre-2001, and if the relationship between smoking status and cigarette prices was also relatively constant between the two time periods, then our smoking rate trends successfully control for the effect of non-tax price changes on smoking rates.

(Comment 224) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it did not account for the fact that Canada's Tobacco Act's prohibitions on advertising and promotion came into full effect after the introduction of the graphic cigarette labels. The comment went on to state that other local regulations (such as restrictions on the retail display of tobacco products and advertisements) that came into effect in Canada after the year 2000 also may have had an effect on smoking rates in Canada, and thereby would have inflated FDA's estimate of the expected rule-induced reduction in smoking rates.

(Response) From 2001 to 2008, at least 41 states, plus the District of Columbia, enacted or substantially updated legislation regarding tobacco advertising and promotion, youth access or sampling and distribution (Ref. 114). FDA concludes, therefore, that the U.S. experience provides a reasonably good control for the effect of local and regional policy changes on national smoking rates.

(Comment 225) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to account for the fact that, in April 2001, the Government of Canada launched a Federal public education, outreach, and mass media campaign that had a goal of reducing tobacco-related death and disease among Canadians.

(Response) The U.S. experience provides a reasonably good control for the effect of media campaigns on smoking rates because antismoking initiatives have been active in the United States in the past decade. For example, the ''Truth'' Campaign, a nationwide advertising effort aimed at discouraging youth smoking, launched in the United States in 2000 and continued into the 2000s.

(Comment 226) One comment stated that FDA's preliminary estimate of the rule-induced smoking rate reduction was too high, in that it failed to account for the fact that individuals over age 65 are less likely to be smokers than younger individuals and Canada's population is aging more rapidly than that of the United States. Specifically, during the period 2001 through 2009, Canada's over-65 population grew by 21 percent while the U.S. over-65 population grew by only 12 percent. Canada's over-65 population represented 13.9 percent of its total population in 2009, up from 12.9 percent in 2001. This compares to the U.S. over-65 population which increased to 12.9 percent in 2009, up from 12.4 percent in 2001.

(Response) FDA notes that the comment's finding (that individuals over age 65 have a lower probability of being smokers than individuals aged 65 and below) does not necessarily imply that aging causes individuals to cease smoking. Smoking rates are much lower in the over-65 age category than in the 65-and-under category because smokers are less likely than nonsmokers to survive to and live past the age of 65.

Possible reasons for the aging of a nation's population include: A decrease in the birth rate, net emigration of relatively young people, net immigration of relatively old people, a decrease in the death rate of relatively old people, or an increase in the death rate of relatively young people. If the changes in these population phenomena in the United States and Canada follow the same pattern post-2000 as they did pre-2001, and if the relationship between smoking status and the population phenomena was also relatively constant between the two time periods, then our smoking rate trends successfully control for the effect of population changes on smoking rates. (Of course, there is a correlation between smoking rates and death rates, but it operates with sufficient lag so as not to confound our results to a meaningful degree.)

(Comment 227) Several comments suggested that the lack of statistical significance of FDA's estimate of the effect of graphic warning labels on Canada's smoking rate implies that there is no sound basis for concluding that the proposed (and now final) rule's benefits exceed costs and that this creates a

violation of Executive Order 12866, which requires government agencies to show the quantitative benefits exceed the quantitative cost from a regulation. One comment further noted that FDA did not, in the preliminary analysis, report whether its secondary methodology (in the Uncertainty Analysis) produced an estimate that was statistically significant.

(Response) Executive Order 12866 states that: ''Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.'' The point estimates indicate that the benefits of the rule justify the costs. Although our analysis concludes, on this basis, that graphic warning labels will be effective at reducing smoking, we recognize there is large uncertainty about the size of the effect. The lack of statistical significance in FDA's smoking rate estimate reflects this uncertainty, as well as the noisiness of data derived from surveys and the small number of observations.

The use of a point estimate (which indicates that graphic warning labels have decreased the smoking rate in Canada) is appropriate for the main portion of our analysis as long as we state clearly the lack of statistical significance. Moreover, in the final analysis, we report the results of Monte Carlo simulations to better show the uncertainty. In doing so, we follow the advice of Vining and Weimer (Ref. 115): ''In view of the large number of uncertain effects and shadow prices involved in applying BCA [benefit-cost analysis] to social policies, analysts must take special care in dealing with uncertainty. Rather than setting estimates of effects equal to zero when their estimates are statistically insignificant, a more appropriate approach is to take account of the uncertainty of these effects in Monte Carlo simulations.''

In addition to reporting Monte Carlo results, FDA has added additional discussion which will allow the interested reader to examine our empirical approaches in greater detail.

(Comment 228) One comment stated that FDA has no explicit measures linking each graphic warning label with expected reductions in the risks of cigarette smoking. An example of such linking would include answering the following questions: What percentage of smoking mothers blow smoke into their children's faces, what is the probability that such behavior leads to cancer, and how much cancer reduction will be effected by the graphic warning label that depicts a baby being exposed to secondhand smoke?

(Response) The research study commissioned by FDA and included in the docket analyzes the reactions of consumers to each image. We cannot yet know the effectiveness of each image on improving health outcomes (such as avoidance of cancer) because the images have not yet appeared on cigarette packages or advertisements. Our best estimate of the images' collective effect comes from Canada's experience with a collection of graphic warning labels.

(Comment 229) One comment stated that FDA should use worldwide data if its model of smoking reduction cannot achieve statistical significance using only Canadian data.

(Response) FDA disagrees because, culturally and geographically, Canada provides a closer comparison for the United States than any other country. Moreover, in most countries, graphic warning labels have been implemented for only a few years, so any international additions to our data set would likely contribute only a small number of data points while simultaneously necessitating the addition of extra variables (for example, geographic and time fixed effects) into the model, thus producing only a small overall increase in degrees of freedom and introducing potential errors due to more omitted variables.

(Comment 230) One comment stated that FDA should use data from New York City's experience with a graphic image media campaign, which reduced smoking prevalence in that State by 1.4 percentage points between 2005 and 2006.

(Response) FDA prefers the Canada-United States empirical model over a potential New York model both because Canada's graphic warning policy is much more similar to the present rule than is New York's television-based campaign and because Canada's policy has been in place for a longer period of time than New York's, thus providing more data points. Furthermore, we note that the New York experience would likely yield a much lower (than 1.4 percentage points) estimate of the effect of graphic images if only the excess smoking rate changes, beyond New York's own trend and the changes experienced simultaneously in comparable cities or States, were included.

(Comment 231) Several comments stated that Sloan and coauthors' estimates of the number of life-years lost by smokers are too low and recommended that FDA use other, higher estimates that appear in the scholarly literature.

(Response) The comments making this point have confused the life-years lost for a lifetime smoker (compared with a nonsmoker or quitter) with the measure that FDA needs for its analysis: the adjusted life expectancy changes that make up the incremental effects of reduced smoking rates induced by the final rule.

Regarding life-years lost for a lifetime smoker (compared with a nonsmoker or quitter), Sloan and coauthors' estimates (Ref. 116) do not differ much from those reported in other studies. Specifically, Sloan *et al.* use results from the Taylor *et al.* (Ref. 117) study, which reports that men who quit smoking at age 35 gain 8.5 years of life expectancy and male never-smokers gain 10.5 years. In comparison, Doll *et al.* (Ref. 118) find that if an individual avoids smoking entirely or quits at age 30, he increases his life expectancy by 10 years. Strandberg *et al.* (Ref. 119) find that smoking shortens life expectancy for males by 7 to 10 years.

Sloan *et al.* adjust the Taylor *et al.* results to account for the probability that an individual who smokes at a given age will quit sometime later in his or her life and for confounding factors, such as differences in demographic characteristics and behaviors between average smokers and nonsmokers. Unlike Sloan *et al.,* the studies cited in comments estimate the longevity gains to an individual from not smoking or from quitting at a given age but do not incorporate the *probabilities* of quitting at each age or isolate the effect of cigarette consumption from other risk factors that tend to be correlated with smoking. These studies are therefore inappropriate for a regulatory impact analysis estimating the incremental effects of warning labels on lifetime mortality consequences related to smoking at a particular age.

(Comment 232) Two comments expressed concern that Sloan and his coauthors' analysis is outdated. One of the comments went on to state that Sloan *et al.'s* literature review contains some studies that have been funded by the tobacco industry and their ''defense of rational addiction'' may be undermining FDA's effort to ''ensure that its economic analysis is based on empirical evidence, not theoretical predictions from the rational addiction model.''

(Response) The Sloan *et al.* results that FDA uses are empirical, not theoretical. In producing these empirical results, Sloan and coauthors use data from the 1990s; while this is somewhat out-of-date, no analysis as

detailed as that of Sloan *et al.* has been released more recently. The comment critiques some of the literature reviewed by Sloan and coauthors but not the methods Sloan *et al.* use to produce their life tables and other results. FDA has thus continued to use these results in its Final Regulatory Impact Analysis.

(Comment 233) One comment stated that the FDA provided in its preliminary Analysis of Impacts virtually no details on its calculation of the benefit of expected life-years saved.

(Response) FDA has added a more detailed explanation to the final Analysis of Impacts.

(Comment 234) One comment stated that, in its estimate of rule-induced emphysema reductions, FDA did not provide any documentation supporting its calculations.

(Response) FDA has replaced its analysis of rule-induced emphysema reductions with an analysis of general health effects. Simultaneous with this change has been an expansion of our explanation of methodology.

(Comment 235) Several comments stated that morbidity effects other than emphysema were inappropriately excluded from FDA's preliminary analysis.

(Response) FDA has expanded its morbidity estimates for the final Analysis of Impacts. Instead of analyzing individual diseases, we have calculated rule-induced changes in general health status (categorized as poor, fair, good, very good, or excellent).

(Comment 236) Several comments stated that benefits due to reductions in secondhand smoke exposure and mothers smoking during pregnancy were inappropriately excluded from FDA's preliminary analysis.

(Response) FDA did not exclude discussion of these effects from the preliminary Analysis of Impacts, but we were not able to quantify them due to the difficulty of projecting future secondhand smoke exposure levels from historical trends. Similarly, we were not able to project future reductions in maternal smoking during pregnancy. In the Final Regulatory Impact Analysis, FDA has again been unable to quantify these benefits.

(Comment 237) One comment stated that FDA's analysis includes only health benefits that accrue in the distant future, not immediate benefits of cessation or avoided initiation.

(Response) FDA's preliminary and final estimates of morbidity and mortality effects include discounted totals of all future effects, both short-term and long-term. For example, we obtained our life expectancy estimates from Sloan *et al.*'s life tables. Calculated for 24-year-olds, these tables include survival probability differences for smokers and nonsmokers as early as the 25th birthday.

(Comment 238) One comment stated that FDA's assumptions regarding the distribution of benefits over dissuaded smokers' lifetimes were incorrect.

(Response) In many cases, FDA's sources reported smoking-related effects only as present values calculated with a single discount rate and for a particular age group. In order to expand our results to other age groups or discount rates, it was necessary that we make assumptions about the timing of benefits. The absence of data prevents FDA from confirming the degree of inaccuracy of our assumptions. For the final analysis, we have expanded our discussion of the likely direction of estimation error that may be caused by our assumptions and, in one case, have accounted for uncertainty related to assumption-making in our Monte Carlo analysis.

(Comment 239) One comment stated that Sloan *et al.*'s estimates of smoking-attributable medical cost ($3,757 per female and $2,617 per male) are too low. The comment went on to recommend the use of Thomas Hodgson's estimate (Ref. 120) that this cost, in 2009 dollars and discounted at a 3 percent rate, is $18,967.

(Response) FDA believes that Sloan *et al.*'s estimates are to be preferred over Hodgson's because Hodgson does not adjust for confounding effects (by analyzing ''nonsmoking smokers,'' a theoretical comparison group Sloan *et al.* used to account for the effects of other risky behaviors) and Sloan *et al.*'s data sets are more recent (from the 1990s, rather than 1978 through 1988).

The comment calculates the present-dollar value of Hodgson's medical cost estimates using the medical component of the consumer price index (CPI). For the Final Regulatory Impact Analysis, FDA will do the same because medical costs have risen at a very different rate than overall price levels and thus the measure of inflation we used in the PRIA—the gross domestic product (GDP) deflator—is not the best available option for updating medical costs.

(Comment 240) One comment stated that FDA's medical cost results were not adjusted for inflation in the preliminary Analysis of Impacts.

(Response) FDA's medical cost estimates were adjusted for inflation in the analysis of the proposed rule; however, our language on this issue was unclear and has been revised for the analysis of the final rule.

(Comment 241) One comment stated that, in the preliminary analysis, FDA provided only a very high-level and cursory description of how it arrived at its estimate of reduced fire costs.

(Response) For the final analysis, FDA has expanded the discussion of how fire loss reductions were calculated.

(Comment 242) One comment stated that FDA's assumption that the introduction of self-extinguishing cigarettes would reduce the incidence of smoking-related fires, with or without the proposed rule, by 50 percent was arbitrary.

(Response) FDA agrees that the 50 percent assumption lacked empirical support. For the final analysis, we use a data-driven estimate of the effectiveness of self-extinguishing cigarettes at preventing accidental fires.

(Comment 243) Two comments stated that FDA's preliminary benefits analysis inappropriately excluded effects of the rule on employee productivity.

(Response) FDA estimates morbidity and mortality effects using a willingness-to-pay approach, estimated using the QALY metric as the base. Willingness-to-pay to avoid morbidity, as we use it in this analysis, includes the subjective value of avoiding an illness that affects mobility, self-care, usual activities (including work), pain or discomfort, and anxiety or depression. These elements encompass the value of market and nonmarket productivity, and much else. Therefore, in general, the value to smoking employees of productivity effects is implicitly included in both morbidity and mortality benefits; adding productivity effects separately would almost certainly lead to double counting of some of the benefits that accrue to dissuaded smokers. Economic theory predicts that, for employers, rule-induced productivity effects generate no long-term net benefit or cost because greater firm output will be offset by the greater wages commanded by the more productive employees.

(Comment 244) One comment stated that ''FDA's analysis could benefit from a more fulsome explanation of the concept of QALY.''

(Response) FDA has edited the final analysis accordingly.

(Comment 245) FDA received several comments in regard to its downward adjustment of benefits estimates to account for consumer surplus loss. One comment stated that such an adjustment should not be performed at all because doing so requires an inaccurate assumption that smokers enjoy smoking. Three comments suggested that, if an adjustment is performed, it should not be 50 percent of gross health benefits, as suggested in FDA's cited reference, because that analysis assumes perfect

rationality on the part of smokers. Another comment objected to the model in the cited reference because it is very simplified and stylized, with a linear demand curve for smoking. One of the comments suggested FDA should instead consider modern economic analyses of addiction that account for time inconsistencies in preferences, including the work of Fritz Laux (Ref. 109) or Jonathan Gruber and Botond Köszegi (Ref. 104). Another of the comments suggested past regulatory changes and their effect on smoking be used to measure demand and the lost surplus associated with those changes to get a more empirically relevant measure of the effect of the proposed rule.

(Response) The concept of consumer surplus is a basic tool of welfare economics. If consumers respond to price, information, or other market changes, there will be a change in consumer surplus. Although some economists describe consumer surplus as a measure of the pleasure, satisfaction, or usefulness that a product provides to consumers, others simply say that whatever generates a demand for the product generates consumer surplus. Moreover, how we qualitatively describe consumer surplus does not affect how it is measured—the measurement is independent of the description. In an analysis of benefits based on willingness-to-pay, we cannot reject this tool and still fulfill our obligation to conduct a full and an objective economic analysis under Executive Orders 12866 and 13563.

Although it does not affect our use of consumer surplus, we note that virtually all studies of the economics of smoking and addiction assume that smoking is pleasurable to smokers. In their 2001 paper in *The Quarterly Journal of Economics,* Gruber and Köszegi state that ''smoking is a short-term *pleasure''* (emphasis added) (Ref. 104). Economists Warner and Mendez state: ''Many members of the tobacco control community dismiss the notion that smoking can be pleasurable. But those people were never smokers or, if they were, have selective memory. For some smokers, the relief of withdrawal symptoms might suffice as a 'pleasure.' But smokers derive much more from their cigarettes, including everything from 'mouth feel' to the nicotine drug rush, from relaxation to self-image (think Marlboro Man), and from enhanced ability to concentrate to companionship'' (Ref. 121).

FDA's approach to the economics of smoking treats it as an addiction and draws on many economic theories of addiction, including the studies cited in the comments, as already detailed in our response to comments on market failure.

FDA agrees that the model we used in the PRIA to explain changes in consumer surplus is not detailed enough to fully explain the assumptions about consumer behavior underlying our estimates. In the revised analysis, we have made some important changes in the presentation and the model used to adjust our estimates and account for uncertainty. The key assumption made explicit in the new model is that, on average, smokers are informed of, and able to internalize, some but not all health and life expectancy effects of their smoking. Full graphical and algebraic analyses have been added to the final analysis, as has a discussion of the implications of Gruber and Köszegi's work in the context of the new model. Moreover, we have supplemented our benefits analysis with another approach, in which we replace the steps of summing all health effects and then subtracting lost consumer surplus with a direct estimation of the value to smokers and potential smokers of cessation and avoided initiation, as shown by their willingness-to-pay for cessation programs.

(Comment 246) One comment stated that FDA's preliminary benefits analysis inappropriately excluded the effects of the rule on employer and government cleaning and maintenance costs.

(Response) Reductions in the cost of cleaning and maintenance were not included in the analysis because we did not find reliable data.

(Comment 247) One comment stated that FDA should conduct its uncertainty analysis by performing a Monte Carlo simulation.

(Response) FDA agrees and has conducted a Monte Carlo simulation for the Final Regulatory Impact Analysis.

(Comment 248) Two comments stated that FDA's preliminary analysis inappropriately excluded the effects of the rule on government-funded health care and Social Security expenditures.

(Response) In our analysis of the proposed rule, FDA did not exclude government health care costs. In section VIII.C.6 of the PRIA, FDA reported estimates of reductions in smoking-related medical expenditures, paid for both by smokers themselves and by nonsmokers via insurance premiums or, notably, taxes used to fund government health care. For the Distributional Effects portion of the Final Regulatory Impact Analysis, we have expanded the discussion of this effect of the rule to include greater detail.

We have also added a discussion of Social Security payments to the Distributional Effects section of the final analysis. We note, however, that the cost to taxpayers of Social Security are exactly offset by payments to Social Security recipients or users of any other government programs and services funded with Social Security contributions, so this effect does not generate a substantial net social cost or benefit, with the exception of a probably small deadweight loss.

(Comment 249) One comment stated that the FDA's preliminary analysis did not, as required by the Office of Management and Budget, provide a year-by-year schedule of undiscounted cash flows that displays the timing of estimated rule-induced benefits.

(Response) FDA has added stream-of-benefits and -costs tables as appendices to the final analysis.

4. Costs

In the analysis of the proposed rule, FDA focused on three main costs to industry: The cost of changing cigarette package labels, the cost of conducting market testing for redesigned packages, and the cost of removing noncompliant point-of-sale advertising. FDA received several comments about costs, which are summarized and responded to in the following paragraphs.

(Comment 250) One comment took issue with FDA's characterization of the up-front costs associated with a major label change as ''large'' by pointing out: ''In the context of tobacco marketing, with the companies spending $12.5 billion on marketing and promotion in 2006, the amounts of money being described are not 'large.'''

(Response) FDA has removed the term ''large.''

(Comment 251) One comment asserted that the cost section was systematically biased, and that all costs were upper bound estimates as opposed to ''best'' point estimates.

(Response) FDA did not rely on upper bound estimates of any costs. The label change costs (the largest single cost component FDA estimated) and the market testing costs have low, medium, and high estimates. For the other cost components, we use our best estimates.

(Comment 252) One comment argued that because tobacco manufacturers spend large amounts of money on marketing activities, changing labels is just an ordinary cost of business to them, and one that they can ''write off.'' Furthermore, the comment argued that manufacturers can, to some extent, pass the costs on to consumers. The comment ends by stating: ''It is not appropriate for the FDA to fear that its regulatory efforts on this industry might impose costs on them, and to use these costs as a reason not to proceed with its

regulations. The agency is supposed to act in the public interest, not the interest of a particular industry to protect it from protecting the public in the first place.''

(Response) The baseline expenditures of the tobacco industry are irrelevant. There is a cost to society when its scarce resources are expended to comply with this rule. The costs the comment refers to are economic or opportunity costs. Cost estimation is concerned with the value of the resources used to carry out some activity, not their incidence (*i.e.,* who ultimately pays), which is a separate question. As acknowledged in the proposed rule (section VIII.D, *Costs*), although cigarette manufacturers are legally responsible for complying with this rule, the costs may be borne at least in part by tobacco consumers. The potential for ''passing costs on'' to consumers is a matter of economic incidence but does not negate the fact that there are costs, nor does it change those costs.

In the cost-benefit analysis we estimate costs and benefits that accrue to citizens and residents of the United States (Ref. 103) regardless of who we think may bear them. The ''interest of a particular industry'' is a subject we rightly leave to the ''Distributional Effects'' section of our analysis.

(Comment 253) A comment stated that FDA should estimate ''the *marginal* cost of changing the warning labels that the cigarette companies would incur accounting for ongoing expenses associated with producing cigarette packages and assuming that the companies implemented the new labels using economical strategies.''

(Response) The labeling cost model's baseline already accounts for ongoing expenses associated with producing cigarette packages. Manufacturers change product labels at regular intervals without regulatory changes in labeling requirements. Based on both product type and compliance period, the model provides an estimate of the percent of UPCs that can be coordinated with a previously scheduled labeling change. For those UPCs, the only costs assumed by the model are a small fraction of the administrative labor cost and recordkeeping costs.

If anything, this approach taken by the model quite possibly understates the labeling costs for so-called coordinated UPCs. For example, even though a graphic designer can redesign a label to satisfy both regulatory and nonregulatory goals at once, such a redesign would plausibly take longer than a redesign to satisfy only nonregulatory requirements, and time devoted to regulatory compliance must be taken away from other activities. However, because this rule requires a set of 9 plates for the 9 different graphic labels, we manually adjust the model to add back the 8 extra plates.

(Comment 254) A comment asserted that although there are 3,324 different UPCs, each UPC would not have to be redesigned because product varieties within a brand family share essential trade dress and package design features. The comment asserted that using a number equal to 10 percent of the number of UPCs, 332, would still result in an overestimate of costs.

(Response) Although products within a brand family share certain package design features, the packages for different UPCs still contain unique features. Thus, every individual UPC represents a separate design job. Furthermore, the labeling cost model presents an *average cost per UPC* of similar types within a product category, not the cost of changing one UPC. The model therefore accounts for the existence of brand families with similar label designs.

(Comment 255) A comment asserted that FDA overestimates production and printing costs by ''not accounting for the realities of how such work is actually done.'' The comment provided the following quote from an unknown large job printer: ''In looking at the costs associated with each label, this might be fairly accurate for 1 label, but they don't take into account the economies of scale. After the first one, the second and subsequent package costs will go down exponentially. The only costs that might remain static would be the costs of printing plates, which depending on how they print them, could be reduced if they gang run several different packages of similar production runs together on the same sheet. All the non-production costs would be amortized over the whole.''

(Response) The labeling cost model does not measure the cost of changing one label, but the average cost when a large number of labels are changed at once. Due to resource constraints, the economic cost could be higher when a large number of labels are changed at once. The comment did not provide either alternate cost estimates for FDA to consider, or potential sources for such data.

(Comment 256) A comment asserted that design costs should not be inflated due to the requirement to use nine different warnings because all warnings would occupy the same portion of each package, so the redesign would only have to be done once regardless of which warning would be used.

(Response) The comment appears to misunderstand which cost elements are affected by the need for nine labels. The term ''Design costs,'' as used in the labeling cost model, could refer to all per-UPC costs associated with a labeling change or specifically to graphic design labor costs. FDA inflated some, but not all, per-UPC labeling change costs by a factor of nine.

For graphic design labor costs, FDA agrees that the part of the package design that is under the control of the manufacturer will probably be the same regardless of which of the nine warning labels is used. Therefore, the work of designing the new package label only has to be done once for each UPC; in the cost estimates, graphic design labor costs were not inflated by a factor of nine.

Likewise, FDA assumed that the need to incorporate nine different warnings on every package would have a negligible impact on administrative labor costs, prepress labor costs, and recordkeeping labor costs. These costs therefore were not inflated by a factor of nine.

It was only for materials costs, which specifically includes prepress materials and printing plate costs, that FDA assumed costs increased by a factor of nine due to the need to incorporate nine separate warning labels. We employed this assumption because nine times as many printing plates will be needed upfront.

(Comment 257) A comment argued that some of the costs attributed to the label change would be incurred on an ongoing basis. The example provided is that printing plates wear out after a few million impressions and have to be replaced at regular intervals. The comment argued our cost estimates need to be adjusted to account for this. An analysis follows which claims to demonstrate that the average cigarette label printing plate has to be replaced every 3 weeks.

(Response) The calculation provided in the comment contains errors. Once those errors are fixed, the calculation no longer supports the assertion that printing cylinders are being constantly replaced, as discussed in the following paragraphs. Furthermore, the model accounts for possible coordination with previously scheduled labeling changes, which provides the most likely opportunity for cigarette manufacturers to avoid *some* of the incremental cost from new printing plates (cylinders). New cylinders must be engraved when a nonregulatory labeling change takes place. Given the expense of the printing cylinders, manufacturers would avoid engraving new cylinders right before a

nonregulatory labeling change. In other words, we would expect some coordination between cylinder wear out and nonregulatory changes.

Rotogravure plates are the longest lasting, good for making millions of labels. The comment assumed a life of only 3 million labels and did not justify this point estimate. For rotogravure, this estimate is too low.

In attempting to determine weekly sales per UPC, the comment divided weekly cigarette sales (in packs) by their estimate of the number of brands, not by the number of UPCs. Dividing by the number of UPCs, even under the assumption that plates wear out after 3 million labels, yields a life of 29 weeks for the average brand. Updating this analysis for the revised number of cigarette UPCs yields a life of 38 weeks for the average brand.

Additional calculations can be performed for the ''average'' brand, but it is important to keep in mind that most brands are not average. A few products will have high volume. A large number of lesser-known products will have low volume.

Because manufacturers will have to buy nine plates up front for each UPC, those nine plates would have a life of 346 weeks, or 6.6 years, based on the comment's assumptions about the life of a rotogravure plate and the updated UPC count. Manufacturers of the average product would not wear out all these plates before they changed labels again for nonregulatory reasons.

(Comment 258) Multiple comments argued that FDA should not include 10 percent rush charges in calculating the cost of changing labels in 15 months. In particular, the argument was made that cigarette manufacturers have known this was coming before publication of the final rule.

(Response) Although it is true that manufacturers have known this rule was coming, in some form, since the passage of the Tobacco Control Act, it is only with the publication of the final rule that they will know its exact form, *i.e.,* what the images will be. Tobacco companies will need to see the final images and the exact provisions of the final rule before the bulk of the work for a labeling change can be undertaken.

In evaluating the need for rush charges, it is important to keep in mind that the labeling model is designed to measure the cost of changing a large number of labels at once. Resources are scarce and a large number of labeling changes cannot be simultaneously rushed without increasing costs.

The previous labeling cost model assumed 10 percent rush charges for compliance periods shorter than 2 years. The new labeling cost model assumes constant rush charges equal to 40 percent for compliance periods of 3 to 15 months. In reality, rush charges are likely to decline continuously as the compliance period increases. The rush charges under a 3-month compliance period could exceed 40 percent, and the rush charges for a 15-month compliance period are likely to be far less. FDA has therefore retained the original assumption of 10 percent rush charges for a 15-month compliance period.

(Comment 259) One comment stated that FDA has underestimated costs because of technical implementation difficulties associated with providing for equal, random, simultaneous display of nine different images.

(Response) FDA does not agree that there is a technical infeasibility. Similar requirements have been successfully implemented in other countries. The cost analysis for the label change includes administrative labor and recordkeeping costs, part of which would be associated with devising and implementing a method for ensuring equal random display. However, FDA is now persuaded that there will be some ongoing cost associated with equal, random display. In other words, once a system for compliance is designed and implemented, it will require some work to ensure continuing compliance with equal, random display. Therefore, in the Final Regulatory Impact Analysis FDA has added recordkeeping costs and administrative costs as ongoing costs in years 2 through 20 after the final rule takes effect.

(Comment 260) Comments argued that market testing costs undertaken by the tobacco industry should not be counted. Various arguments were presented: Such costs would be beyond the minimal cost required to implement the law ''effectively and in good faith.'' Such costs would be incurred in order to ''undermine the effect of Congressionally-mandated warning labels.'' Such costs would not be societal costs at all, but distributional effects because the cost to the tobacco companies would be a benefit to employees or contractors paid to do the work. If FDA includes market testing costs, it should also include legal fees for potential challenges to this rule and lobbying fees to get the statute repealed.

(Response) We do not simply estimate the cost of minimal compliance. In benefit-cost analyses of regulations, we assume agents react to a new regulation by changing behavior in many ways. The analysis itself then compares the expected outcomes with and without the rule. Regardless of whether the rule requires it, if manufacturers conduct market testing as a direct result of this rule, the costs are attributable to this rule. Resources devoted to this market testing have an opportunity cost, so there is a social cost. We have been unable to obtain reliable data with which to quantify potential costs incurred to challenge the rule in litigation. Lobbying costs associated with the repeal of the statute do not represent incremental costs of this rule and therefore are appropriately excluded from the analysis.

(Comment 261) A comment stated that cigarette manufacturers and retailers change advertisements and labels frequently and only the incremental cost of replacements that would not have otherwise been made should be attributed to this rule. The comment asserted that this incremental cost is negligible.

(Response) FDA only looked at the cost of removing point-of-sale advertisements. Other forms of cigarette advertisements are now relatively rare. The comment assumes that some or all manufacturers and retailers could perform the removal of noncompliant point-of-sale advertising at zero cost by coordinating it with the usual replacement schedule for point-of-sale advertising. Manufacturers and retailers would only remove noncompliant advertising early if the benefit from keeping them longer did not justify the modest cost (between $12 and $198 per establishment) of removing the advertising at the deadline. FDA expects that the most likely response will be for most establishments to continue displaying noncompliant advertisements up until the enforcement deadline and resources will therefore be expended to achieve compliance at the deadline.

(Comment 262) One comment stated that the cost analysis needs to include reduced government revenue from lost taxes due to lowered cigarette sales.

(Response) FDA notes that, leaving aside potential deadweight loss, there are two principal effects of tax reductions: Gains to former payers and losses to former recipients. Because these effects exactly offset each other, there is no net social cost or benefit associated with the reduction in excise tax collections induced by the rule. As such, we discuss rule-induced changes in tax collections in the Distributional Effects section of our analysis (section XI.G.5 of this document).

(Comment 263) One comment stated that the disturbing nature of the graphic warning labels will cause adverse mental reactions in those who view them, especially cashiers at cigarette-

selling retail establishments because they must handle these products daily.

(Response) FDA is not aware of any scientific evidence that mental or emotional costs would be incurred by the general public as a result of this regulation, and the comment did not provide any.

5. Distributional Effects

In the analysis of the proposed rule, FDA estimated a variety of effects that are experienced as transfers away from some segments of society and as roughly equal transfers to other segments of society. FDA received several comments about these distributional effects.

(Comment 264) One comment stated that FDA's preliminary analysis of the rule's effect on tax collections ignored offsetting effects due to increased sales of other taxable goods and services even though the Joint Committee on Taxation estimates this offset at 25 percent of a policy's direct effect.

(Response) FDA agrees with the comment and has adjusted its analysis of rule-induced changes in tax collections accordingly.

(Comment 265) One comment stated that, in its preliminary analysis of the rule's impact on tax collection, FDA suggested that inelastic demand for cigarettes means that some or all lost tax revenue could be offset through higher tax rates. The comment went on to note that FDA undertook no analysis of whether State and local governments could or would increase excise taxes on cigarettes in response to the graphic warning label rule and that the political environment, as demonstrated by recent elections, may not be amenable to tax increases.

(Response) FDA did not claim any increases in State or Federal cigarette taxes are likely to occur. Instead, we merely pointed out that cigarette demand has been shown to be inelastic; therefore, an increase in tax levels will increase revenue. For the final analysis, we have removed some of our more confusing language on this issue. We continue to assume that tax rates will rise at the rate of inflation because, without such an assumption, we need a reliable forecast of inflation in order to express the stream of future tax revenue changes in current dollars. However, we have added discussion of alternative approaches, including the possible forecasting of inflation using the difference between interest rates for Treasury Inflation-Protected Securities (TIPS) and standard Treasury bills.

(Comment 266) One comment stated that, to the extent that State and local excise taxes are based on the price of cigarettes, increased price competition that could result from the proposed rule would reduce tax revenues beyond what FDA reports in its analysis.

(Response) At present, all State and Federal cigarette taxes are applied per unit, not ad valorem; therefore, changes in the pre-tax price of cigarettes will not change the total excise tax collection separately from changes caused by decreases in the quantity sold. Sales taxes, on the other hand, are applied to cigarettes on the basis of price. FDA has not quantified the effect of the rule on sales tax collections, but we expect it to be small, both because sales taxes make up a very small portion of total cigarette-related tax collections and because any rule-induced change in cigarette prices is also likely to be small.

(Comment 267) One comment stated that, in its preliminary analysis, FDA failed to note that research indicates that U.S. employment will increase if smoking decreases.

(Response) In the PRIA (sectionVIII.F.2), FDA stated that decreases in smoking may cause increases in national employment, citing (Ref. 122) the same paper to which the comment refers.

(Comment 268) One comment stated that FDA, in its preliminary analysis, estimated that the proposed rule would result in 500 to 600 displaced jobs among manufacturers, warehouses and wholesalers but failed to note that these lost jobs probably would occur during a period of high unemployment, when the displaced individuals would likely have difficulty obtaining new jobs with similar remuneration. The comment went on to state that the average unemployment duration in November 2010 was 34.5 weeks and that one could, by multiplying the average wage by the average duration of unemployment, obtain a rough estimate of lost wages.

(Response) The wages lost are not the appropriate cost to attribute to the rule; instead, we must include the difference between wages lost from tobacco-related jobs and the value of next-best options. FDA is unable to quantify this difference. For instance, average unemployment tenure from late 2010 would likely give a skewed estimate of length of rule-induced unemployment because compliance with the rule is not required until 2012. Unemployment may change substantially between now and then, especially because the United States is currently in the early stages of recovery from a recession.

(Comment 269) One comment stated that manufacturing, warehouse, and wholesaler jobs displaced by the rule would be permanent losses to the economy. In addition to failing to note this permanence, FDA did not account for any job losses in the retail sector. The comment went on to state that convenience stores are highly dependent on tobacco sales, both in terms of cigarette sales' portion of profit margins and as a generator of customer traffic to spur the sale of ancillary products. Even the small reductions in revenue caused by the graphic warning label rule could cause retailers to reduce employment, with some stores possibly going out of business entirely.

(Response) The portion of dissuaded smokers' budgets that would, in the absence of the rule, have been spent on cigarettes will, in the presence of the rule, be spent on other goods and services, thus creating jobs in other segments of the economy. Only the difference between losses borne by individuals losing cigarette-related jobs and gains realized by individuals obtaining employment in other sectors represents a net social cost. FDA believes this difference to be small and possibly negative (that is, the losses are less than the gains), as found by Warner *et al.* (Ref. 122).

(Comment 270) One comment stated that, in its preliminary analysis, FDA incorrectly concluded that there would be no rule-induced losses experienced by tobacco growers. The comment went on to state that FDA's assumption that acreage taken out of tobacco production could be easily shifted to other crops, with no net loss, is not consistent with economic theory because economic theory indicates that land currently planted in tobacco is being used in its highest-valued use. Another comment suggested that FDA work with the Department of Agriculture on estimating the impact of the rule on tobacco farmers.

(Response) FDA agrees that a transition from tobacco cultivation to the next-best option entails some loss for farmers, but only the difference between first- and second-best uses of land represents a net social cost in terms of reduced efficiency.

(Comment 271) One comment stated that the requirement that cigarette manufacturers print half of their packaging with images supplied by the government would be a burden to all cigarette companies, the costs of which would ultimately be paid by consumers.

(Response) FDA has estimated the cost to cigarette producers of adding graphic warning labels; however, we have not assessed whether cigarette consumers or shareholders of cigarette-producing firms will bear the burden of the cost. We expect that the costs will be shared by consumers and producers but we are unable to estimate the

portions borne by each group. In the cigarette market, increases in variable costs are borne almost entirely by consumers. In the case of the addition of graphic warning labels, however, most of the cost does not vary with the quantity of cigarettes produced. We therefore expect that producers will be unable to pass all of the cost on to consumers through increased prices. Consumer prices could, however, be affected in the long run. For example, one possibility is that some cigarette product lines will be discontinued and this decrease in supply would lead to increased prices paid by consumers. FDA lacks the detailed market data that would be necessary for predicting which of these or other possible outcomes would likely be realized.

(Comment 272) One comment argued that retailers must lose profit when reallocating space away from cigarettes to other products because it was suboptimal to make such an allocation in the absence of the rule.

(Response) This comment ignores the fact that the final rule will reduce demand for cigarettes and increase demand for other products. While it is clear by observation that allocating shelf space away from cigarettes to other products *in the absence of this rule* would be suboptimal, this need not imply that retailers' profits will be lower after they optimally respond to changes in the demand for cigarettes and the demand for other products.

(Comment 273) Some comments argued that retailers (including small retailers such as convenience stores) may not be able to simply shift shelf space to other goods.

(Response) FDA argued in the distributional effects section of the proposed rule, section VIII.F.3, that the retail sector (as a whole) will shift shelf space to other products to take advantage of the increase in demand for noncigarette products. FDA acknowledges that this substitution may not take place wholly within each retail establishment. If cigarette-reliant retailers have some (but less than complete) success shifting shelf space to take advantage of the increase in demand for noncigarette products, they will suffer an overall loss in revenue that is less than their loss of cigarette sales revenue. Other parts of the retail sector would gain sales. This would be a purely distributional effect within the retail sector. Such an effect would be small because this rule is only projected to reduce cigarette consumption by less than one quarter of a percent.

6. Impact on Small Entities

In the initial regulatory flexibility analysis, FDA considered the potential effects on small cigarette manufactures of having to change all cigarette labels in accordance with this rule. FDA also considered the potential impact on small retailers of having to remove noncompliant point-of-sale advertising. FDA received comments from industry pertaining to these matters, which are summarized in the following paragraphs.

(Comment 274) A comment stated that FDA ''grossly underestimates'' costs, referring specifically to the estimates of the label change costs and their impact on small manufacturers. The comment argued that the necessary changes will cost at least $500,000 to $1 million, including such factors as package redesign, dye cuts, and the number of colors needed for the artwork. Further, ''these changes represent global changes for the manufacturers' products, and that change will have a far greater effect on the small manufacturer as opposed to larger entities.'' Many aspects of compliance will require the work of outside contractors.

(Response) It is not clear whether the comment intends to argue that the cost is on average $500,000 to $1 million *per UPC,* when many UPC labels are being changed at once, or that the total cost would be at least this much per firm, among some subset of small manufacturers. FDA does not agree that the average cost per UPC could be nearly this high. Although FDA estimates much higher total costs for the average small manufacturer, $500,000 to $1 million could describe the total costs for a subset of especially small manufacturers.

The cost estimate with which the comment takes issue was based on a combination of the old FDA labeling cost model and early estimates of some values from the new FDA labeling cost model. Costs have been updated in the analysis for the final rule to more fully reflect the estimates of the new model. Interviews with manufacturers and trade associations were conducted in the process of building the new model. FDA believes the model provides the best estimate of the average cost of changing a product label. FDA inflates materials costs by a factor of nine to account for the requirement to use nine separate warnings.

The comment also argued that FDA has underestimated the costs to small businesses but is not specific enough about whether there are additional factors, beyond the results of the labeling cost model, with which the comment disagrees.

FDA agrees that small tobacco product manufacturers are more likely to hire outside contractors for tasks required to comply with this rule. However, from a societal point of view, it makes no difference to costs whether a manufacturer conducts the functions required for compliance in-house or contracts them out.

(Comment 275) A comment argued that small manufacturers do not carry a small inventory of supplies, but must buy materials in bulk to be cost effective (often as much as 6-months worth). The comment stated therefore that it is untrue that all label inventories will be exhausted during the 15-month compliance period. Small manufacturers will have to discard large amounts of advertising and labeling material. Another similar comment argued that small manufacturers purchase long-term quantities of ''advertising pieces such as pole signs and shelf talkers,'' in order to get better prices. FDA should take this into account and give small manufacturers time to use up existing inventories of printed materials. The comment suggested that manufacturers could provide FDA with inventory counts and usage rates.

(Response) FDA believes the first comment combines two separate issues: Label inventory assumptions (the matter at hand in the quote from the preliminary analysis) and advertising inventory assumptions.

FDA stands by its conclusion that the costs of discarded label inventory will be small under a 15-month compliance period. With modern just-in-time inventory control methods, firms keep far less inventory on hand than in decades past. However, rather than assume that there is zero cost for discarded inventory, FDA will accept the new labeling cost model's default assumptions regarding discarded inventory. This assumption results in a low inventory cost being attributed to this final rule, as very little inventory is expected to remain after a 15-month compliance period. While it may be the case that some small manufacturers keep large amounts of inventory on hand, the evidence used to construct the labeling cost model implies that most manufacturers would not have much (if any) label inventory remaining after 15 months and the output of the labeling model accurately represents the average inventory cost.

While it is possible that some manufacturers will have some point-of-sale advertising materials in inventory that will be discarded as a result of this

rule, FDA doubts that this inventory cost is substantial. Manufacturers will have 15 months to use up existing inventory. Cigarette manufacturers are known to be sophisticated advertisers, and effective advertising changes to reflect the times. Therefore, the value of existing advertisements would decline over time as they become more dated and less effective. Additionally, the comments themselves do not provide data with which to estimate any effect that may exist.

(Comment 276) One comment estimated that the label change cost would be between $2.1 million and $5.5 million per average small tobacco product manufacturer, based on an average number of UPCs per firm of 44. The comment asserted that small manufacturers cannot absorb the cost of changing all their cigarette labels and many will leave the cigarette manufacturing business. Two relief options were suggested: Phasing in the rotational warnings over a longer period of time or running the warnings sequentially rather than simultaneously.

(Response) According to this comment, small tobacco product manufacturers have fewer UPCs each than FDA originally estimated. If the UPC estimate from the comment holds, the compliance costs for small firms would be lower than FDA originally estimated. FDA has retained the original method for estimating the number of UPCs for small firms so as to take care not to understate the burden on them.

FDA acknowledges that this rule may put some small manufacturers at risk of going out of business. However, we do not have the information necessary to estimate this risk. In the initial regulatory flexibility analysis, FDA considered the relief that would be provided by allowing small (or all) tobacco product manufacturers additional time to comply with the rule, even though this not in keeping with the statutory mandate. Running nine warnings sequentially rather than in parallel is a complicated alternative for which it is difficult to estimate the amount of relief provided. A very large reduction in costs would only materialize if the warnings were only changed as often as the usual frequency of nonregulatory label changes (every couple of years). However, FDA has now included an analysis of the potential impact of a related relief option, that of letting small manufacturers randomly assign one label to each distinct UPC.

(Comment 277) Some comments argued that some small retailers, such as convenience stores, may go out of business as a result of reduced cigarette sales and loss of revenue from ancillary products, and that this effect of the rule on small entities needs to be reflected in the analysis. Beyond the effect on the retailers themselves, closure of convenience stores would result in loss of convenience to nearby customers and could also adversely affect suppliers.

(Response) Although in the small entity analysis we are only able to quantify the cost of removing noncompliant advertising, we acknowledge that small retailers selling cigarettes could also lose some net sales revenue (to other retailers), to the extent that shifting shelf space to other goods less than fully offsets the reduction in revenue from cigarettes. We expect any such loss of revenue to be modest because the expected reduction in cigarette consumption is modest to begin with. Convenience store closures as a result of this final rule are therefore unlikely.

(Comment 278) One comment recommended that FDA reconsider exempting small cigarette producers.

(Response) The initial regulatory flexibility analysis considered exempting small manufacturers from the label change requirements as a relief option. Exempting small manufacturers from all or part of this regulation would cause a significant proportion of consumers to be exposed to cigarette packages or advertising lacking the new graphic warnings. In 2008, the combined market share of all but the four largest firms was 10.3 percent (Ref. 123). This situation would be inconsistent with the public health objective of the rule as well as FDA's statutory mandate.

C. Need for the Rule

Written with the goal of ameliorating the large toll on public health that is directly attributable to the consumption of tobacco, the Tobacco Control Act mandates the publication of this rule. Section 201 of the Tobacco Control Act modifies section 4 of FCLAA to require that nine new health warning statements, along with color graphics depicting the negative health consequences of smoking, appear on cigarette packages and in cigarette advertisements. As discussed in detail in FDA's response to comments in section XI.B.2 of this document, the economics literature suggests several sources of market failure[11] that the new graphic warning labels will address; these include myopia, lack of salience, time inconsistency, and incomplete information. In the following analysis, we do not attempt to choose among the many models of smoking and addiction that potentially cause market failure, but the models have similar policy implications.

D. Benefits

We estimate the benefits of the final rule by comparing expected life-cycle events of smokers with those of nonsmokers. Nonsmokers tend to live longer and develop fewer cancers, cardiovascular, pulmonary, and other diseases, so the benefits in our analysis include the discounted value of life-years gained, health status improvements and medical services freed for other uses. We also include an estimate of the monetary value of the property and lives saved as a result of the rule-induced reduction in the number of accidental fires caused by smoking. There are other benefits, such as reductions in nonsmokers' morbidity and mortality associated with both passive smoking and mothers smoking during pregnancy, that are likely generated by the final rule, but FDA has been unable to obtain reliable data with which to quantify them. In particular, we were not able to project future levels of exposure to secondhand smoke from historical trends, nor predict future decreases in maternal smoking during pregnancy.

1. Reduced Cigarette Smoking Rates

The changes outlined in this rule are projected to decrease smoking initiation and increase smoking cessation. For each of the first 20 years of the rule's implementation (2012 through 2031),[12] FDA calculates the predicted decrease in the number of U.S. smokers by multiplying together the following:

(a) The estimated effect (percentage point change) of cigarette warning labels on the national cigarette smoking rate and

(b) The population in a particular year in the absence of the regulation (as projected by the U.S. Census Bureau).

To obtain estimates of the effect of cigarette warning labels on smoking rates (item (a) in the list above), we look to the experience of Canada, which has required the use of graphic warning labels since December 2000 (Ref. 124). The advantage of this approach lies in our ability to observe actual consumer behavior—in the form of smoking rates—before and after a graphic warning label requirement went into

[11] A situation in which a market left to itself does not allocate resources efficiently.

[12] The effects of antismoking policies occur over a long period of time, so we want to include at least one full generation in our analysis. Using a 20-year time horizon allows us to do this while still avoiding the extreme uncertainty regarding effects occurring in the more distant future.

effect. The warning labels to be required in the final rule are generally similar to those developed by Health Canada and authorities in other foreign countries. As in Canada, the labels required by the rule will occupy at least half the front and rear display panels of a cigarette package. Moreover, under the rule, there will be a mix of warning statements and images that depict the negative consequences of smoking. Although the rule will follow much the same approach as the Canadian warning label requirements, it will differ in some ways: Canada has 16 labels in rotation, rather than 9; warning statements appear in English on one side of a Canadian package and in French on the other; and health and cessation information is included on leaflets within Canadian cigarette packages (Ref. 125). These details, combined with general differences in legal and social trends, indicate that Canada's experience with warning labels can give only a general idea of the changes in smoking rates to be expected as a result of the rule. In addition, other smoking control initiatives, including new restrictions on smoking in indoor public places, also occurred in both the United States and Canada during the period of our analysis. These and other confounding factors make our estimate of the effect of new graphic warning labels highly uncertain.

Health Canada (Refs. 126 and 127) reports Canadian smoking rates for ages 15 and above for years from 1994 through 2009. FDA obtained smoking rates for adults, aged 18 and above, in the United States from the National Health Interview Survey (Ref. 128) and from ''Health, United States, 2005,'' published by the National Center for Health Statistics (Ref. 129). We used the results from these two reports to calculate the United States-Canada smoking rate difference for individual years. As shown in table 4 of this document, the smoking rate in Canada was, as of the most recent survey estimates, more than three percentage points lower than the rate in the United States and approximately seven percentage points lower than Canada's own smoking rate in the year before graphic warning labels were implemented in that country. It would be unjustified, however, to conclude that the introduction of graphic warning labels in the United States will cause the U.S. smoking rate to fall by seven, or even the three percentage points needed to reach the Canadian rate. Many factors, such as tobacco advertising restrictions, youth access restrictions, educational campaigns regarding the health effects of smoking, restrictions on smoking in indoor public places, and taxes on tobacco products have influenced smoking rates in the two countries. In order to estimate the incremental effect of the present rule, we need to isolate the impact of graphic warning labels on the Canadian smoking rate.

In order to accomplish this, as discussed in detail in Technical Appendix X1, we begin by using data from Health Canada (Refs. 126 and 127), the National Center for Health Statistics (Ref. 129), and the National Health Interview Survey (Ref. 128) to estimate pre-2001 smoking rate trends for both the United States and Canada. Because tax-induced changes in the price of cigarettes have been shown to substantially reduce smoking, in each trend estimation we include the effects of Federal and State or provincial cigarette tax changes on national smoking rates. (After decreasing substantially in the early 1990s, Canada's real average cigarette excise tax level grew by 9 percent between 1995 and 2000 and by 123 percent between 2001 and 2009. Real average cigarette tax levels in the United States grew by 29 percent between 1995 and 2000 and by 117 percent between 2001 and 2009.) Using the estimated trends, we predict smoking rates for the United States and Canada, and the difference between them, for years up to and including 2009. We then subtract the predicted United States-Canada smoking rate differences from the actual differences observed in the data. Implicit in this method is the assumption that these otherwise-unexplained differences may be attributed solely to the presence in Canada of graphic warning labels. We do not account for potential confounding variables or for possible substitution by consumers from cigarettes to other products (such as little cigars) that may produce similar health effects; our method is therefore a rudimentary approach to estimating the smoking reduction that will be effected by the new graphic warning labels and may be producing results that are off by one or more orders of magnitude.

Table 4.--Cigarette Smoking Rates, United States and Canada, 1991-2009

Year(s)	Smoking Rate, Canada[a]	Smoking Rate, United States[b]	Year(s)	Smoking Rate, Canada[a]	Smoking Rate, United States[c]
1991	31.1		2001	21.7	22.6
1994-95	30.5		2002	21.4	22.3
1995		24.6[c]	2003	20.9	21.3
1996-97	28.6		2004	19.6	[e]
1997		24.6	2005	18.7	20.7
1998		23.9	2006	18.6	20.6
1998-99	27.7		2007	19.2	19.4
1999	25.2	23.3	2008	17.9	20.4
2000	24.4	23.1	2009	17.25[d]	20.5

[a] Source: Health Canada (Ref. 127), unless otherwise noted. Canada's reported smoking rates are for ages 15 and above.

[b] Source: FDA analysis of National Health Interview Survey (Ref. 128), unless otherwise noted. Reported smoking rates for the United States are for ages 18 and above.

[c] Source: National Center for Health Statistics (Ref. 129). Reported smoking rates for the United States are for ages 18 and above.

[d] Health Canada (Ref. 126) reports a smoking rate of 17 percentage points; this could be rounded from any value between 17.0 and 17.5, so FDA uses the midpoint of 17.25.

[e] The Sample Adult file of the 2004 NHIS lacks the stratum and primary sampling unit variables necessary for calculating sample statistics.

Using this rudimentary approach, FDA estimates that the average unexplained difference between United States and Canadian national smoking rates is 0.088 percentage points higher for the 2001 through 2009 period than for 1994 through 2000. Applying this estimate to population projections (Ref. 130 provides annual projections only through 2030, so we assume cohort populations will remain the same from 2030 to 2031); summing over all age groups yields an estimate that the rule will reduce (either through cessation or avoided initiation) the United States' smoking population by approximately 213,000 in 2013, with the total decrease rising to approximately 246,000 in 2031 due to the predicted smoking rate decrease being applied to a growing population. FDA has not quantified rule-induced decreases in cigarette consumption among smokers who do not quit entirely, although such decreases have the potential to improve health outcomes for affected individuals.

2. Quantifying Benefits That Accrue to Dissuaded Smokers

a. *Smokers' willingness-to-pay for cessation programs.* One method for estimating dissuaded smokers' net internal benefits involves using the amount smokers are willing to pay to participate in cessation programs. This willingness-to-pay will equal the value of cessation (*i.e.,* the value of health and other benefits of cessation minus any value that smokers attribute to the activity of smoking) multiplied by the participation-related probability of success. Warner *et al.* (Ref. 131) report that the choke price, or the price at which no smokers would participate in cessation programs, may be around $350 (in 2000 dollars), while a maximum of 10 percent of the smoking population would participate in cessation programs even if those programs had a money price of zero. With a linear demand curve, these parameters produce an average willingness-to-pay among potential cessation program participants of $175. Warner and coauthors report that approximately 15 percent of smoking cessation program participants successfully quit without eventual relapse. These parameters indicate that the average value of cessation is $175/0.15 = $1,167, or $1,444 when updated for inflation (using Ref. 132).

We estimate in section XI.D.1 of this document that the final graphic warning label rule would reduce the U.S. adult smoking population by 213,000 in 2013. In the absence of the rule, the baseline 2013 smoking population would be approximately 49.5 million, so a decrease of 213,000 represents a 0.43 percent effectiveness of graphic warning labels. The value to an individual smoker of graphic warning labels equals their effectiveness multiplied by the value of cessation, or 0.0043*$1,444 = $6.22. Multiplying by the predicted 2013 smoking population yields an aggregate value of the rule of $6.22*49.5 million = $307.9 million. For each year from 2014 to 2031, we perform an analogous calculation, but we replace the entire smoking population with only the particular year's newly exposed cohort (consisting of 18-year-olds and new immigrants). This results in a present value of net intrapersonal benefits of $370.3 million, calculated with a 3-percent discount rate, or $322.4 million, calculated with a 7-percent discount rate.

While these values can provide rough estimates of the benefits of the final rule, there are several reasons to believe they are only approximations and probably reflect lower bounds. First, we are implicitly assuming that the value of avoided smoking initiation is equal to the value of cessation and that the value of cessation is equal across the entire smoking population. In fact, we have willingness-to-pay data only from those smokers who are potential participants in cessation programs. The value of avoided initiation is likely much higher than the value of cessation, which would tend to make the present estimates of rule-induced benefits too low. A second reason willingness-to-pay for cessation programs represents a lower bound on the rule's benefits is because it captures only the misinformation and time-inconsistent preferences that smokers themselves recognize and act upon via participation in cessation programs.

b. *Gross and net health benefits.* We now turn to the literature on time inconsistency, which is one of the principal forms of market failure relevant to tobacco, to develop an alternative approach to estimating rule-induced benefits that accrue to dissuaded smokers. The papers we will

discuss use the term ''optimal internality tax,'' but the key point is that taxes and cessation programs are both tools that cause a reduction in smoking, and the dollar prices of those tools represent estimates of the amounts that smokers would be willing to pay to gain the net intrapersonal benefits associated with smoking reduction.

Gruber and Köszegi (Ref. 104) estimate the tax rate that would allow time-inconsistent smokers to consume the quantity that would be optimal under perfect rationality and in the absence of other forms of market failure. They first estimate an internal health cost of $30.45 per pack. From this cost, they calculate an internality tax that ranges from $0.98 to $2.89 (depending on technical parameters of their model), with an average of $2.17. Because the demand for smoking is downward-sloping, a decrease in the smoking rate will decrease the optimal internality tax. In Technical Appendix X5, we account for this complication. Because we find that Gruber and Köszegi's results imply that net internal benefits of the rule equal roughly 7 (=100 − 93) percent of the gross internal (health) benefits, the average optimal tax over the relevant portion of the demand curve is 0.07*$30.45 = $2.05 per pack. Multiplying this optimal tax by the predicted rule-induced reduction in cigarette consumption would yield an estimate of benefits that accrue to dissuaded smokers.

In other writings, Gruber (Ref. 133) suggests that, because his work with Köszegi considered only a limited degree of time inconsistency, the optimal internality tax on cigarettes could be much higher than the level estimated with Köszegi, perhaps between 5 and 10 dollars per pack. (Even this amount does not, however, account for other forms of market failure that might be relevant to tobacco use.) The midpoint of the 5 to 10 dollar range, $7.50, yields a net internal benefits result equal to roughly 24 percent of rule-induced internal health benefits. Other models of addiction and smoking would imply different net internal benefits, depending on the implied severity of the market failure. One comment on the proposed rule, from a scholar who has done a great deal of professional research on the economics of smoking, suggested that smokers would assess the value of quitting smoking as 90 percent of the value of health gained from smoking. Although this and other public comments suggested high ratios of net to gross health benefits, none provided evidence supporting their suggestions.

The applicability of any of the suggested net-to-gross internal benefits ratios requires an estimate of the gross benefits realized by individuals who are dissuaded from smoking. Gruber and Köszegi admit that their $30.45 per pack estimate is not exhaustive, so we now turn to quantifying morbidity, mortality, and other effects of smoking cessation and avoided initiation.

i. *Expected life-years saved.* The largest health consequence of smoking is the increased rate of mortality from pulmonary and cardiovascular disease, cancer, and certain other illnesses. As a result, the largest benefits of this rule stem from the increased life expectancies for those individuals who, in the absence of the rule, would be smokers and thus susceptible to premature mortality from one of these often-fatal diseases. We calculate the number of life-years saved using differences in the probabilities of survival for smokers and nonsmokers. Sloan *et al.* (Ref. 116) construct life tables for various categories of individuals, including ''nonsmoking smokers'' and typical 24-year-old smokers. A nonsmoking smoker is someone who does not use cigarettes but otherwise exhibits the lifestyle and personal characteristics of the average smoker.[13] A typical 24-year-old smoker does not necessarily smoke for his or her entire life, but instead faces cessation probabilities that are in line with values observed for all ages in the National Health Interview Survey; the life expectancy effects of cessation at older ages are netted out of life expectancy effects of avoiding smoking at age 24 (results reported below). Sloan *et al.*'s life tables allow us to calculate how many additional deaths, per 100,000 population, may be expected among typical smokers than among nonsmoking smokers between the 24th and 25th birthdays, the 25th and 26th, and so on until the 100th birthday. (FDA assumes that differences in yearly survival probabilities for smokers and nonsmokers are negligible below age 24 and above age 100.)

Overall, Sloan *et al.* find that an average (or what Sloan *et al.* call ''typical'') 24-year-old female smoker can expect to live another 55.5 years, while a comparable nonsmoker can expect another 57.8 years of life, producing an overall regulation-induced gain of 2.4 undiscounted life-years per individual who is prevented from starting to smoke. Comparing male 24-year-old typical and nonsmoking smokers, life expectancy increases from 49.8 to 54.2 years, producing a gain of 4.4 undiscounted years. The gap between male and female life expectancy results may be due to different physiological responses to equal amounts of smoking, different lifetime cessation patterns, or different smoking intensities. Taylor *et al.* (Ref. 117), for instance, find that male smokers are more likely than female smokers to consume more than a pack a day. Sloan *et al.* do not report how much of the male-female difference in their estimated life expectancy effects may be attributed to each possible mechanism. In spite of this limitation, FDA considers Sloan *et al.*'s methodology to be the most suitable in the literature for purposes of the present analysis due to other studies' omissions of a nonsmoking smoker adjustment, a lifetime cessation probability adjustment, or both.

We assume that each person who reaches ages 18 to 24 during the 20 years (2012 to 2031) of our analysis and is dissuaded from smoking extends his or her life by the gender-specific amount Sloan and coauthors report. For older individuals, whose post-smoking cessation survival probabilities cannot be plausibly assumed to equal those of individuals who were nonsmokers at age 24, we predict life extensions using former smoker life tables that we construct using Sloan *et al.*'s results and cessation probabilities from the 1998 National Health Interview Survey (Ref. 128). The details of these adjustments appear in Technical Appendix X2.

ii. *Benefits of reduced premature mortality.* OMB Circular A–4 (Ref. 103) advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Three life-year values (also known as values of a statistical life-year, or VSLY) used frequently in the literature and in previous analyses are $100,000, $200,000, and $300,000 (Refs. 134 and 135; 74 FR 33030, July 9, 2009), which we update to $106,308, $212,615, and $318,923 in 2009 prices. These values constitute our estimates of willingness-to-pay for a year of life preserved in the present. The economic assessment of a future life-year requires discounting its value to make it commensurate with the value of present events. As required by OMB Circular A–4, we use 3-percent and 7-percent discount rates to calculate the present value of the life-years we predict will be saved.

For each dissuaded smoker, we multiply a VSLY by the relevant age- and gender-specific life extension and

[13] In their multivariate regression analysis, Sloan *et al.* control for alcohol intake, body mass index, financial planning horizon, race, education, and marital status.

then discount appropriately to arrive at a per-person value of reduced mortality. For 24-year-olds, this value ranges from $9,280 (for a female applying a VSLY of $106,308 and a 7-percent discount rate to her 2.4 life-years gained due to smoking avoidance) to $363,333 (for a male applying a VSLY of $318,923 and a 3-percent discount rate to his 4.4 life-years gained due to smoking avoidance). Multiplying the per-person values by the predicted number of dissuaded smokers and discounting the results back to year 2011 yields estimates of rule-induced mortality benefits that range from $1.45 to $22.56 billion.

Table 5.--Gross Present Value of Lifetime Reduced Smoker Mortality ($ mil)

Value of a Statistical Life-Year = $106,308		Value of a Statistical Life-Year = $212,615		Value of a Statistical Life-Year = $318,923	
3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
7,520.9	1,450.6	15,041.7	2,901.1	22,562.6	4,351.7

These totals may understate the full value of rule-induced reductions in mortality because they do not account for increasing trends in life expectancy. Sloan *et al.*'s results, from which our mortality estimates are derived, are based on data from the late 1990s. Arias (Ref. 136) reports that between 1999 to 2001 and 2006 (the most recent year for which life tables have been developed), life expectancy at age 25 increased from 50.54 to 51.5 years, or 1.90 percent, for males and from 55.41 to 56.1 years, or 1.25 percent, for females. If these percentage changes are approximately correct for the typical smoker and nonsmoking smoker populations, then our estimates of smoking-related life expectancy effects would need to be adjusted upward accordingly (or perhaps by different percentages because life expectancy has continued to change since 2006).

A further reason to believe the values in table 5 of this document may be underestimates is their lack of quantification of any reduction in either the external effects attributable to passive smoking or the infant and child fatalities caused by mothers smoking during pregnancy. Sloan *et al.* (Ref. 116) indicate that, historically, the inclusion of spouse and infant deaths from exposure to secondhand smoke or mothers smoking while pregnant increased estimates of smoking's mortality effects by approximately 26.3 percent. We do not incorporate this adjustment into our analysis, however, because recent restrictions on indoor public smoking and educational campaigns have significantly reduced, though not eliminated, nonsmokers' exposure to secondhand smoke. In other words, an analysis of the rule's impact on health benefits that accrue to individuals other than smokers themselves requires three pieces of estimation: (1) The rule-induced change in the number of U.S. smokers, (2) the relationship between the number of smokers and exposure of nonsmoking individuals to the harmful effects of cigarettes, and (3) the effect of cigarette exposure on nonsmokers' mortality. The ever-changing level of nonsmoker cigarette exposure means that a simple extrapolation from the recent past provides a much less reliable prediction of the near future for element (2) than for other pieces of this analysis. Any estimation of (2) would therefore be highly data-intensive and subject to an unacceptable level of potential error. In general, FDA has been unable to obtain data with which to solve this problem; it is for this reason that we do not quantify health benefits that will accrue to individuals other than smokers themselves.

We do, however, note that the Robert Wood Johnson Foundation (Ref. 137) reports that the percentage of the U.S. population living in homes where smoking was permitted decreased from 56.9 percent in 1992 to 1993 to 20.9 percent in 2006 to 2007. This may indicate that the ratio of spouse and infant mortality effects (related to passive smoking) to smoker mortality effects is now approximately 36.7 (= 20.9/56.9) percent as large as the 26.3 percent ratio derived from Sloan *et al.*'s results (which were calculated using data from the 1990s). Using this very rough approximation yields a present value of spouse and infant mortality benefits ranging from $140.3 million (= 0.263*0.367*$1.45 billion) to $2.18 billion (= 0.263*0.367*$22.56 billion). Although there are serious weaknesses with this estimation approach that make it inappropriate to include in our overall benefits analysis, the results may give a sense of the magnitude of mortality benefits generated by the rule via reductions in spousal and fetal smoking exposure.

iii. *Improved health status (or reduced morbidity).* In the previous section, we estimated the benefits that will accrue as a result of the rule-induced reduction in premature deaths from cancer, pulmonary and cardiovascular disease, and other smoking-caused illnesses. Cigarette smoking also imposes costs on smokers in the form of pain, distress, and impaired function even before these illnesses cause fatalities. As with premature death, individuals are assumed to be willing to give up valuable resources in order to avoid reductions in quality of life associated with smoking-related illnesses.

Sloan *et al.* (Ref. 116) examine survey respondents' self-reported health status (which can be categorized as poor, fair, good, very good, or excellent) and estimate that a 24-year-old smoker can expect, on average, an extra 1.086 discounted years (using a discount rate of 3 percent and averaging over Sloan's estimates for males and females) or 0.521 discounted years (using a discount rate of 7 percent and again averaging over males and females) of fair or poor health over his or her lifetime, as compared with a nonsmoking smoker.

In order to quantify the value of rule-induced reductions in years spent in fair or poor health, we scale our estimates of the VSLY ($106,308, $212,615, and $318,923, as discussed in the previous section of this document) by a ratio representing the trade-off individuals are willing to make between time spent in best-possible and lesser levels of health. Nyman *et al.* (Ref. 138) estimate this trade-off by matching survey respondents' self-reported subjective health statuses with their EuroQol–5D (EQ–5D) health index scores. The EQ–5D survey responses—to questions about five areas of health, including mobility, self-care, pain, anxiety, and ability to perform usual activities—are mapped so that a score of one represents best measurable health, a score of zero represents death, and fractional values represent intermediate levels of health. Nyman *et al.*'s analysis indicates that, relative to the health index score of an individual with excellent health, a very good health score will be lower by 0.03,

a good health score will be lower by 0.078, a fair health score will be lower by 0.194 and a poor health score will be lower by 0.392. Weighting by Nyman *et al.*'s reported percentages of respondents in each health category, FDA finds that the health index score for the average individual in good, very good, or excellent health is lower than the index for excellent health by 0.036 and the health index score for the average individual in fair or poor health is lower than the index for excellent health by 0.244; the difference between these averages is 0.208. This result may be interpreted as follows: The harm experienced by an individual whose health changes, for 1 year, from good, very good, or excellent to fair or poor is equal, on average, to the harm experienced by an individual in the best possible health whose death is hastened by 0.208 years. Thus, the welfare effect of smoking-related health status changes may be found by multiplying a plausible life-year value (such as $106,308, $212,615, or $318,923) by 0.208; this multiplication yields estimates of $21,800, $43,600, and $65,400 for the amounts individuals are willing to pay to avoid a year of reduced health status.

The U.S. Census Bureau (Ref. 130) predicts that the nation's 24-year-old cohort will be 2.17 million females and 2.25 million males in 2013 and rise steadily to approximately 2.25 million females and 2.33 million males in 2031. FDA's estimate of a 0.088 percentage point reduction in the U.S. smoking rate thus translates to a decrease of 3,906 24-year-old smokers in 2013, with the decrease rising to approximately 4,154 in 2037. Multiplying these estimates of the rule-induced reduction in the number of smokers by Sloan *et al.*'s predictions of discounted reduced health-years per smoker and the quality-of-life loss per year of fair or poor health derived from Nyman *et al.,* and discounting appropriately, yields a rule-induced welfare gain of $0.5 to $4.7 billion. Detailed results appear in table 6 of this document.

Table 6.--Present Value of 24-year-olds' Lifetime Health Status Improvements ($ mil)

Value of a Statistical Life-Year = $106,308		Value of a Statistical Life-Year = $212,615		Value of a Statistical Life-Year = $318,923	
3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
1,580.7	500.5	3,161.4	1,001.0	4,742.2	1,501.5

Sloan and coauthors do not report the effect of smoking on fair or poor health years for dissuaded smokers of ages other than 24; in the absence of a reliable estimate of the morbidity effect of smoking cessation for individuals aged 25 and above, FDA takes the conservative approach of estimating benefits only for adults who are at or below that age sometime during the first 20 years of the rule's implementation. Smoking cessation brought about by this rule will improve health status, in some cases substantially, for many individuals who are over age 24 at the time of the rule's implementation. Our omission of these benefits to older individuals produces an underestimate of the rule's morbidity benefits (which is why we describe our estimate as conservative) but there are several reasons to believe the magnitude of the underestimate may not be overwhelmingly large. First, although individuals aged 24 and below make up a fairly small portion of the smokers we estimate will be dissuaded from smoking in 2013, they make up the vast majority of smokers newly dissuaded in years 2014 to 2031 because it is young people and a few immigrants who will be exposed to graphic warning labels for the first time in those later years. Overall, then, our morbidity results include effects for 98,355, or 33.8 percent, of our estimated 291,103 (undiscounted) smoking dissuasions. Second, the reduction in health risk experienced by smokers who quit at ages 25 and above will be smaller than the benefits experienced by individuals who quit at age 24 and below or who avoid smoking initiation altogether. Third, in a study conducted with a methodology very different from the one used in this regulatory impact analysis, Stewart *et al.* (Ref. 139) estimate that smoking avoidance can increase discounted life expectancy by 1.73 years and quality-adjusted life expectancy by 2.17 years; this implies that, in the realm of smoking avoidance, the magnitude of morbidity benefits is around 25 percent of the magnitude of mortality benefits. Compared with this independent evidence, FDA's morbidity results, which are 15.3 percent (undiscounted), 21.0 percent (discounted at a 3-percent rate) or 34.5 percent (discounted at a 7-percent rate) as large as mortality effects, appear to be only moderate underestimates.

iv. *Medical services.* Sloan *et al.* (Ref. 116) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker (in 2000 dollars and with a 3-percent discount rate). Of the female smoker's net cost, $2,031 will be borne by the smoker herself and the remainder by nonsmokers in the form of increases in private insurance premiums or taxes used to fund government health programs such as Medicaid. Of the male smoker's net cost, $1,372 will be borne by the smoker himself and the remainder by nonsmokers. We adjust these cost estimates for inflation using the most recent medical care CPI (Ref. 140).

Sloan and coauthors do not report expected medical costs for former smokers, so estimating benefits for individuals aged 25 and above who cease smoking as a result of the rule requires some assumptions. For this analysis, we assume that smoking-related annual excess medical costs are the same whether smokers are compared with never-smokers or former smokers and that the payments, reported by Sloan *et al.* as present values for 24-year-olds, are distributed equally from ages 24 to 100 (in other words, we annualize Sloan *et al.*'s estimated present value over the 77 years between ages 24 and 100). With these assumptions, given FDA's projected 20-year reductions in smoking prevalence, we anticipate that the regulation will cause smoking-related medical expenditures to fall by $859.9 million, of which $458.2 million will be realized as savings by smokers themselves and $401.7 million by nonsmokers. With a 7-percent discount rate, the total decrease in expenditure becomes $491.3 million, with $261.2 million of those savings accruing to smokers and $230.1 million to nonsmokers. Further details about the nonsmoker portion of expenditures appear in the Distributional Effects portion of this analysis.

In the absence of the rule, some portion of smoking-related medical expenditures accrues to health service providers as economic rent (also known

as producer surplus [14]). Any reduction of this portion will not contribute to the social benefit of the rule but will instead be a transfer of resources from health service providers to consumers, public and private insurers, and others. A further complication in the analysis of the market for health is generated because nonsmokers' payments take the form of a subsidy for smoking-related medical services and thus some portion of their expenditure in the absence of the rule is greater than smokers' own willingness-to-pay for those medical services. Both for this reason and due to the existence of economic rent, the avoidance of at least some portion of nonsmokers' smoking-related spending will transfer value from one portion of society to another but not contribute to an overall social benefit of the rule. We do not know the size of this portion relative to nonsmokers' overall rule-induced expenditure change, so we assume that 50 percent of nonsmokers' smoking-related spending accrues as a net social benefit of the rule. This produces an overall estimate of rule-induced reductions in medical expenditures of $659.0 million, calculated with a 3-percent discount rate, or $376.3 million, calculated with a 7-percent discount rate.

v. *Other financial effects of smoking cessation.* In section XI.F.6 of this document, we will discuss in detail the effects of the rule on Social Security, income taxes, private pensions, and life insurance. Summaries of these effects will appear in table 23 of this document. For the most part, we will characterize the values appearing in table 23 as transfers, having equal and offsetting effects on various members of society. There are, however, some additional consequences of these transfers that must be considered in light of the optimal internality tax estimation approach and the related need to estimate gross internal benefits and costs of dissuaded smoking. The mixture of positive and negative values in table 23 shows that societal transfers can take the form of both subsidies and additional costs of smoking; when summed together, the positive and negative effects in table 23 show a net smoking subsidy, which individuals relinquish when they avoid initiating or quit smoking.

There is a difficulty in quantifying the effect of the types of transfers appearing in table 23 of this document on internal benefits. Smokers' experience of these transfers may already be included in the section XI.D.2.b.ii and XI.D.2.b.iii of this document estimates of gross health benefits because the willingness-to-pay measure on which we base our morbidity and mortality calculations includes all the effects a person will likely experience as a result of improving his or her health and extending his or her life. These effects include increased opportunities to collect Social Security and defined benefit pension payments, a decreased chance of leaving survivors enough life insurance to make up for the amount paid in premiums, and increases in pension and income tax payments (due to working longer and receiving higher wages in compensation for higher productivity). If the results in section XI.D.2.b.ii and XI.D.2.b.iii of this document already reflect these phenomena, what is missing from our analysis is not the intrapersonal effect associated with smokers' experience of table 23 transfers but the direct benefit to the general public of no longer providing a net smoking subsidy; in this case, the total value of the subsidy, or 100 percent of the values in table 23, would need to be added to our net benefits estimate. Because morbidity and mortality are the primary but not the only ways in which smoking affects Social Security, income tax, pension, and life insurance payments and receipts, we do not know the extent to which our morbidity and mortality willingness-to-pay measures capture smokers' experience of these transfers. We will assume that 50 percent of the midpoint values in table 23 are included in our morbidity and mortality estimates; with this assumption, our estimated net benefits will change in two opposing directions: They will increase by 100 percent of the midpoint values in table 23 (representing the reduced subsidy payment from the general public), but will decrease by an amount equal to 50 percent of the table 23 midpoint values times the net-to-gross benefits ratio (representing the effects on dissuaded smokers that are not included in the morbidity and mortality estimates).

Summing our estimates of rule-induced life-year extensions, health status improvements, medical cost reductions, and financial effects, we find that the present value of health-related and financial benefits accruing to dissuaded smokers totals $9.29 to $27.50 billion (with a 3-percent discount rate) or $2.10 to $6.01 billion (with a 7-percent discount rate). As shown in table 7 of this document, the present value of financial benefits accruing to the general public totals $733.1 million (with a 3-percent discount rate) or $330.3 million (with a 7-percent discount rate).

Table 7.--Financial Benefits Accruing to General Public ($ million)

	Discount Rate = 3%	Discount Rate = 7%
Smoking-Related Medical Cost Subsidies, Net of Reduced Producer Surplus for Health Care Providers	200.9	115.0
Social Security Outlays	-649.2	-263.2
Income Taxes on Social Security-Taxable Earnings	746.5	301.5
Defined Benefit Private Pension Outlays	-906.8	-366.1
Life Insurance Outlays	1,341.7	543.1
Total	733.1	330.3

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

vi. *Summary of benefits accruing to dissuaded smokers.* Table 8 of this document presents benefits estimates that reflect a variety of net-to-gross ratios, ranging, as discussed in Technical Appendix X5, from the 7

[14] The difference between what a supplier is paid for a good or service and the marginal cost of supplying that good or service.

percent derived from the work of Gruber and Köszegi to the 90 percent suggested in a public comment. Also presented are the net internal benefits results derived from Warner *et al.*'s work on the value to smokers of cessation programs. For each discount rate and VSLY, we also report the midpoint between the lower and upper bound benefits estimates, where the upper bound is yielded by the 90 percent net-to-gross benefits ratio and the lower bound by the 7-percent ratio in some cases and by the cessation value approach in others. Given the great variation in estimates of net benefits to dissuaded smokers, we follow the recommendation of OMB Circular A–4 and use the midpoints for our primary calculations in the remainder of this analysis. The resulting midpoints range from $4.37 to $12.56 billion (with a 3-percent discount rate) or $1.02 to $2.86 billion (with a 7-percent discount rate). We emphasize that all the net benefits appearing in table 8 are intrapersonal and thus could not be positive if all tobacco consumers were time-consistent, fully rational, self-controlled, able to resist temptation, and in possession of perfect and complete information; instead, our results are qualitatively consistent with policy implications of economic models in which consumers are characterized by hyperbolic discounting, incorrect forecasting, temptation utility or self-control problems (in addition to Gruber and Köszegi (Ref. 104), *see* Bernheim and Rangel (Ref. 105) and Gul and Pesendorfer (Ref. 110)) and with Gruber and Mullainathan's (Ref. 182) examination of the effect of cigarette excise taxes on the happiness of individuals with a high propensity to smoke.

Table 8.--Present Value of Net Internal (i.e., Intrapersonal) Benefits ($ millions)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90 Percent Ratio Derived from Public Comment	8,364.3	1,894.2	16,555.7	3,650.2	24,747.1	5,406.1
24 Percent Ratio Derived from Gruber (Ref. 133)	2,254.7	506.9	4,478.0	983.5	6,701.3	1,460.1
7 Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	624.2	137.7	1,250.7	272.0	1,877.2	406.3
Value of Cessation Derived from Warner et al. (Ref. 131)	370.3	322.4	370.3	322.4	370.3	322.4
Midpoint Between Lower and Upper Bounds	4,367.3	1,016.0	8,463.0	1,961.1	12,558.7	2,864.2
Allocation of Midpoint Total:						
Life-Years	3,534.2	700.2	6,920.2	1,402.8	10,305.1	2,075.0
Health Status	742.8	241.6	1,454.5	484.0	2,165.9	715.9
Medical Expenditure Reduction	215.3	126.1	210.8	126.3	209.3	124.6
Other Financial Effects	-125.0	-51.9	-122.4	-52.0	-121.5	-51.3

3. Reduced Fire Costs

Each year, fires started by lighted tobacco products kill and injure people and destroy structures and other property. In the United States in 2007, civilian deaths caused by smoking-related fires totaled 720, with direct property damage of $530 million (Ref. 141). A reduction in the number of smokers, and the coinciding number of cigarettes smoked, will reduce the number of future fires.

FDA estimates the rule-induced decrease in cigarettes smoked by multiplying together the percentage change in smoking whose calculation was described in section XI.D.1 of this document, the projected population in a given year (Ref. 130) and age-appropriate discounted lifetime cigarette consumption (in packs) per smoker. FDA calculates average consumption for 18- to 23-year-olds using the May 2006, August 2006, and January 2007 Tobacco Use Supplements to the Current Population Survey (Ref. 142). Sloan *et al.* (Ref. 116) report lifetime discounted consumption for typical 24-year-old smokers. Comparing against total consumption in 2006 (the most recent year for which the FTC (Ref. 143) reports cigarette sales), we find that discounted lifetime cigarette consumption will decrease by an amount equivalent to 3.9 percent (using a 3-percent discount rate) or 2.1 percent (using a 7-percent discount rate) of a present-day annual total as a result of the final rule.

The rule-induced percentage reduction in fires may not equal the percentage reduction in cigarette consumption, however, because all 50 States have passed legislation that requires cigarettes to be self-extinguishing or fire-safe (Ref. 144). FDA acknowledges some uncertainty in the effectiveness rate of fire-safe cigarettes;[15] for this analysis, we

[15] One of the first States to enact these laws, New York, requires cigarettes to self-extinguish 75 percent of the time (Ref. 145). Data from New York show a reduction in smoking-caused fires of about 10.6 percent from the average of the 4 years (2000 to 2003) prior to passage of the fire-safe cigarette law to the first 2 years (2006 to 2007) after implementation was complete (Ref. 146).

estimate that 10.6 percent of apparently rule-induced future fire reductions would have been avoided even without this final rule due to fire-safe cigarette design.

The National Fire Protection Association (Ref. 147) reports the percentages of fire fatalities by age category; along with the CDC's estimate of average American life expectancy (Ref. 136), these data allow FDA to calculate that the average number of life-years lost by fire victims is approximately 37.3; we project that total discounted life-years saved as a result of the rule will be 317.4 (at a 7-percent discount rate) or 1,198.5 (at a 3-percent discount rate). Using—as in sections XI.D.2.b.ii and XI.D.2.b.iii of this document—VSLY ranging from $106,308 to $318,923, FDA estimates total rule-induced fire-cost savings of $106.0 to $262.5 million (at a 3-percent discount rate) or $34.1 to $76.5 million (at a 7-percent discount rate); of these totals, $12.9 (7-percent discount rate) or $27.7 million (3-percent discount rate) consists of averted property damage, with the remainder being the value of life-years saved. These estimated savings may significantly underestimate the final rule's fire-related benefits because they exclude noncivilian mortality and the value of reduction in fire-caused nonfatal injuries. There will, however, be some double counting between the estimated fire-related mortality benefits and the mortality benefits estimated in section XI.D.2.b.ii of this document to the extent that it is smokers themselves who are killed in cigarette-caused fires.

4. Summary of Benefits

The discussion above demonstrates the considerable magnitude of the economic benefits available from smoking reduction efforts. As shown in table 9a of this document, our midpoint benefits estimates range from $5.21 to $13.55 billion (with a 3-percent discount rate) or $1.38 to $3.27 billion (with a 7-percent discount rate). Estimates are presented as annualized values in table 9b of this document, reported over time in Appendix X3, and subjected to Uncertainty Analysis in Technical Appendix X6. Nonquantified benefits include reductions in nonsmoker morbidity and mortality associated with passive smoking and mothers smoking during pregnancy.

Table 9a.--Present Value of Benefits ($ mil)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90 Percent Ratio Derived from Public Comment	8,470.3	1,928.3	16,740.0	3,705.5	25,009.7	5,482.6
24 Percent Ratio Derived from Gruber (Ref. 133)	2,360.7	541.0	4,662.3	1,038.8	6,963.8	1,536.6
7 Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	730.2	171.8	1,435.0	327.3	2,139.7	482.8
Value of Cessation Derived from Warner et al. (Ref. 131)	476.3	356.5	554.6	377.7	632.8	398.9
Midpoint Between Lower and Upper Bounds	5,206.4	1,380.3	9,380.3	2,346.6	13,554.3	3,271.0
Allocation of Midpoint Total:						
Life-Years	3,534.2	700.2	6,920.2	1,402.8	10,305.1	2,075.0
Health Status	742.8	241.6	1,454.5	484.0	2,165.9	715.9
Medical Expenditure Reduction	416.2	241.2	411.7	241.4	410.1	239.6
Other Financial Effects	407.2	163.3	409.8	163.2	410.7	163.9
Fire Loss	106.0	34.1	184.3	55.3	262.5	76.5

Table 9b.--Annualized Value of Benefits ($ mil)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Totals Calculated with Alternative Methods or Net-to-Gross Benefits Ratios:						
90-Percent Ratio Derived from Public Comment	569.3	182.0	1,125.2	349.8	1,681.0	517.5
24-Percent Ratio Derived from Gruber (Ref. 133)	158.7	51.1	313.4	98.1	468.1	145.0
7-Percent Ratio Derived from Gruber and Köszegi (Ref. 104)	49.1	16.2	96.5	30.9	143.9	45.6
Value of Cessation Derived from Warner et al. (Ref. 131)	32.0	33.6	37.3	35.7	42.5	37.7
Midpoint Between Lower and Upper Bounds	349.9	130.3	630.5	221.5	911.1	308.8
Allocation of Midpoint Total:						
Life-Years	237.6	66.1	465.1	132.4	692.7	195.9
Health Status	49.9	22.8	97.8	45.7	145.6	67.6
Medical Expenditure Reduction	28.0	22.8	27.7	22.8	27.6	22.6
Other Financial Effects	27.4	15.4	27.5	15.4	27.6	15.5
Fire Loss	7.1	3.2	12.4	5.2	17.6	7.2

E. Costs

Implementation of this final rule, and the statutory requirements directly linked to it, will create new burdens for cigarette manufacturers. In particular, manufacturers will incur the upfront costs associated with a major labeling change.[16] There will be additional ongoing costs associated with equal and random display of the warnings required in this rule, as mandated by the Tobacco Control Act. Cigarette manufacturers and retailers will be responsible for the removal of noncompliant point-of-sale advertising. Consumers are likely to ultimately bear a share of these costs in the form of increased prices. In addition, the tobacco industry and possibly other sectors will experience lost sales and employment, but these revenue transfers will be offset by gains to other sectors, as discussed in the ''Distributional Effects'' section of this document.

1. Number of Affected Entities

Labeling and advertising requirements will affect domestic cigarette manufacturers and importers of foreign-made cigarettes. Statistics of U.S. Businesses data show that there were 24 cigarette manufacturing firms in the United States in 2007 (Ref. 148). An undetermined number of importers will also be affected.

Noncompliant point-of-sale advertising will be removed by manufacturers (or importers) and retailers. We use detailed data from the 2002 Economic Census report on product line sales for establishments with payroll to estimate the percentage of various types of retail establishments that sell tobacco products. Searching by the Economic Census product line 20150 (cigars, cigarettes, tobacco, & smokers' accessories), we find accommodation and food service establishments (NAICS 72) and retail trade establishments (NAICS 44–45) that report tobacco sales (Refs. 149 and 150). Although some establishments in other industries may have unreported sales of tobacco products, the product line sales data provide a reasonable basis to determine which establishments will be affected by the rule.

[16] All of the upfront costs of this rule are assumed to occur in the first period of the time horizon of this rule (2012). The cost tables present raw undiscounted calculations of these one-time costs. For summary tables requiring a present value, these costs are discounted 1 year back to the present (2011).

Table 10.--Establishments With Payroll That Sell Tobacco Products, 2002 Economic Census

Kind of Business	NAICS	Number in NAICS	Number Selling Tobacco Products	Percentage Selling Tobacco Products
General merchandise	452	40,723	6,991	17%
Food & beverage	445 excluding 44512	119,592	65,255	55%
Convenience[a]	44512	29,212	24,871	85%
Gasoline stations with convenience[a]	44711	93,691	86,152	92%
Gasoline stations	44719	27,755	8,745	32%
Health & personal care	446	81,797	17,761	22%
Other retail establishments	[a]	595,558	3,470	1%
Accommodation and food services	72 excluding 7224	516,734	12,347	2%
Drinking places	7224	48,856	11,490	24%
Tobacco stores	453991	6,184	6,184	100%
Nonstore retailers	454	49,000	848	2%
Vending machine operators	4542	5,921	892	15%
TOTAL		1,615,023	245,006	15%

Sources: Refs. 149 and 150

[a] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991

Because the 2007 Census data on product line sales for retail establishments with employees are not yet available, we update the number of various types of retail establishments using 2007 Statistics of U.S. Businesses data but assume the share of establishments selling tobacco products is unchanged (since 2002) within each category. Likewise, we lack 2007 Census data on product line sales for nonemployer establishments. Without additional information, we assume that, within a NAICS category, the share of establishments selling tobacco products will be the same for nonemployer establishments in 2007 as for establishments with payroll in the 2002 Census. As shown in table 11 of this document, we estimate that about 249,000 retail establishments with payroll and 126,000 nonemployer establishments sell tobacco products.

Table 11.--Establishments That Sell Tobacco Products

Kind of Business	NAICS		Establishments With Payroll		Nonemployer Establishments	
		Percentage Selling Tobacco Products[a]	Number[b]	Estimated Number Selling Tobacco Products	Number[c]	Estimated Number Selling Tobacco Products
General merchandise stores	452	17%	47,456	8,147	32,978	5,661
Food & beverage stores	445 excluding 44512	55%	122,858	67,037	104,026	56,761
Convenience stores	44512	85%	28,173	23,986	e	
Gasoline stations with convenience stores	44711	92%	95,389	87,713	e	
Gasoline stations	44719	32%	20,144	6,347	9,454	2,979
Health & personal care stores	446	22%	89,406	19,413	138,800	30,138
Other retail stores	D	1%	600,537	3,499	735,266	4,284
Accommodation and food services	72 excluding 7224	2%	585,541	13,991	281,104	6,717
Drinking places	7224	24%	46,948	11,041	27,170	6,390
Tobacco stores	453991	100%	6,458	6,458	e	
Nonstore retailers	454 excluding 4542	2%	42,565	737	782,759	13,547
Vending machine operators	4542	15%	5,158	777	27,595	4,157
Total		15%	1,690,633	249,147	2,139,152	126,477

[a] Percentage of establishments with payroll from table 10 of this document.
[b] Ref. 148
[c] Ref. 151
[d] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991
[e] Data on nonemployer establishments unavailable for this NAICS category

2. Costs of Changing Cigarette Labels

We have updated our analysis of the cost of changing cigarette labels based on the availability of improved estimates generated by the new FDA labeling cost model. Unless stated otherwise, our estimates in this analysis come from the new model.

The front and back of every cigarette package must be redesigned to incorporate graphic warnings that will occupy the entire top half, and the current warning will be eliminated. This is classified by the labeling model as a major change. (Any change that affects more than one color or changes the layout enough to require a redesign is major.) In addition, the requirement to incorporate nine different warnings will increase costs beyond what the labeling model estimates. FDA accounted for the additional warnings by first calculating the standard cost of a major change for cigarette labels and then inflating specific cost components expected to increase as a direct result of the requirement for nine warnings.

The FDA labeling cost model incorporates three potential cost components of a labeling change: Label design costs (incurred on a per-UPC basis), inventory costs (incurred on a per-unit basis), and testing costs (incurred on a per-formulation basis). Because the model has a greater focus on analytic testing (*e.g.,* measuring fat grams in a candy bar) than on market testing (which is the aspect of testing applicable to cigarettes), we perform several modifications to the model's testing cost estimation. First, we calculate costs on a per-brand, rather than per-formulation, basis and, second, we restrict the calculation of market testing costs to the largest firms. The large cigarette manufacturers can plausibly be expected to conduct quantitative studies and focus group testing for each of their brands to gauge the effect of the new graphic warnings and to study how they might best be able to mitigate their effects. By contrast, small manufacturers with lower sales revenues are highly unlikely to conduct expensive market testing in response to the new requirements. Further details of our estimation approach will be discussed in section XI.E.4 of this document.

The labeling model estimates that a total of 4,312 cigarette UPCs (3,789 branded and 523 private label) will be affected by this rule. However, it is estimated that label changes for 335 UPCs (8 percent of branded and 6 percent of private label) can be coordinated with previously scheduled, nonregulatory labeling changes. Coordination of a regulatory change with a nonregulatory change reduces the incremental burden of the regulatory change.

As discussed in the responses to comments, FDA follows its previous labeling cost model (Ref. 152) in assuming 10-percent rush charges under a 15-month compliance period. Using the labeling model cost estimates for uncoordinated changes and incorporating 10-percent rush charges, we estimate that labor costs for label design, including administrative labor costs as well as graphic design and prepress labor costs, are $4,147 to $10,890. Materials costs are estimated to be $6,644 to $10,934; included in this total are both prepress materials and printing plate costs.[17] Recordkeeping costs are estimated to be $55 to $99. Summing labor, materials, and recordkeeping costs yields a per-UPC label design cost of $10,846 to $21,923. The model estimates that for coordinated labeling changes, there is a per-UPC cost of $340 to $840. This cost is nonzero because there will still be

[17] Rotogravure, the most expensive printing method, is used for cigarette package labels.

some administrative labor and recordkeeping associated with coordinating a regulatory change with a previously scheduled, nonregulatory change. Total label design costs of this change are thus estimated to be $43 to $87 million.

Manufacturers incur costs if they discard unused label inventory at the end of the compliance period and thus have to print new labels instead of using that inventory. (There is also a small cost associated with disposal.) The labeling model estimates that 767,016 labels will be discarded at the end of the 15-month compliance period, each having a cost of $0.028 to $0.039. The inventory-replacement cost of this labeling change would then be $21,000 to $30,000. Table 12 of this document summarizes the total cost of a standard major labeling change (one warning per UPC), which is estimated to be $43 to $88 million.

Table 12.--Cost of a Standard Major Label Change for Cigarettes

	Low Cost	Medium Cost	High Cost
Label Design Costs			
Number of uncoordinated UPCs	3,978	3,978	3,978
Labor cost ($)	4,147	6,380	10,890
Materials cost ($)	6,644	6,996	10,934
Recordkeeping cost ($)	55	88	99
Per-UPC cost ($)	10,846	13,464	21,923
Label Design Costs for Uncoordinated UPCs ($)	43,145,388	53,559,792	87,209,694
Number of coordinated UPCs	335	335	335
Labor cost ($)	310	550	790
Materials cost ($)	0	0	0
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	340	590	840
Label Design costs for Uncoordinated UPCs ($)	113,900	197,650	281,400
Total Label Design Costs ($)	43,259,288	53,757,442	87,491,094
Inventory Costs			
Number of discarded Labels	767,016	767,016	767,016
Unit cost per discarded label ($)	0.028	0.033	0.039
Total Inventory Costs ($)	21,093	25,312	29,530
Total Cost ($)	43,280,381	53,782,754	87,520,624

We expect materials costs for printing plates and prepress activities to be approximately nine times as large as previously calculated for uncoordinated UPCs because of the requirement for nine separate warnings. Each UPC will require nine printing plates, one for each warning label. Additionally, the incremental materials cost of a coordinated label change will be eight times the uncoordinated materials costs, because eight extra printing plates will be needed. We assume that this adjustment accounts for all the one-time costs that arise from the requirement to use nine warnings.[18] Table 13 of this document shows the total costs of the cigarette labeling change, making the adjustment for the nine-warning requirement. The labeling cost range increases to $273 million to $465 million.

[18] Some of the subcomponents of other cost categories might increase due to the nine-warning requirement, but there is far less reason to believe there will be a direct, proportional relationship between those cost categories and the number of warnings. For example, the part of the label that is under the manufacturer's control only has to be designed once because the same design will be paired with all nine labels. Likewise, the amount of unused inventory discarded is unaffected by the number of warnings used under the new requirements.

Table 13.--Cost of a Major Cigarette Label Change With Nine Warning Labels

	Low Cost	Medium Cost	High Cost
Label Design Costs[a]			
Number of uncoordinated UPCs	3,978	3,978	3,978
Labor cost ($)	4,147	6,380	10,890
Materials cost ($)	*59,796*	*62,964*	*98,406*
Recordkeeping cost ($)	55	88	99
Per-UPC cost ($)	63,998	69,432	109,395
Label Design Costs for Uncoordinated UPCs ($)	254,584,044	276,200,496	435,173,310
Number of coordinated UPCs	335	335	335
Labor cost ($)	310	550	790
Materials cost ($)	*53,152*	*55,968*	*87,472*
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	53,492	56,558	88,312
Label Design costs for Uncoordinated UPCs ($)	17,919,820	18,946,930	29,584,520
Total Label Design Costs ($)	272,503,864	295,147,426	464,757,830
Inventory Costs			
Number of discarded Labels	767,016	767,016	767,016
Unit cost per discarded label ($)	0.0275	0.033	0.0385
Total Inventory Costs ($)	21,093	25,312	29,530
Total Cost ($)	272,524,957	295,172,738	464,787,360

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

The cost of changing cigarette labels is largely driven by materials costs. The distribution for the estimate of materials costs is extremely skewed to the right, as evidenced by the fact that the low and medium estimate are much closer than the medium and high estimates. We report the 90th percentile range but note that the high value appears to be driven by a few extremely high values.

3. Ongoing Costs of Equal and Random Display

The Tobacco Control Act calls for equal and random display of the graphic warning images required by this rule. Although the initial design and implementation of a system for equal and random display will be part of the upfront label change, continued operation of such a system in subsequent years will have incremental ongoing administrative and recordkeeping costs. Such a system will be more burdensome than the current system of quarterly rotation of four warnings. FDA assumes that the ongoing yearly administrative labor cost per UPC will be equal to 10 percent of the (non-rush) administrative labor cost of an uncoordinated labeling change, and the yearly recordkeeping cost will be equal to 50 percent of the (non-rush) recordkeeping cost of an uncoordinated labeling change. As shown in table 14 of this document, FDA estimates that, under these assumptions, ongoing annual administrative and recordkeeping costs equal $375,000 to $876,000.

Table 14.--Estimated Ongoing Costs for Equal Random Display[a]

	Low Cost	Medium Cost	High Cost
Number of UPCs	4,313	4,313	4,313
Ongoing Admin. Costs per UPC	62	110	158
Total Ongoing Admin Costs	267,406	474,430	681,454
Ongoing RK Costs per UPC	25	40	45
Total Ongoing Recordkeeping Costs	107,825	172,520	194,085
Total Ongoing Costs	375,231	646,950	875,539

[a] Costs for maintaining a system of equal random display are assumed to be incurred in years 2 through 20 of the time horizon of this rule.

4. Market Testing Costs Associated With Changing Cigarette Package Labels

As stated previously, FDA expects that only the large manufacturers will conduct market tests for their brands. Using several State directories of certified tobacco products, FDA estimates that 75 brands are marketed by the 4 largest domestic manufacturers (Refs. 153 through 158). If we assume (as in the labeling model) that 8 percent of changes for these brands are coordinated, then changes for the remaining 69 brands are not coordinated. Including rush charges, the cost of focus group testing is estimated to range from $8,000 to $14,000 per brand, and the cost of a quantitative study is estimated to range from $14,000 to $105,000 per brand. Assuming both types of testing are conducted for 69 brands yields a total cost estimate ranging from $1.5 to $8.2 million with a medium estimate of $2.1 million, as shown in table 15 of this document. We assume that the requirement to use nine

different color graphic-text pairs does not affect these costs.

Table 15.--Cost of Market Testing[a]

	Low Cost	Medium Cost	High Cost
Number of brands to be tested	69	69	69
Cost of focus group testing ($)	8,030	11,000	13,970
Cost of quantitative studies ($)	13,750	19,800	105,160
Market testing cost per brand ($)	21,780	30,800	119,130
Total Market Testing Cost ($)	1,502,820	2,125,200	8,219,970

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

5. Advertising Restrictions: Removal of Noncompliant Point-of-Sale Advertising

The principal effect of the restrictions on advertising in the rule stem from the requirement that retailers and manufacturers of cigarettes remove any point-of-sale advertising for cigarettes that fails to conform to the requirements. In this analysis, we estimate the social resource costs for the removal. In the analysis of FDA's 1996 final tobacco rule, we based much of our estimate of the cost of removing noncompliant point-of-sale advertising on a report from the Barents Group that used average removal costs for seven types of retail establishments, calculated using in-store surveys conducted by A.T. Kearney, Inc. (61 FR 44396 at 44580). We retain our assumptions from 1996 about the level of effort required to remove point-of-sale advertising. We acknowledge, however, that this approach may overstate or understate the costs for a particular action or type of business.

Table 16 of this document regroups the information from table 11 of this document according to the categories studied by A.T. Kearney. Because our analysis considers only the removal of point-of-sale advertising from physical retail locations, we do not include nonstore establishments. Table 17 of this document shows that, in current dollars, one-time per-establishment costs range from about $12 for ''other establishments'' to about $198 for convenience stores. To estimate the total costs to comply with the restriction on point-of-sale advertising, we apply the updated per-establishment costs from table 17 to affected establishments. As shown in table 18 of this document, the one-time costs to remove point-of-sale materials will total $45.4 million.

Table 16.--Estimated Number of Establishments Selling Cigarettes Products Affected by the Rule

Kind of Business	Establishments With Payroll[a]	Nonemployer Establishments[a]	Total
AT Kearney Category			
General Merchandise	8,147	5,661	13,808
Supermarket & Grocery	67,037	56,761	123,799
Convenience Stores	23,986		23,986
Convenience Stores with Gas	87,713		87,713
Service Stations	6,347	2,979	9,326
Drug Stores	19,413	30,138	49,552
Specialty Tobacco Stores	6,458		6,458
Other establishments [b]	28,531	17,391	45,922
Total	247,633	112,931	360,564

[a] Source: Table 11 of this document

[b] Includes miscellaneous retail establishments and accommodations and food services establishments (including drinking places), but excludes nonstore retailers.

Table 17.--Estimated Average Per-Establishment Costs to Remove Prohibited Materials[a]

AT Kearney Business Category	Remove Promotional Materials ($)	
	1996 dollars	Current dollars
General Merchandise	23.42	30.94
Supermarket & Grocery	125.14	165.30
Convenience Stores	150.02	198.16
Convenience Stores with Gas	146.43	193.42
Service Stations	36.09	47.67
Drug Stores	11.72	15.48
Specialty Tobacco Stores	123.21	162.75
Other establishments [b]	9.37	12.38

[a] Sources: 61 FR 44396 at 44585, Table 8; 1996 to 2009 (most recent) GDP deflator rose 32.1% (Ref. 132)
[b] Excludes adult-only establishments, nonstore retailers and vending machine operators.

Table 18.--Estimated One-Time Costs to Remove Point-of-Sale Materials from Affected Establishments

A.T. Kearney Category	Number of Establishments	Average Cost ($)	Total One-time Costs[b] ($ million)
General Merchandise	13,808	30.94	0.4
Supermarket & Grocery	123,799	165.30	20.5
Convenience Stores	23,986	198.16	4.8
Convenience Stores with Gas	87,713	193.42	17.0
Service Stations	9,326	47.67	0.4
Drug Stores	49,552	15.48	0.8
Specialty Tobacco Stores	6,458	162.75	1.1
Other establishments[a]	45,922	12.38	0.6
Total	360,564		45.4

Sources: Tables 16 and 17 of this document.
[a] Excludes adult-only establishments and nonstore retailers.
[b] Undiscounted costs assumed to be incurred in the first period of the time horizon of this rule.

6. Government Administration and Enforcement Costs

FDA's estimated internal costs for administering and enforcing this regulation are uncertain. As a best estimate, however, FDA projects that 25 full-time equivalent employees (FTEs) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (*e.g.,* field inspectors versus administrative), but an average of $247,049 per FTE places the dollar cost at approximately $6.2 million per year.

An additional cost of the final rule, borne by government but not necessarily FDA, arises due to the required reference to the cessation resource. The rule requires the final graphic warning labels to refer to an already-existing cessation resource. Therefore, only costs associated with additional traffic to that resource are attributable to this final rule. FDA has not quantified these costs.

7. Summary of Costs

Table 19 of this document summarizes the cost estimates from the preceding sections and table 20 of this document displays the present value and annualized value of costs. The tables in Technical Appendix X4 show the undiscounted stream of costs. The range of total costs presented in table 20 of this document is an approximate 90 percent confidence interval and, as such, corresponds to the uncertainty range of benefits presented in table 51 of this document. The distributions of costs and benefits, however, are not correlated; in other words, it may be the case that the actual effects of the rule fall in the high end of the cost range and the low end of the benefits range, or vice versa.

Table 19.--Summary of Costs

Requirements of the Rule	Annual ($ million)			One-Time ($ million)[a]		
	Low	Med	High	Low	Med	High
Private Sector						
Label Change				272.5	295.2	464.8
Market Testing				1.5	2.1	8.2
Point-of-Sale Advertising				45.4	45.4	45.4
Continuing Admin and Recordkeeping[b]	0.4	0.6	0.9			
Subtotal	0.4	0.6	0.9	319.5	342.7	518.4
Government						
FDA[c]	6.2	6.2	6.2			
Other (Cessation Resource)[c]						
Subtotal	6.2	6.2	6.2	-	-	-
TOTAL	6.6	6.8	7.1	319.5	342.7	518.4

[a] Undiscounted value of one-time costs assumed to be incurred in the first period of the time horizon of this rule.
[b] Ongoing cost assumed to be incurred in years 2 through 20.
[c] Annual costs assumed to be incurred in each period for a total of 20 years.

Table 20.--Present Value and Annualized Value of Costs

Requirements of the Rule	Present Value ($ million)						Annualized Costs ($ million)					
	3 percent			7 percent			3 percent			7 percent		
	Low	Med	High	Low	Med	High	Low	Med	High	Low	Med	High
Private Sector												
Label Change	264.6	286.6	451.2	254.7	275.9	434.4	17.8	19.3	30.3	24.0	26.0	41.0
Market Testing	1.5	2.1	8.0	1.4	2.0	7.7	0.1	0.1	0.5	0.1	0.2	0.7
Point-of-Sale Advertising	44.1	44.1	44.1	42.5	42.5	42.5	3.0	3.0	3.0	4.0	4.0	4.0
Continuing Admin and RK	5.2	9.0	12.2	3.6	6.2	8.5	0.4	0.6	0.8	0.3	0.6	0.8
Subtotal	315.4	341.8	515.5	302.2	326.6	493.0	21.2	23.0	34.7	28.5	30.8	46.5
Government												
FDA	91.9	91.9	91.9	65.4	65.4	65.4	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)												
Subtotal	91.9	91.9	91.9	65.4	65.4	65.4	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	407.3	433.6	607.4	367.6	392.0	558.4	27.4	29.1	40.8	34.7	37.0	52.7

F. Cost-Effectiveness Analysis

We measure the effectiveness of the final rule as the sum of saved life-years and QALYs. In order to assess the cost-effectiveness of the rule, we must adjust the costs to account for effects that are not captured by life-years or QALYs. As shown in detail in the previous section, we calculated the first 20 years' costs attributable to the rule and found present values of $367.6 to $558.4 million (using a 7-percent discount rate) or $407.3 to $607.4 million (using a 3-percent discount rate). We add to each total the estimated monetary value of lost consumer surplus (as discussed in detail in Technical Appendix X5, this was implicitly netted out of life-years and health improvement benefits estimates calculated in section XI.D.2.b of this document); this yields overall costs of $1.46 to $3.70 billion (using a 7-percent discount rate) or $5.33 to $15.55 billion (using a 3-percent discount rate). In order to focus on the costs associated with extensions of quality-adjusted life (*see* Ref. 103 at pp. 11–12), we then subtract both medical cost reductions and the value of property savings due to reductions in accidental fires and arrive at a net cost of $0.94 to $3.19 billion (using a 7-percent discount rate) or $4.38 to $14.59 billion (using a 3-percent discount rate).

Discounting over the same 20-year time period, we calculate that this rule will lead to 208,535 to 246,137 discounted smoking preventions or cessations. Similarly, we find that 18,534 to 86,326 discounted QALYs will be saved (this includes both fractional life-years associated with reduced morbidity and full life-years associated with reduced premature mortality—both for smokers themselves and for others caught in the path of cigarette-related fires). This yields a cost per smoking prevention of $4,530 to $59,287, and a cost per QALY saved of $50,746 to $172,082. Braithwaite *et al.* (Ref. 159) find that preferences in the United States are such that the threshold for cost-effective interventions is somewhere in the range of $109,000 to $297,000 per QALY saved.

Table 21.--Cost-Effectiveness

Cost ($)	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Per Smoking Prevention	$17,798	$38,243	$59,287	$4,530	$9,470	$15,292
Per QALY Saved	$50,746	$109,040	$169,040	$50,972	$106,563	$172,082

G. Distributional Effects

This final rule will lead to losses to some segments of U.S. society that will most likely be offset by equal gains to some other segments of society; as such, these effects do not constitute net social costs or benefits and have not yet been discussed in detail in this Analysis of Impacts. In general, sectors affiliated with tobacco and tobacco products will lose sales revenues as a result of this final rule. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers, Distributors, and Growers

FDA estimates that implementation of the regulation may reduce the annual cigarette consumption of U.S. smokers by 30.8 million packs (in 2013) to 40.5 million packs (in 2031). Meanwhile, the FTC (Ref. 143) reports that, in 2006, 17.5 billion cigarette packs were manufactured and distributed to consumers. These numbers imply that tobacco manufacturer revenues will be 0.176 percent lower in the rule's first year, and 0.231 percent lower in 2031, than they were in 2006. The U.S. Census Bureau (Ref. 160) reports that tobacco manufacturers' revenues totaled $41.6 billion in 2006; hence, the rule-induced decrease in annual tobacco sales will range from approximately $73.1 to $96.2 million. These estimates would rise somewhat higher if we were accounting for the decrease in price that accompanies the decrease in demand for a good (in this case, cigarettes). Experimental evidence from Mexico (Ref. 101) indicates that graphic warning labels may decrease smokers' willingness-to-pay for cigarettes by 17 percent; however, without supply elasticity data, we cannot determine how much this decline in willingness-to-pay will change cigarettes' market price.

We estimate that the tobacco manufacturing, warehousing, and wholesale trade sectors employ about 74,000 full-time workers (Ref. 148). Under the assumption of constant production-to-employment ratio, we project that a 0.176 to 0.231 percent reduction in sales will result in the displacement of 130 to 171 jobs among manufacturers, warehousers, and wholesalers.

Effects of the rule will also be observed in the agricultural sector. According to USDA's 2007 Census of Agriculture (Ref. 161), there are 16,234 tobacco farms. Upon implementation of the rule, these farms may shift some of their acreage from growing tobacco to producing other agricultural products.

2. National and Regional Employment Patterns

Several studies estimate the contribution of tobacco to the U.S. economy or, alternatively, the losses to the U.S. economy that will follow a decline in tobacco-related consumption. Economists have shown both theoretically and empirically that, for the nation as a whole, employment gains from spending on other products will offset any employment losses from reduced spending on tobacco products (Ref. 162). The major tobacco-growing states, however, will experience some adverse economic effects. An economic simulation of the regional impacts of spending on tobacco products carried out in 1994 found that after 8 years, a 2-percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for the effects of this final rule) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment), whereas the nontobacco regions of the United States would gain 56,300 jobs (Ref. 122). That study, if carried out today, would find a much smaller net effect because total employment in tobacco-related industries has fallen. Overall, FDA finds that the income and employment effects associated with the estimated reduction in tobacco consumption will be small.

3. Retail Sector

As will tobacco growers, distributors, and manufacturers, tobacco retailers will be affected by any decrease in cigarette sales. Retailers will, however, be in a position to shift shelf space and promotional activities to nontobacco products, in order to take advantage of the increase in demand for other products that will be expected to accompany the decrease in spending on cigarettes. It is possible that some retailers who rely heavily on cigarette sales may not be able to fully offset their reduction in cigarette sales with sales of other products. Other retailers would then experience some of the gain in sales associated with an increase in demand for other products. This would be a distributional effect within the retail sector.

4. Advertising Industry

The overall impact of the rule on the advertising industry is uncertain. Advertiser revenue may decrease because advertisements with graphic warning labels are less desirable from a cigarette seller's standpoint and thus tobacco manufacturers will choose to conduct less advertising. On the other hand, advertising industry revenue may increase due to cigarette sellers' need to redesign advertisements to accommodate new warning labels and to devise new promotional strategies. In either case, few net social costs or benefits will be generated. Moreover, the effect on advertising revenue will likely be relatively small because spending on cigarette advertising has declined substantially in recent years and is now quite small compared with the 1980s and 1990s (Ref. 143). By 2006, expenditures on magazine advertising had fallen to about $50 million and outdoor advertising to under $1 million. Most of the remaining affected advertising expenditures were point-of-sale promotions, which totaled $240 million (Ref. 143).

5. Excise Tax Revenues

In 2009, Federal tobacco tax revenues totaled $16.3 billion, while State and local tobacco tax revenues totaled $16.5 billion (Ref. 163). This rule will decrease government tobacco tax revenues as fewer Americans consume cigarettes. Sales tax revenues generated through tobacco sales will also fall as a result of the rule, but those changes will be much smaller than the changes in excise tax collections and have not been quantified by FDA.

FDA estimates this change in excise tax revenues by multiplying together the percentage change in smoking rate, whose calculation was described in section XI.D.1 of this document; the projected population in a given year (Ref. 130); age-appropriate discounted lifetime cigarette consumption (in packs) per smoker; and current Federal and average State tax rates (Refs. 164 and 165). FDA calculates average consumption for 18- to 23-year-olds using the May 2006, August 2006, and January 2007 Tobacco Use Supplements to the Current Population Survey (Ref. 142). Sloan *et al.* (Ref. 116) report lifetime discounted consumption for typical 24-year-old smokers.

FDA estimates that average direct annual rule-induced decreases in excise tax collections will be approximately $33.4 million for State governments and $25.7 million for the Federal government. Approximately 25 percent of this reduction may be offset by increased sales of other taxable goods and services (Ref. 166); thus, the annual reductions in tax collections will be $25.1 million for State governments and $19.3 million for the Federal government. Assuming that excise taxes rise, on average, at the rate of inflation allows us to sum these values over the time horizon of our analysis, yielding an

overall revenue loss to State governments of $454.9 million (present value with a 7-percent discount rate) to $977.5 million (present value with a 3-percent discount rate) and to the Federal government of $348.1 million (present value with a 7-percent discount rate) to $749.8 million (present value with a 3-percent discount rate).

Because we cannot know if nominal cigarette excise taxes actually will increase at the rate of inflation, we also calculate these discounted present values for the case in which tax rates remain at their current nominal levels. In this case, the real tax rate will fall at the rate of inflation, which we forecast using the difference between interest rates for standard and inflation-protected long-term Treasury bills. The U.S. Department of the Treasury (Ref. 167) reports that, as of February 11, 2011, the composite rate for long-term standard bills was 4.33 percent, while the composite rate for long-term inflation-protected bills was 2.00 percent; the difference yields an inflation forecast of 2.33 percent per year. At this rate of inflation, the overall rule-induced tax revenue loss to State governments will be $327.8 to $590.0 million and to the Federal government will be $250.6 to $451.9 million. FDA emphasizes that these estimates would be altered, possibly a great deal, either by future changes in tax rates or inaccuracy in the inflation forecast.

We note that, leaving aside potential deadweight loss, there are two principal effects of tax reductions: Gains to former payers and losses to former recipients. Because these transfers exactly offset each other, there is no net social cost or benefit associated with the reduction in excise tax collections induced by the rule.

6. Government-Funded Medical Services, Insurance Premiums, and Social Security

Sloan *et al.* (Ref. 116) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers; in 2000 dollars and discounted at a 3-percent rate, specific net costs are $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker. Smokers bear a portion of these net costs themselves, but a portion equaling $1,726 per female smoker or $1,245 per male smoker is borne by nonsmokers through increased private insurance premiums or taxes used to fund government health care programs; hence, a reduction in the U.S. smoking population will transfer value from smokers (who receive medical services paid partially by the general public) to nonsmokers. If nonsmokers' payment portions are adjusted for inflation and distributed over ages 24 to 100 as described in section XI.D.2.b.iv of this document (''Medical Services''), given FDA's projected 20-year reductions in smoking prevalence, this transfer totals $401.7 million. With a 7-percent discount rate, the total becomes $230.1 million. Sloan *et al.* indicate that this reduction will be distributed unequally across Medicare, Medicaid, and other insurance types. Details appear in table 22 of this document.

Table 22.--Distribution of Medical Cost Reductions ($ millions)

Discount Rate	Medicaid	Medicare Part A	Medicare Part B	Other Government	Private	Uninsured	Total
3%	104.2	-13.1	-174.1	50.4	359.1	75.2	401.7
7%	50.3	-14.5	-109.1	28.5	231.0	43.9	230.1

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

Sloan *et al.* (Ref. 116, at p. 255) estimate the effect of smoking, per male and female smoker, on net Social Security, private pension, and life insurance outlays, as well as on income tax payments. In the cases of Social Security and private pension outlays, smoking-related premature mortality causes smokers to collect less from the programs than they contribute during their lifetimes. Therefore, any rule-induced reduction in the U.S. smoking population will shift value from members of the general public who pay Social Security taxes and who contribute to private pension plans to the individuals who are dissuaded from smoking by the regulation. A transfer in the opposite direction—from individuals dissuaded from smoking by the regulation to the general public—will occur in the realms of life insurance programs and income taxes.

Because Sloan *et al.* only report effects for 24-year-olds, we can only directly calculate these transfer effects for cohorts who are no older than 24 during the period from 2012 to 2031. The sum of these effects appears in the lower bound columns of table 23 of this document. For the upper bounds, we assume that effects are the same for smokers aged 25 and above as they are for 24-year-olds. In converting Sloan *et al.'s* present values, calculated with a 3-percent discount rate, to present values calculated with a 7-percent discount rate, further assumptions are necessary. We calculate the ratios of 7-percent present values to 3-percent present values for all gross benefits categories (life-years, health status, medical cost reductions, and fire loss reductions) and use the lowest and highest ratios for the lower and upper bounds in table 23. Finally, we note that we update Sloan *et al.'s* estimates using the most recent annual GDP deflator (Ref. 132).

Table 23.--Social Security, Income Taxes, Private Pensions, and Life Insurance Transfers ($ millions)

	Lower Bound Effect of Rule, Discounted at 3%	Midpoint Effect of Rule, Discounted at 3%	Upper Bound Effect of Rule, Discounted at 3%	Lower Bound Effect of Rule, Discounted at 7%	Midpoint Effect of Rule, Discounted at 7%	Upper Bound Effect of Rule, Discounted at 7%
Social Security Outlays	-280.4	-649.2	-1,017.9	-35.3	-263.2	-491.0
Income Taxes on Social Security-Taxable Earnings	327.0	746.5	1,166.1	41.1	301.5	561.8
Defined Benefit Private Pension Outlays	-397.4	-906.8	-1,416.2	-50.0	-366.1	-682.3
Life Insurance Outlays	582.7	1,341.7	2,100.6	73.3	543.1	1,102.8
Total	231.8	532.2	832.6	29.2	215.2	401.3

Note: Positive entries in the table represent transfers of value from individuals dissuaded from smoking to the general public. Negative entries represent transfers in the opposite direction.

H. International Effects

Of the $87.9 billion worth of tobacco products consumed in the United States in 2009 (Ref. 168), only $156 million consisted of imported cigarettes, with another $897 million imported as tobacco in a less-processed state (Refs. 169 and 170). As in the United States, foreign manufacturers, distributors, and growers of tobacco and tobacco products will lose revenue as a result of the rule, though their loss will be a small fraction of the overall revenue loss. As consumers who would have been smokers purchase other products, there could be a shift in patterns of international trade, depending on where the preferred substitute products are made.

The rule does not apply to cigarettes manufactured for export, whose value totaled $417 million in 2009 (Ref. 169).

I. Regulatory Alternatives

We compare the rule to two hypothetical alternatives: An otherwise identical rule with a 24-month compliance period and an otherwise identical rule with a 6-month compliance period. Even though we estimate costs and benefits for these alternatives, they do not provide viable regulatory options, as they are inconsistent with FDA's statutory mandate. We also describe alternatives associated with different graphical warnings.

1. 24-Month Compliance Period

Extension of the compliance period to 24 months reduces the one-time costs of this rule through three avenues: The number of UPCs that can be coordinated with a previously scheduled labeling change is increased, rush charges for the label design and market testing costs are eliminated, and discarded inventory costs are eliminated.

Table 24 of this document shows that extending the compliance period to 24 months would reduce the upfront label change cost by $30 to $53 million, to a total of $242 to $411 million. Table 25 of this document shows that market testing costs would be reduced by $0.3 to $1.8 million to a total of $1.2 to $6.4 million.[19] Extending the compliance period to 24 months would also delay all costs by about 9 months. We account for this by discounting the present value of costs an extra 9 months in the summary of alternatives table at the end of this section.

[19] The increase in the proportion of UPCs that can be coordinated is also expected to affect the number of brands that are market tested.

Table 24.--Cost of a Major Cigarette Label Change With Nine Warning Labels (24-Month)

	Low Cost	Medium Cost	High Cost
Label Design Costs[a]			
Number of uncoordinated UPCs	3,395	3,395	3,395
Labor cost ($)	3,770	5,800	9,900
Materials cost ($)	*54,360*	*57,240*	*89,460*
Recordkeeping cost ($)	50	80	90
Per-UPC cost ($)	58,180	63,120	99,450
Label Design Costs for Uncoordinated UPCs ($)	197,521,100	214,292,400	337,632,750
Number of coordinated UPCs	917	917	917
Labor cost ($)	310	550	790
Materials cost ($)	*48,320*	*50,880*	*79,520*
Recordkeeping cost ($)	30	40	50
Per-UPC cost ($)	48,660	51,470	80,360
Label Design costs for Uncoordinated UPCs ($)	44,621,220	47,197,990	73,690,120
Total Label Design Costs ($)	242,142,320	261,490,390	411,322,870
Total Cost ($)	242,142,320	261,490,390	411,322,870
Change from 15-month Compliance Period	-30,382,637	-33,682,348	-53,464,490

[a] Undiscounted amount assumed to be incurred in the first period of the time horizon of this rule.

Table 25.--Market Testing Cost With a 24-Month Compliance Period

Market Testing Cost[a]	Low Cost	Medium Cost	High Cost
Number of brands to be tested	59	59	59
Cost of focus group testing ($)	7,300	10,000	12,700
Cost of quantitative studies ($)	12,500	18,000	95,600
Market testing cost per brand ($)	19,800	28,000	108,300
Total Market Testing Cost ($)	1,168,200	1,652,000	6,389,700
Change from 15-month Compliance Period	-334,620	-473,200	-1,830,270

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Extending the compliance period to 24 months would delay the accrual of health and fire reduction benefits by 9 months. An approximation of the effect of this delay may be found by discounting, at 3- and 7-percent discount rates, the previously calculated total benefits. As shown in table 26 of this document, FDA finds that a 24-month compliance period would decrease the present value of benefits by between $65.4 and $294.6 million.

Table 26.--Present Value of Benefits with 24-Month Compliance Period ($ million)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Life-Years	3,456.7	665.6	6,768.4	1,333.4	10,079.1	1,972.4
Health Status	726.5	229.6	1,422.6	460.1	2,118.4	680.5
Medical Expenditure Reduction	407.0	229.2	402.6	229.4	401.1	227.8
Other Financial Effects	398.2	155.2	400.8	155.1	401.7	155.8
Fire Loss	103.7	32.4	180.2	52.6	256.8	72.7
TOTAL	5,092.2	1,312.0	9,174.7	2,230.5	13,257.1	3,109.2
Change from 15-Month Compliance Period	-114.2	-68.3	-205.7	-116.1	-297.2	-161.8

2. 6-Month Compliance Period

With a 6-month compliance period, the labeling cost model assumes that there is not enough time for any of the labeling changes to be coordinated with previously scheduled changes. Also, FDA accepts the labeling model's assumption of 40 percent rush charges, rather than assuming 10-percent rush charges as we did with a 15-month compliance period. The labeling model further assumes that 12 months is the shortest compliance period that can be met without resorting to covering up the old labels with stickers as a temporary solution. Therefore, with a 6-month compliance period, the cost of discarded inventory is the same as under a 12-month compliance period, but there is an additional cost for applying appropriate stickers to cover the old package label design.

The model, based on current sales data, estimates the number of units sold annually to be about 8 billion. Therefore, 4 billion units would be relabeled with stickers. The per-unit cost for the sticker and application is between $0.045 and $0.323. Reducing the compliance period to 6 months would then increase label change costs by $258 to $1,430 million to a total of $531 to $1,895 million. It would also increase the market testing costs by $0.6 to $3 million to a total of $2 to $11 million. Finally, shortening the compliance period to 6 months would move all costs up by about 9 months. We account for this by compounding the present value of costs 9 months in the summary of alternatives table at the end of this section.

Table 27.--Cost of a Major Cigarette Label Change With Nine Warning Labels (6-Month)

	Low Cost	Medium Cost	High Cost
Per-UPC Costs[a]			
Number of uncoordinated UPCs	4,312	4,312	4,312
Labor cost ($)	5,278	8,120	13,860
Materials cost ($)	*76,104*	*80,136*	*125,244*
Recordkeeping cost ($)	70	112	126
Per-UPC cost ($)	81,452	88,368	139,230
Per-UPC costs for Uncoordinated UPCs ($)	351,221,024	381,042,816	600,359,760
Total Per-UPC Costs ($)	351,221,024	381,042,816	600,359,760
Per-Unit Costs			
Number of discarded labels	1,087,966	1,087,966	1,087,966
Unit cost per discarded label ($)	0.035	0.042	0.049
Discarded Inventory Cost	38,079	45,695	53,310
Sticker and application costs per unit ($)	0.0448	0.115	0.3234
Number of units sold in 6 months	4,002,097,332	4,002,097,332	4,002,097,332
Sticker cost ($)	179,293,960	459,440,774	1,294,278,277
Total Per-Unit Costs	179,332,039	459,486,468	1,294,331,588
Total Cost ($)	530,553,063	840,529,284	1,894,691,348
Change from 15-month Compliance Period	258,028,106	545,356,547	1,429,903,987

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Table 28.--Market Testing Cost With a 6-Month Compliance Period

Market Testing Cost[a]	Low Cost	Medium Cost	High Cost
Number of brands to be tested	75	75	75
Cost of focus group testing ($)	10,220	14,000	17,780
Cost of quantitative studies ($)	17,500	25,200	133,840
Market testing cost per brand ($)	27,720	39,200	151,620
Total Market Testing Cost ($)	2,079,000	2,940,000	11,371,500
Change from 15-month Compliance Period	576,180	814,800	3,151,530

[a] Undiscounted value of costs assumed to be incurred in the first period of the time horizon of this rule.

Reducing the compliance period to 6 months would hasten the accrual of health and fire reduction benefits by 9 months. An approximation of the effect of this change in timing may be found by compounding, at 3- and 7-percent discount rates, the previously calculated total benefits. As shown in table 29 of this document, FDA finds that a 6-month compliance period would increase benefits by between $68.8 and $301.2 million.

Table 29.--Present Value of Benefits With 6-Month Compliance Period ($ million)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Life-Years	3,613.4	736.7	7,075.3	1,475.8	10,536.1	2,183.1
Health Status	759.5	254.2	1,487.1	509.2	2,214.5	753.2
Medical Expenditure Reduction	425.5	253.7	420.9	253.9	419.3	252.1
Other Financial Effects	416.3	171.8	419.0	171.7	419.9	172.5
Fire Loss	108.4	35.9	188.4	58.2	268.4	80.5
TOTAL	5,323.1	1,452.2	9,590.6	2,468.8	13,858.1	3,441.3
Change from 15-Month Compliance Period	116.7	71.9	210.3	122.2	303.8	170.3

3. Alternative Graphic Images

A legally available alternative to this rule would be to select a different set of graphic images. Although we are unable to quantify the effects of different graphic images, we note that some images may have a larger impact on smoking rates than other images.

Another alternative suggested would be to use more than nine graphic images to accompany the nine statutory warnings. We cannot assess the effect of additional images on the benefits of the rule but more images would increase costs. Although not all costs rise in proportion to the number of graphic images, the materials cost, which is the largest cost component, would rise in proportion to the number of images.

4. Summary of Regulatory Alternatives

Table 30 of this document summarizes the regulatory alternatives related to the compliance period by displaying ranges for the present values of the total benefits and total costs. Estimated ranges for the cost ratios (per smoking prevention and per life-year saved) of the rule and its regulatory alternatives appear in table 31 of this document.

Table 30.--Summary of Regulatory Alternatives

Compliance Period		Present Value of Total Benefits ($ million)[a]		Present Value of Total Costs($ million)[b]	
		3%	7%	3%	7%
24-Month	Total	5,092.2 to 13,257.1	1,312.0 to 3,109.2	369.2 to 541.6	322.1 to 481.7
(Final Rule) 15-Month	*Total*	*5,206.4 to 13,554.3*	*1,380.3 to 3,271.0*	*407.3 to 607.4*	*367.6 to 558.4*
6-Month	Total	5,323.1 to 13,858.1	1,452.2 to 3,441.3	673.1 to 2,043.5	641.0 to 1,996.5

[a] Range in benefits is based on a VSLY of $106,308 to $318,923.

[b] Range in costs is based on low cost and high cost values.

Table 31.--Incremental Cost-Effectiveness (CE) of Regulatory Alternatives

	Discount Rate = 3 percent				Discount Rate = 7 percent			
	Low	Incremental CE*	High	Incremental CE*	Low	Incremental CE*	High	Incremental CE*
24-Month Compliance:								
Per Smoking Prevention	$17,677	N/A	$59,068	N/A	$4,476	N/A	$15,413	N/A
Per QALY Saved	$50,401	N/A	$168,419	N/A	$50,369	N/A	$173,452	N/A
15-Month Compliance:								
Per Smoking Prevention	$17,798	$23,203	$59,287	$69,016	$4,530	$5,559	$15,292	$12,953
Per QALY Saved	$50,746	$66,157	$169,040	$196,782	$50,972	$62,557	$172,082	$145,766
6-Month Compliance:								
Per Smoking Prevention	$18,818	$64,322	$64,939	$317,100	$5,607	$26,299	$21,354	$137,819
Per QALY Saved	$53,655	$183,398	$185,157	$904,129	$63,094	$295,952	$240,304	$1,550,925

* As the compliance period decreases, the number of rule-induced smoking preventions and life-years saved increases. Hence, the incremental costs of 15-Month Compliance are calculated relative to 24-Month Compliance, and the incremental costs of 6-Month Compliance are calculated relative to 15-Month Compliance.

J. Impact on Small Entities

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a final rule will have a significant effect on a substantial number of small entities. We expect this rule to have a significant effect on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The final rule will affect small entities in several industries, from tobacco farming to the retail industry. Most of the Nation's 16,234 tobacco farms are small; between 90.7 and 95.8 percent (between 14,732 and 15,555) of the farms growing tobacco in 2007 had total farm sales under the U.S. Small Business Administration (SBA) small business size standard of $750,000 (Refs. 161 and 171).

Table 32 of this document shows the breakdown of domestic cigarette manufacturers by employment size. Census data indicate that most cigarette manufacturing firms are small businesses, with only 4 of 24 firms employing more than 500 employees, while the small business size standard established by the SBA for this industry is 1,000 employees, so 20 small cigarette manufacturers will be affected (Refs. 148 and 171).

Table 32.--Cigarette Manufacturers by Number of Employees

Size by Number of Employees	Number of Firms
Less than 20	9
20 to 99	7
100 to 499	4

Source: Ref. 171
SBA size standard: 1,000 employees

Statistics of U.S. Businesses data show that 1,067 of 1,159 tobacco wholesale trade firms (92 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA (Refs. 148 and 171). If the size distribution of cigarette importers is similar to that of all tobacco wholesale trade firms, then 92 percent of them will be affected small businesses.

Also likely to be affected by the regulation are small retail and service entities that sell cigarettes. Retail establishments bear shared responsibility with manufacturers for the cost of removing noncompliant advertising. SBA size standards for the retail trade and the accommodations and food services industries differ from size categories used by the U.S. Census. Table 33 of this document shows the 2002 Census size categories that most closely match the SBA size standards. In all cases, the closest Census size category is smaller than the SBA size standard. As a consequence, any estimate based on the Census size categories may underestimate the number of affected small entities.

Table 33.--SBA Size Standards and Census Size Categories for Retail and Service Firms in NAICS Categories With Tobacco Product Line Sales[a]

NAICS with Tobacco Product Line Sales	Description of NAICS Category	SBA Size Standard ($ million)	Census Size Category ($ million)
General Merchandise			
452990	Other General Merchandise	11	10
452 excluding 452990	Department , Discount Department, Warehouse Clubs and Superstores	27	25
Supermarket and Grocery			
4452 and 4453	Other Food and Beverage Stores	7	5
445110	Supermarkets and Grocery	27	25
445120	Convenience Stores	27	25
447110	Convenience Stores with Gas	27	25
447190	Service Stations	9	5
446	Health and Personal Care Stores	7	5
453991	Specialty Tobacco Stores	7	5
[b]	Other Kinds of Business	Varies	Varies

Source: Refs. 171 through 173.
[a] Includes only firms with payroll.
[b] Includes NAICS 4413, 443112, 444, 448, 451, 4532, 453998, 72 (excluding 72231), 722310.

The Census reports establishment numbers for business by product line, and establishment and firm size by type of business, but provides no size data by type of business and product line. To estimate the number of affected entities that SBA classifies as small, we begin by counting the number of firms that fall below the Census size standard shown in table 33 of this document, including only firms in NAICS categories with tobacco product line sales. Next, we calculate the percentage of small firms in each NAICS category. Depending on the category of business, the percentage of small firms ranges from 41 percent for Discount Department, Warehouse Clubs and Superstores to almost 100 percent for Convenience Stores.

Table 34.--Estimated Percentage of Small Retail and Service Firms in NAICS Categories With Tobacco Product Line Sales[a]

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard[b]	Percentage of Small Firms (%)
General Merchandise				
452110 452910	Discount Department, Warehouse Clubs and Superstores	88	36	40.9
452990	Other General Merchandise	7,451	7,320	98.2
General Merchandise Subtotal		7,539	7,356	97.6
Supermarket & Grocery				
445110	Supermarkets & Grocery	34,017	33,328	98.0
4452 and 4453	Other Food and Beverage Stores	34,807	34,082	97.9
Supermarket & Grocery Subtotal		68,824	67,410	97.9
445120	Convenience Stores	18,705	18,676	99.8
447110	Convenience Stores with Gas	37,437	36,848	98.4
447190	Service Stations	19,822	18,103	91.3
4461	Drug Stores	36,198	33,894	93.6
453991	Tobacco Stores	3,238	3,017	93.2
	Other Kinds of Business	589,400	572,619	97.2

Source: Refs. 172, 173, 149, and 150.

[a] Includes only firms with payroll.

[b] Based on the Census size standards shown in table 33 of this document.

Finally, we apply the percentages in table 34 of this document to our current estimate of the number of affected establishments with payroll (table 16 of this document). This approach implicitly assumes that small establishments are similar whether or not they sell tobacco products. In addition, we classify all nonemployer establishments as small. In total, we estimate that about 355,000 small retail and service establishments will be affected by the rule. This number represents about 98 percent of the estimated 361,000 establishments selling tobacco products.

Table 35.--Estimated Number of Small Establishments With Tobacco Product Line Sales by Kind of Business

Kind of Business	Percentage of Small[a] (%)	Number with Payroll[b]	Small with Payroll	Non-employers[b]	Estimated Total Number of Small Establishments
General Merchandise	97.6	8,147	7,949	5,661	13,611
Supermarket & Grocery	98.0	67,037	65,679	56,761	122,441
Convenience Stores	99.8	23,986	23,949	0	23,949
Convenience Stores with Gas	98.4	87,713	86,333	0	86,333
Service Stations	91.3	6,347	5,797	2,979	8,775
Drug Stores	93.6	19,413	18,178	30,138	48,316
Specialty Tobacco Stores	93.2	6,458	6,017	0	6,017
Other Establishments	97.2	28,531	27,719	17,391	45,110
Total		247,633	241,621	112,931	354,552

[a] From table 34 of this document.

[b] From table 16 of this document.

2. Description of the Potential Impacts of the Final Rule on Small Entities

a. *Effect on manufacturers.* In order to estimate how much of the label change and rotation costs will be incurred by small domestic cigarette manufacturers, FDA subtracts from the total costs those costs estimated to be incurred by large domestic manufacturers and foreign manufacturers. Scanner data from AC Nielsen indicate that approximately 49 percent of UPCs can be readily identified as belonging to a brand marketed by one of the four largest cigarette firms by volume (Refs. 153 through 158). Because the costs of label changes are roughly proportional to the number of UPCs, FDA then attributes 49 percent of the total label design and inventory costs to the four firms employing at least 500 people. FDA attributes an additional 3 percent of the label change costs to foreign manufacturers.[20] These adjustments leave 48 percent of costs, or $131 to $223 million in upfront costs and $180,000 to $420,000 in ongoing costs, to be incurred by the 20 small manufacturers. Assuming costs are distributed equally among these firms implies one-time costs of $6.5 to $11.2 million and ongoing costs of $9,000 to $21,000 per firm. Table 36 of this document compares these estimated compliance costs to average annual receipts in order to gauge the potential impact of labeling change requirements on small cigarette manufacturing firms. Because the number of UPCs is probably larger for larger firms, costs are likely greater for larger firms than for smaller firms; if so, this method overstates the impact on the smallest firms and understates the impact on the largest firms (within the category of firms employing fewer than 500 people).

Table 36.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a % of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	6,541,000	11,155,000	58%	100%
20 to 99	7	21,265,000	6,541,000	11,155,000	31%	52%
100 to 499	4	147,896,000	6,541,000	11,155,000	4%	8%
Panel 2: Ongoing Rotation Costs						
Less than 20	9	11,195,000	9,000	21,000	0.1%	0.2%
20 to 99	7	21,265,000	9,000	21,000	0.0%	0.1%
100 to 499	4	147,896,000	9,000	21,000	0.0%	0.0%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

b. *Effect on retailers.* As shown in table 37 of this document, retail trade businesses account for almost all sales of tobacco products (Refs. 149 and 150). About 90 percent of tobacco product line sales occur at gasoline stations, food and beverage stores, general merchandise stores, or tobacco stores. Convenience stores (with gasoline stations and stand-alone convenience stores) account for about half of all tobacco product line sales.

[20] In 2008, 9.9 billion out of 345.3 billion individual cigarettes sold were imported (Ref. 123). FDA assumes the same proportion holds for UPCs. These UPCs should not overlap with those produced by the four largest domestic producers.

Table 37.--Sales of Tobacco Product Line by Kind of Business and Industry Sector[a]

Kind of Business and Industry Sector	Sales of Tobacco Product Line by Kind of Business		Sales of Tobacco Product Line by Industry Sector	
	($ billion)	(%)	($ billion)	(%)
Retail Trade				
NAICS 447-Gasoline Stations			22.2	43.3
Convenience Stores with Gas	21.2	41.3		
Gasoline Stations	1.0	2.0		
NAICS 445-Food and Beverage Stores			13.4	26.2
Supermarket & Grocery	7.7	15.0		
Convenience Stores	4.5	8.8		
Liquor Stores	1.2	2.4		
NAICS 452-General Merchandise			7.1	13.9
General Merchandise	7.1	13.9		
NAICS 453-Miscellaneous Store Retailers			5.8	11.3
Tobacco Stores	5.7	11.1		
Miscellaneous store retailers	0.1	0.3		
NAICS 446-Health and Personal Care Stores			1.5	3.0
Drug Stores	1.5	3.0		
NAICS 454-Nonstore Retailers			0.7	1.3
Nonstore Retailers	0.5	1.0		
Vending machine operators	0.2	0.4		
Other Subsectors [b]			0.1	0.2
Other Kinds of Business	0.1	0.2		
Accommodation & Food Services				
NAICS 72			0.4	0.8
Other establishments	0.3	0.5		
Drinking places	0.1	0.3		
Total			51.2	100

[a] Includes establishments with payroll with tobacco product line sales.

[b] Includes establishments in NAICS 441320, 443112, 444130, 444220, 448110, 448320, 451110, 451211, 451212, and 451220.

To illustrate the effects of the rule on a typical small retail store, we look at one-time costs for a convenience store and a convenience store with gasoline. We select these businesses because, as illustrated in table 37 of this document, sales of tobacco products in these stores account for about 50 percent of all tobacco sales. In addition, tobacco products are an important part of overall revenue for these stores, composing over 12 percent of total sales (as shown in table 38 of this document).

Table 38.--The Importance of Tobacco Sales by Kind of Business: Ranked by the Percentage of Total Sales From Tobacco Product Line

Kind of Business	Sales From Tobacco Product Line[a] ($ billion)	Total Sales From All Product Lines ($ billion)[b]	Percentage of Total Sales From Tobacco Product Line (%)
Tobacco Stores	5.7	6.5	86.9
Convenience Stores	4.5	18.1	25.0
Nonstore Retailers	0.5	2.4	20.3
Convenience Stores with Gas	21.2	173.4	12.2
Vending Machine Operators	0.2	1.7	11.2
Miscellaneous store retailers	0.1	1.2	11.2
Liquor Stores	1.2	12.8	9.7
Other Kinds of Business	0.1	1.4	6.5
Drinking places	0.1	3.9	3.5
Gasoline Stations	1.0	29.4	3.5
General Merchandise	7.1	246.1	2.9
Supermarket & Grocery	7.7	383.5	2.0
Drug Stores	1.5	80.0	1.9
Other Accommodation & Foodservice	0.3	33.3	0.8
Total	51.2	993.9	5.2

[a] Tobacco sales from table 37 of this document.

[b] Includes total sales for firms with tobacco product line sales (Refs. 149 and 150).

For both types of convenience stores, table 39 of this document shows that for the smallest firms with less than $250,000 in annual sales, the one-time costs of the rule will equal less than 2 percent of annual average sales of tobacco products. Furthermore, one-time costs total less than 0.1 percent of annual average sales of tobacco products for stores with $1 million or more in average annual sales. Although the impact on other small retail and service entities is uncertain, this example suggests that the rule will be unlikely to create a significant direct burden on small retail stores or service establishments.

If individual small retailers are unable to fully offset reduced cigarette sales with increased sales of other items, their sales revenue may fall. Although this decline would not be a social cost (as discussed in the distributional effects section) it would be a cost to the retailers who experience it. FDA has not quantified this additional potential effect, but believes that it is minor because the overall reduction in cigarette consumption is predicted to be less than one half of a percent, the demand for other goods is expected to increase, and retailers can be expected to shift shelf space to the other goods for which demand increases.

Table 39.--One-Time Costs as a Percentage of Average Sales of Tobacco Products for Convenience Stores and Convenience Stores With Gasoline

Sales Size of Firm	Number of Establishments	Sales	Sales of Tobacco Products	
			Average	One-time Costs as Percentage of Average
		($ million)	($ million)	(%)
Convenience Store-NAICS 445120[a]				
Less than $250,000	4,231	653	0.0	0.5
$250,000 to $499,999	5,296	1,920	0.1	0.2
$500,000 to $999,999	5,150	3,646	0.2	0.1
$1,000,000 to $2,499,999	3,586	4,915	0.3	0.1
$2,500,000 to $4,999,999	659	1,601	0.6	0.0
5,000,000 to 9,999,999	324	712	0.5	0.0
10,000,000 to 24,999,999	215	440	0.5	0.0
Convenience Stores with Gasoline- NAICS 447110[b]				
Less than $250,000	2,246	343	0.0	1.0
$250,000 to $499,999	3,801	1,425	0.0	0.4
$500,000 to $999,999	7,667	5,624	0.1	0.2
$1,000,000 to $2,499,999	14,309	22,303	0.2	0.1
$2,500,000 to $4,999,999	7,977	22,786	0.3	0.1

Source: Ref. 167.

[a] Tobacco product line sales account for 25.0 percent of sales for all firms in NAICS 445120 (see table 38 of this document); One-time costs equal $198.16 (see table 17 of this document).

[b] Tobacco product line sales account for 12.2 percent of sales for all firms in NAICS 447110 (see table 38); One-time costs equal $193.42 (see table 17).

3. Alternatives To Minimize the Burden on Small Entities

a. *Increase the compliance period to 24 months for small manufacturers or all manufacturers.* Allowing all manufacturers, or only small manufacturers, 24 months to comply with the label changes would eliminate overtime and rush charges, eliminate costs for replacing discarded inventory, and increase the number of UPCs for which the addition of graphic warning labels could be coordinated with previously scheduled label changes. Under a 24-month compliance period, the one-time label change costs would fall by an average of $0.7 to $1.3 million per small firm. Table 40 of this document compares the reduced estimated compliance costs to average annual receipts in order to gauge the potential impact of this regulatory alternative on cigarette manufacturing firms employing fewer than 500 people. As a comparison with table 36 of this document shows, this option would provide some relief, but the burden would remain significant. It would also delay the public health benefits of the rule and be inconsistent with FDA's statutory mandate.

Table 40.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers With a 24-Month Compliance Period

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a % of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	5,811,000	9,872,000	52%	88%
20 to 99	7	21,265,000	5,811,000	9,872,000	27%	46%
100 to 499	4	147,896,000	5,811,000	9,872,000	4%	7%
Panel 2: Ongoing Rotation Costs						
Less than 20	9	11,195,000	9,000	21,000	0.1%	0.2%
20 to 99	7	21,265,000	9,000	21,000	0.0%	0.1%
100 to 499	4	147,896,000	9,000	21,000	0.0%	0.0%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

b. *Allow small manufacturers to use one warning per UPC.* Allowing small cigarette manufacturers to use only one randomly selected warning and graphic image per UPC would reduce their upfront label change cost substantially. The costs to small businesses of implementing this option can be approximated by assuming that the 20

smallest firms bear 48 percent of the cost of a standard (one warning) cigarette label change. The average cost per small manufacturer would be reduced by $5.5 to $9 million per firm. Additionally, there would be some small cost at the beginning to ensure random selection of the warnings, but the ongoing annual rotation cost of $9,000 to $21,000 per firm would be eliminated. Table 41 of this document compares the reduced estimated compliance costs to average annual receipts in order to gauge the potential impact of this regulatory alternative on cigarette manufacturing firms employing fewer than 500 people. As a comparison with table 36 of this document shows, this alternative would provide significant relief. However, it is inconsistent with FDA's statutory mandate. Smokers who use only one specific product would not be exposed to all the warnings, which would likely hinder the effectiveness of this rule.

Table 41.--Potential Impact of Compliance Costs on the 20 Small Cigarette Manufacturers With One Label per UPC

Size by Number of Employees	Number of Firms	Average Annual Receipts ($)	Average Compliance Costs ($)		Average Compliance Costs as a Percentage of Average Annual Receipts	
			Lower Bound	Upper Bound	Lower Bound	Upper Bound
Panel 1: Upfront Label Change Costs						
Less than 20	9	11,195,000	1,039,000	2,100,000	9%	19%
20 to 99	7	21,265,000	1,039,000	2,100,000	5%	10%
100 to 499	4	147,896,000	1,039,000	2,100,000	1%	1%

Source: Statistics of U.S. Businesses, 2007 (Ref. 148)
SBA size standard: 1,000 employees

c. *Exempt small manufacturers from the labeling change requirements.* Exempting small manufacturers from the label change requirements would eliminate their label change costs and ongoing rotation costs (an average reduction of $6.5 to $11.2 million in upfront costs and $9,000 to $21,000 in ongoing costs), thus providing maximum relief. The combined market share of the four largest manufacturers was 89.7 percent in 2008 (Ref. 123). The immediate impact of exempting small manufacturers would therefore be to allow 10.3 percent of cigarettes to be marketed without graphic warning labels. This proportion would grow over time, however, as some consumers would be expected to switch to brands marketed without graphic warnings. This approach would be inconsistent with both FDA's statutory mandate and the public health objectives of this rule.

d. *Exempt small cigarette retailers from the point-of-sale advertising requirements.* Exempting small cigarette retailers from the point-of-sale advertising requirements would eliminate their need to remove noncompliant advertising, reducing their direct costs to zero. However, table 35 of this document shows that the overwhelming majority of retail establishments selling cigarettes are small. Although the few establishments operated by large firms might be expected to have higher volume, a significant proportion of consumers would continue to be exposed to advertising lacking the new graphic warnings. This situation would be inconsistent with the public health objective of the rule as well as FDA's statutory mandate.

XII. Paperwork Reduction Act of 1995

The required warning disclosures are the ''public disclosure of information originally supplied by the Federal government to the recipient for th[at] purpose,'' and are, therefore, not within the scope of the Paperwork Reduction Act (*see* 5 CFR 1320.3(c)(2)).

XIII. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. (FDA has verified Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. Centers for Disease Control and Prevention, ''Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004,'' *Morbidity and Mortality Weekly Report,* 57(45); 1226–1228, Nov. 14, 2008, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.*
2. U.S. Department of Health and Human Services, ''The Health Consequences of Smoking,'' A Report of the Surgeon General; 2004, available at *http://www.surgeongeneral.gov/library/smokingconsequences/index.html.*
3. Institute of Medicine of the National Academies, ''Ending the Tobacco Problem: A Blueprint for the Nation,'' 2007, available at *http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A–Blueprint-for-the-Nation.aspx.*
4. Centers for Disease Control and Prevention, ''Vital Signs: Current Cigarette Smoking Among Adults Aged > 18 Years—United States, 2009,'' *Morbidity and Mortality Weekly Report,* 59(35), 1135–40, Sept. 10, 2010, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5935a3.htm.*
5. Centers for Disease Control and Prevention, ''Youth Risk Behavior Surveillance—United States, 2009,'' *Morbidity and Mortality Weekly Report 2010,* 59 (No. SS–5); June 4, 2010, available at *http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf.*
6. Centers for Disease Control and Prevention, ''Tobacco Use Among Middle and High School Students—United States, 2000–2009,'' *Morbidity and Mortality Weekly Report,* 59(33); 1063–68, Aug. 27, 2010, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a2.htm.*
7. Substance Abuse and Mental Health Services Administration, ''Results from the 2008 National Survey on Drug Use and Health: National Findings,'' Rockville, MD: 2009, available at *http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf.*
8. Taioli, E., and Wynder, E.L., ''Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood,'' *The New England Journal of Medicine,* 325(13); 968–69, 1991.
9. Chen, J., and Millar, W, ''Age of smoking initiation: implications for quitting,'' *Health Reports* (Statistics Canada, Catalogue 82–003–XPB), 9(4); 39–46, 1998.
10. Breslau, N., and Peterson, E., ''Smoking Cessation in Young Adults: Age at Initiation of Cigarette Smoking and Other

Suspected Influences,'' *American Journal of Public Health,* 86(2); 214–20, 1996.
11. Hammond, D., ''Tobacco Labelling & Packaging Toolkit: A guide to FCTC Article 11,'' Feb. 2009, available at *http://www.tobaccolabels.ca/download/tobaccolab/iuatldtook?attachment=1.*
12. Max, W., *et al.,* ''The Disproportionate Cost of Smoking for African Americans in California,'' *American Journal of Public Health,* 100(1); 152–58, 2010.
13. Lee, J.G.L., Griffin, G.K., and Melvin, C.L., ''Tobacco use among sexual minorities in the USA, 1987 to May 2007: A systematic review,'' *Tobacco Control,* 18; 275–82, 2009.
14. Helyer, A.J., *et al.,* ''Economic Consequences of Tobacco Use for the Department of Defense, 1995'' *Military Medicine,* 163(4); 217–21, 1998.
15. Bray, R.M., *et al.,* ''Substance Use and Mental Health Trends Among U.S. Military Active Duty Personnel: Key Findings From the 2008 DoD Health Behavior Survey,'' *Military Medicine,* 175(6); 390–99, 2010.
16. U.S. Department of Health and Human Services, ''The Health Consequences of Smoking: Nicotine Addiction,'' A Report of the Surgeon General; 1988, available at *http://www.surgeongeneral.gov/library/reports/.*
17. U.S. Department of Health and Human Services, ''The Health Consequences of Involuntary Exposure to Tobacco Smoke,'' A Report of the Surgeon General; 2006, available at *http://www.surgeongeneral.gov/library/secondhandsmoke/report/fullreport.pdf.*
18. U.S. Department of Health and Human Services, ''Youth & Tobacco; Preventing Tobacco Use Among Young People,'' A Report of the Surgeon General; 1994, available at *http://www.surgeongeneral.gov/library/reports/.*
19. Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths,* Washington, DC: National Academy Press (1994).
20. Hammond, D., *et al.,* ''Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study,'' *American Journal of Preventive Medicine,* 32(3); 202–209, 2007.
21. Strecher, V.J., *et al.,* ''Do Cigarette Smokers Have Unrealistic Perceptions of Their Heart Attack, Cancer, and Stroke Risks?,'' *Journal of Behavioral Medicine,* 18; 45–54, 1995.
22. Slovic, P., ''Do Adolescent Smokers Know the Risks?,'' *Duke Law Journal,* 47; 1133–41, 1998.
23. Survey of 900 adult smokers in the U.S. conducted by American Legacy Foundation and GlaxoSmithKline Consumer Healthcare, August 2007. *http://www.americanlegacy.org/304.aspx.*
24. Finney Rutten, L.J., *et al.,* ''Smoking knowledge and behavior in the United States: Sociodemographic, smoking status, and geographic patterns,'' *Nicotine & Tobacco Research,* 10 (10); 1559–70, 2008.
25. Ayanian, J.Z., and Cleary, P.D., ''Perceived risks of heart disease and cancer among cigarette smokers,'' *Journal of the American Medical Association,* 281(11); 1019–21, 1999.
26. Hammond, D., Fong, G.T. and McNeill, A., *et al.,* ''Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: Findings from the International Tobacco Control (ITC) Four Country Survey,'' *Tobacco Control,* 15(III); iii19–iii25, 2006, available at *http://tc.bmjjournals.com/cgi/content/full/15/suppl_3/iii19.*
27. Oncken, C., *et al.,* ''Knowledge and perceived risk of smoking-related conditions: A survey of cigarette smokers,'' *Preventive Medicine,* 40(6); 779–84, 2005.
28. Weinstein ND, *et al.,* ''Public understanding of the illnesses caused by cigarette smoking,'' *Nicotine & Tobacco Research,* 6(2); 349–55, April 2004.
29. Cummings, K.M., *et al.* ''Are smokers adequately informed about the health risks of smoking and medicinal nicotine?,'' *Nicotine & Tobacco Research,* 6 (Supp. 3); S333–40, December 2004.
30. Johnston, LD, *et al.,* National survey results on drug use from the Monitoring the Future study, 1975–1997, Volume I: Secondary school students, National Institute on Drug Abuse, Rockville, MD, NIH Publication No. 98–4345, 1998.
31. Romer, D., Jamieson, P, ''The role of perceived risk in starting and stopping smoking,'' in Slovic, P. (Ed.), *Smoking: Risk, Perception and Public Policy,* Thousand Oaks, CA: Sage Publications, Inc. (2001).
32. Davis, T.C., *et al.,* ''Low literacy impairs comprehension of prescription drug warning labels,'' *Journal of General Internal Medicine,* 21(8); 847–51, 2006.
33. Wolf, M.S., *et al.,* ''Misunderstanding of prescription drug warning labels among patients with low literacy,'' *American Journal Health-System Pharmacy,* 63(11); 1048–55, 2006.
34. Haddock, C.K., *et al.,* ''Modified tobacco use and lifestyle change in risk-reducing beliefs about smoking,'' *American Journal of Preventive Medicine,* 27(1); 35–41, 2004.
35. Jamieson, P.E., *et al.,* ''Sure smoking causes cancer but it won't happen to me.'' Robert Wood Johnson Foundation, July 2001, available at *http://www.rwjf.org/reports/grr/037045.htm.*
36. Weinstein, N.D., ''Accuracy of smoker's risk perception,'' *Nicotine & Tobacco Research,* 1(Supp. 1); S123–S130, 1999.
37. U.S. Department of Health and Human Services, ''How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease,'' A Report of the Surgeon General; 2010, available at *http://www.surgeongeneral.gov/library/tobaccosmoke/report/index.html.*
38. Farber, H.J., *et al.,* ''Secondhand tobacco smoke in children with asthma: Sources of and parental perceptions about exposure in children and parental readiness to change,'' *Chest,* 133(6); 1367–74, 2008.
39. Hyland, A, *et al.,* ''Attitudes and beliefs about secondhand smoke and smoke-free policies in four countries: Findings from the International Tobacco Control Four Country Survey,'' *Nicotine & Tobacco Research,* 11(6); 642–49, 2009.
40. Elliott & Shanahan Research, ''Literature Review: Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008,'' prepared for Department of Health and Ageing, Commonwealth of Australia, 2009.
41. Borland, R., Wilson, N., Fong, G.T., *et al.,* ''Impact of graphic and text warnings on cigarette packs: Findings from four countries over five years,'' *Tobacco Control,* 18(5); 358–64, 2009.
42. European Health Research Partnership and Centre for Tobacco Control Research, ''Research into the Labelling of Tobacco Products in Europe,'' report submitted to the European Commission; Sept. 15, 2001, available at *http://www.ashaust.org.au/pdfs/EuroWarns0306.pdf.*
43. Baxter, L.A. & Babbie, E. 2004. The basics of communication research. Toronto, ON: Thomson Wadsworth.
44. Hammond, D., Fong, G.T., *et al.,* ''Graphic Canadian Cigarette Warning Labels and Adverse Outcomes: Evidence from Canadian Smokers,'' *American Journal of Public Health,* 94(8); 1442–5, 2004.
45. Peters, E., *et al.,* ''The impact and acceptability of Canadian-style cigarette warning labels among U.S. smokers and nonsmokers,'' *Nicotine & Tobacco Research,* 9(4); 473–481, April 2007.
46. Fong, G.T., Hammond, D., and Hitchman, S.C., ''The impact of pictures on the effectiveness of tobacco warnings,'' *Bulletin of the World Health Organization,* 87; 640–43, 2009, available at *http://www.who.int/bulletin/volumes/87/8/09–069575.pdf.*
47. Vardavas, C.I., Connolly, G., *et al.,* ''Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels,'' *European Journal of Public Health,* 19(2); 212–17, 2009.
48. Elliott & Shanahan Research, ''Developmental Research for New Australian Health Warnings on Tobacco Products Stage 2,'' prepared for Population Health Division, Department of Health and Ageing, Commonwealth of Australia, August 2003, available at *http://www.health.gov.au/internet/main/publishing.nsf/Content/4FA9E17EB0A1FB6ECA25776900054914/$File/warnres2.pdf.*
49. Nonnemaker, J., *et al.,* ''Experimental Study of Graphic Cigarette Warning Labels: Final Results Report Prepared for Center for Tobacco Products, Food and Drug Administration,'' Contract No. HHSF–223–2009–10135G, Dec. 2010.
50. RTI International, ''Errata to Experimental Study of Graphic Cigarette Warning Labels,'' Contract No. HHSF–223–2009–10135G, May 2011.
51. Dillard, J.P., Weber, K.M., and Vail, R.G., ''The Relationship Between the

Perceived and Actual Effectiveness of Persuasive Messages: A Meta-Analysis With Implications for Formative Campaign Research,'' *Journal of Communication,* 57; 613–631, 2007.
52. Kees, J., *et al.,* ''Understanding How Graphic Pictorial Warnings Work on Cigarette Packaging,'' *Journal of Public Policy & Marketing,* 29(2); 265–76, 2010.
53. Goodall, C., and Appiah, O., ''Adolescents' Perceptions of Canadian Cigarette Package Warning Labels: Investigating the Effects of Message Framing,'' *Health Communications,* 23; 117–27, 2008.
54. National Cancer Institute, ''The Role of the Media in Promoting and Reducing Tobacco Use,'' NCI Tobacco Control Monograph Series, Monograph 19, NIH Publication No. 07–6242, 2008, available at *http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html.*
55. Strahan E.J., *et al.,* ''Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective,'' *Tobacco Control,* 11(3); 183–90, 2002.
56. ''The international language of ISO graphical symbols,'' 2010, available at *http://www.iso.org/iso/graphical-symbols_booklet.pdf.*
57. Wogalter, M.S., Kalsher, M.J., and Rashid, R., ''Effect of signal word and source attribution on judgments of warning credibility and compliance likelihood,'' *International Journal of Industrial Ergonomics,* 24(2); 185–92, 1999.
58. Shaw, G.M., *et al.,* ''Orofacial Clefts, Parental Cigarette Smoking, and Transforming Growth Factor-Alpha Gene Variants,'' *American Journal of Human Genetics,* 58; 551–61, 1996.
59. Guttman, N. and Peleg, H., ''Public Preferences for an Attribution to Government or to Medical Research Versus Unattributed Messages in Cigarette Warning Labels in Israel,'' *Health Communication,* 15(1); 1–25, 2003.
60. Framework Convention on Tobacco Control, *adopted* May 21, 2003, available at *http://whqlibdoc.who.int/publications/2003/9241591013.pdf.*
61. Hammond D., ''Health warnings on tobacco packages: Summary of evidence and legal challenges,'' January 2008, available at *http://tobaccofreecenter.org/files/pdfs/en/India-study-warningLabels-DHammond-Jan08.pdf.*
62. Wogalter, M.S., Conzola, V.C., and Smith-Jackson, T.L., ''Research-based guidelines for warning design and evaluation,'' *Applied Ergonomics,* 33; 219–30, 2002.
63. Borland, R. and Hill, D., ''Initial impact of the new Australian tobacco health warnings on knowledge and beliefs,'' *Tobacco Control,* 6(4); 317–25, 1997.
64. U.S. Food and Drug Administration, ''Cigarette Required Warnings—PDF Files,'' June 2011.
65. Centers for Disease Control and Prevention, ''Cigarette smoking among adults—United States, 2007,'' *Morbidity and Mortality Weekly Report,* 57(45); 1221–26, 2008.
66. Fiore, M.C., Jaen C.R., Baker T.B., *et al.,* ''Treating Tobacco Use and Dependence: 2008 Update,'' Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, 2008, available at *http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.*
67. Miller, C., Hill, D., and Quester, P., ''Impact on the Australian Quitline of the new graphic cigarette pack warnings including the Quitline number,'' *Tobacco Control,* 18; 235–237, 2009.
68. Wilson, N., Li, J,, Hoek, J. et. al., ''Long-term benefit of increasing the prominence of a quitline number on cigarette packaging: 3 years of Quitline call data,'' *New Zealand Medical Journal,* 123(1321); 109–11, Aug. 2010.
69. Wilson, N., Weerasekera, D., Hoek, J., *et al.,* ''Increased smoker recognition of a national quitline number following introduction of improved pack warnings: ITC Project New Zealand,'' *Nicotine & Tobacco Research,* 12 (Supp.); S72–7, Oct. 2010.
70. UK Department of Health, ''Consultation on the Introduction of Picture Warnings on Tobacco Packs,'' August 2007, available at *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_077962.pdf.*
71. Bot, S., *et al.,* ''Impact of Telephone Numbers on Cigarette Packets on Call Volumes to Quitlines,'' STIVIRO, den Haag, the Netherlands, 2007, available at *http://enqonline.org/presentations/Impact_of_Quitline_Telephone_Numbers_on_Cigarette_Packets_final.pdf.*
72. Willemsen, M.C., Simons, C., and Zeeman, G., ''Impacts of the new EU health warnings on the Dutch quit line,'' *Tobacco Control,* 11; 381–82, 2002.
73. Cavalcante, T.M., ''Labelling and Packaging in Brazil,'' available at *http://www.who.int/tobacco/training/success_stories/en/best_practices_brazil_labelling.pdf.*
74. Showing the truth, saving lives: the case for pictorial health warnings (2009). Washington, DC, PAHO: Pan American Health Organization.
75. Brown J.H., D'Emidio-Caston, M., and Pollard, J.A., ''Students and substances: Social power in drug education,'' *Educational Evaluation and Policy Analysis,* 19; 65–82, 1997.
76. Keller, P.A., and Block, L.G., ''Increasing the persuasiveness of fear appeals: The effect of arousal and elaboration,'' *Journal of Consumer Research,* 22; 448–59, 1996.
77. Moscato, S., *et al.,* ''Evaluating a fear appeal message to reduce alcohol use among 'Greeks','' *American Journal of Health Behavior,* 25(5); 481–91, 2001.
78. Pechmann, C., *et al.,* ''What to convey in antismoking advertisements for adolescents: The use of protection motivation theory to identify effective message themes,'' *Journal of Marketing for Mental Health,* 67; 1–18, 2003.
79. Gore, T.D., and Bracken, C.C., ''Testing the theoretical design of a health risk message: reexamining the major tenets of the extended parallel process model,'' *Health Education & Behavior,* 32(1); 27–41, Feb. 2005.
80. Ruiter, R.A.C., *et al.,* ''Danger and fear control in response to fear appeals: The role of need for cognition,'' *Basic and Applied Social Psychology,* 26; 13–24, 2004.
81. Witte, K., and Allen, M., ''A meta-analysis of fear appeals: implications for effective public health campaigns,'' *Health Education & Behavior,* 27(5); 591–615, Oct. 2000.
82. Ossip-Klein, D., Giovino, G.A., Megahed, N., *et al.,* ''Effects of a Smokers' Hotline: Results of a 10–County Self-Help Trial,'' *Journal of Consulting and Clinical Psychology,* 59(2); 325–32, 1991.
83. Li, J., and Grigg, M., ''New Zealand: New Graphic Warnings Encourage Registrations with the Quitline,'' *Tobacco Control,* 18(1); 72, 2009.
84. Avery, R., *et al.,* ''Private Profits and Public Health: Does Advertising of Smoking Cessation Products Encourage Smokers to Quit?'' *Journal of Political Economy,* 115(3); 447–81, 2007.
85. Farrelly, M.C., *et al.,* ''Getting to the Truth: Evaluating National Tobacco Countermarketing Campaigns,'' *American Journal of Public Health,* 92(6); 901–07, 2002.
86. Wakefield, M., *et al.,* ''Effect of Televised Tobacco Company-Funded Smoking Prevention Advertising on Youth Smoking-Related Beliefs, Intentions, and Behavior,'' *American Journal of Public Health,* 96(12); 2154–60, 2006.
87. Cokkinides, V.E., *et al.,* ''Racial and Ethnic Disparities in Smoking-Cessation Interventions: Analysis of the 2005 National Health Interview Survey,'' *American Journal of Preventive Medicine,* 34(5); 404–12, 2008.
88. Stead, L.F., Perera, R., and Lancaster, T., ''Telephone Counselling for Smoking Cessation (Review),'' *Cochrane Database of Systematic Reviews,* Issue 3, 2009.
89. U.S. Department of Health and Human Services, ''Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan for the U.S. Department of Health and Human Services,'' Nov. 10, 2010, available at *http://www.hhs.gov/ash/initiatives/tobacco/tobaccostrategicplan2010.pdf.*
90. Centers for Disease Control and Prevention, ''Telephone Quitlines: A Resource for Development, Implementation, and Evaluation,'' U.S. Department of Health and Human Services; 2004, available at *http://www.cdc.gov/tobacco/quit_smoking/cessation/quitlines/pdfs/quitlines.pdf.*
91. Universal Service Monitoring Report, CC Docket No. 98–202, Section 6, 2010, available at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC–303886A1.pdf.*
92. NTIA Research Preview, *Digital Nation: Expanding Internet Usage,* U.S. Department of Commerce: National Telecommunications and Information Administration, February 2011, available at *http://www.ntia.doc.gov/reports/2011/NTIA_Internet_Use_Report_February_2011.pdf.*

93. Sheffer, M.A., *et al.,* ''Creating a Perfect Storm to Increase Consumer Demand for Wisconsin's Tobacco Quitline,'' *American Journal of Preventive Medicine,* 38(3S); S343–46, 2010.
94. Lancaster, T., and Stead, L.F., ''Physician advice for smoking cessation,'' *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD000165.
95. Brotherton, S.E., and Etzel, S.I., ''Graduate Medical Education, 2007–2008,'' *Journal of the American Medical Association,* 300(10); 1228–43, 2008.
96. Schnoll, R.A., *et al.,* ''Smoking Cessation Treatment by Primary Care Physicians: An Update and Call for Training,'' *American Journal of Preventive Medicine,* 31(3); 233–39, 2006.
97. Kempf, D.S., and Harmon, S.K., ''Examining the effectiveness of proposed cigarette package warning labels with graphic images among U.S. college students,'' *Academy of Marketing Studies Journal,* 10(2); 77–93, 2006.
98. Centers for Disease Control and Prevention, Office on Smoking and Health Web site, available at *http://www.cdc.gov/tobacco/index.htm.*
99. Hammond, D., Fong, G.T., and McDonald, P.W., *et al.,* ''Impact of the graphic Canadian warning labels on adult smoking behaviour,'' *Tobacco Control,* 12(4); 391–95, 2003.
100. Hammond, D., McDonald, P.W., and Fong, G.T., *et al.,* ''The Impact of Cigarette Warning Labels and Smoke-free Bylaws on Smoking Cessation—Evidence from Former Smokers,'' *Canadian Journal of Public Health/Revue Canadienne de Sante Publique,* 95(3); 201–04, May–June 2004.
101. Thrasher, James F. *et al.* ''Estimating the Impact of Different Cigarette Package Warning Label Policies: The Auction Method,'' *Addictive Behaviors,* 32; 2916–25, 2007.
102. U.S. Census Bureau, ''Language Use and English-Speaking Ability: 2000,'' October 2003, available at *http://www.census.gov/prod/2003pubs/c2kbr-29.pdf.*
103. OMB Circular A–4.
104. Gruber, J. and Köszegi, B., ''Is Addiction 'Rational'? Theory and Evidence,'' *Quarterly Journal of Economics,* 116(4); 1261–1303, November 2001.
105. Bernheim, B. D. and Rangel, A., ''Addiction and Cue-Triggered Decision Processes,'' *American Economic Review* 94(5); 1558–90, December 2004.
106. Schelling, T., ''Egonomics, or the Art of Self-Management,'' *American Economic Review,* 68; 290–94, 1978.
107. Schelling, T., ''The Intimate Contest for Self-Command,'' *The Public Interest,* 60; 94–113, 1980.
108. Schelling, T., ''Self-Command in Practice, Policy and in a Theory of Rational Choice,'' *American Economic Review,* 74; 1–11, 1984.
109. Laux, F.L., ''Addiction as a Market Failure: Using Rational Addiction Results to Justify Tobacco Regulation,'' *Journal of Health Economics,* 19; 421–437, 2000.
110. Gul, F. and Pesendorfer, W., ''Harmful Addiction,'' *Review of Economic Studies,* 74; 147–172, 2007.
111. O'Hegarty, M., Pederson, L.L., *et al.,* ''Young Adults' Perceptions of Cigarette Warning Labels in the United States and Canada,'' *Preventing Chronic Disease,* 4(2); 1–9, 2007.
112. Khwaja, A., Sloan, F. and Chung, S., ''The Relationship between Individual Expectations and Behaviors: Mortality Expectations and Smoking Decisions,'' *Journal of Risk and Uncertainty,* 35; 179–201, September 2007.
113. National Center for Education Statistics, ''National Assessment of Adult Literacy (NAAL),'' available at *http://nces.ed.gov/naal/kf_demographics.asp.*
114. Carr, T., ''State Legislated Actions on Tobacco Issues, 2009,'' New York, NY: American Lung Association, 2009, available at *http://www.lungusa2.org/slati/reports/SLATI_2009_Final_Web.pdf.*
115. Vining, A. and Weimer, D.L., ''An Assessment of Important Issues Concerning the Application of Benefit-Cost Analysis to Social Policy,'' *Journal of Benefit-Cost Analysis,* 1(1); Article 6, 2010, available at *http://www.bepress.com/jbca/vol1/iss1/6.*
116. Sloan F.A., Ostermann, J., Conover, C., *et al., The Price of Smoking,* Cambridge, MA: MIT Press, 2004.
117. Taylor, D.H., Hassenblad, V., Henley, S.J., *et al.,* ''Benefits of Smoking Cessation for Longevity,'' *American Journal of Public Health,* 92(6); 990–996, June 2002.
118. Doll, R., Peto, R., Boreham, J., *et al.,* ''Mortality in Relation to Smoking: 50 Years' Observations on Male British Doctors,'' *British Medical Journal,* 328(7455); 1519 Epub, June 2004.
119. Strandberg, A.Y., Strandberg, T.E., Pitkälä, K., *et al.,* ''The Effect of Smoking in Midlife on Health-Related Quality of Life in Old Age: A 26-Year Prospective Study,'' *Archives of Internal Medicine,* 168(18); 1968–1974, October 13, 2008.
120. Hodgson, T.A. ''Cigarette Smoking and Lifetime Medical Expenditures.'' *The Milbank Quarterly,* 70(1); 81–125, 1992.
121. Warner, K.E. and Mendez, D., ''Tobacco Control Policy in Developed Countries: Yesterday, Today and Tomorrow,'' *Nicotine & Tobacco Research,* 12(9); 876–87, September 2010.
122. Warner, K.E., *et al.,* ''Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States,'' *Journal of the American Medical Association,* 275(16); 1241–6, 1996.
123. Maxwell, J.C., *The Maxwell Report: Year-End and Fourth Quarter 2008 Sales Estimates for the Cigarette Industry,* Richmond, VA: John C. Maxwell, Jr., February 2009.
124. Tobacco Labelling Resource Centre, ''Country Information: Canada,'' available at *http://www.tobaccolabels.ca/currentl/canada.*
125. Eastern Research Group, Inc., ''Baseline of State and International Tobacco Laws,'' June 25, 2010.
126. Health Canada, ''Overview of Historical Data, Wave 1, 1999–2009,'' available at *http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/_ctums-esutc_2009/w-p-1_histo-eng.php.*
127. Health Canada, Tobacco Directorate, ''Long-Term Trends in the Prevalence of Current Smokers,'' Mimeo, May 14, 2009.
128. National Center for Health Statistics (U.S. Department of Health and Human Services), ''National Health Interview Survey: Questionnaires, Datasets and Related Documentation, 1997 to the Present,'' available at *http://www.cdc.gov/nchs/nhis/quest_data_related_1997_forward.htm* (accessed July 23, 2010).
129. National Center for Health Statistics, ''Health, United States, 2005, (Table 63),'' Hyattsville, MD: National Center for Health Statistics, 2005, available at *http://www.cdc.gov/nchs/data/hus/hus05.pdf.*
130. U.S. Census Bureau, Population Division, Interim State Population Projections, 2005, File 4: Interim State Projections of Population by Single Year of Age and Sex: July 1, 2004 to 2030, available at *http://www.census.gov/population/www/projections/projectionsagesex.html.*
131. Warner, K.E., Mendez, D., and Smith D.G., ''The Financial Implications of Coverage of Smoking Cessation Treatment by Managed Care Organizations,'' *Inquiry* 41; 57–69, Spring 2004.
132. U.S. Department of Commerce, Bureau of Economic Analysis, 2010, National Economic Accounts: Current-dollar and ''real'' GDP, available at *http://www.bea.gov/national/index.htm.*
133. Gruber, J., ''Smoking's 'Internalities,''' *Regulation,* 25(4); 52–57, Winter 2002–2003.
134. Cutler, D., ''Are We Finally Winning the War on Cancer?'' *Journal of Economic Perspectives,* 22; 3–26, 2008.
135. Murphy, K.M. and Topel, R.H., ''The Value of Health and Longevity,'' *Journal of Political Economy,* 114(5); 871–904, 2006.
136. Arias, E., ''United States Life Tables, 2006,'' *National Vital Statistics Reports,* 58(21); June 28, 2010, available at *http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_21.pdf.*
137. Giovino, G.A., Chaloupka, F.J., Hartman, A.M., *et al., Cigarette Smoking Prevalence and Policies in the 50 States: An Era of Change—The Robert Wood Johnson Foundation ImpacTeen Tobacco Chart Book,* Buffalo, NY: University at Buffalo, State University of New York, 2009.
138. Nyman, J.A., Barleen, N.A., Dowd, B.E., *et al.,* ''Quality-of-Life Weights for the U.S. Population: Self-Reported Health Status and Priority Health Conditions, by Demographic Characteristics,'' *Medical Care,* 45(7); 618–28, July 2007.
139. Stewart, S.T., Cutler, D.M., and Rosen, A.B., ''Forecasting the Effects of Obesity and Smoking on U.S. Life Expectancy,'' *The New England Journal of Medicine,* 361(23); 2252–60, December 3, 2009.

140. U.S. Department of Labor, Bureau of Labor Statistics. Consumer Price Index Detailed Report, (complete text and tables), December 2010, available at *http://www.bls.gov/cpi/cpid1012.pdf.*
141. Hall, J.R., Jr., ''*The Smoking-Material Fire Problem,''* Quincy, MA: National Fire Protection Association, March 2010.
142. U.S. Department of Commerce, Census Bureau 2008, National Cancer Institute and Centers for Disease Control and Prevention co-sponsored Tobacco Use Supplement to the Current Population Survey 2006–2007, available at *http://www.nber.org/data/current-population-survey-data.html.*
143. Federal Trade Commission, ''Cigarette Report for 2006,'' 2009, available at *http://www.ftc.gov/os/2009/-8/090812cigarettereport.pdf.*
144. Markowitz, S., ''Where There's Smoking, There's Fire: The Effects of Smoking Policies on the Incidence of Fires in the United States,'' National Bureau of Economic Research, Working Paper 16625, December 2010, available at *http://www.nber.org/papers/w16625.*
145. National Fire Protection Association, News Release, July 16, 2004.
146. Coalition for Fire-Safe Cigarettes, ''The New York Experience,'' available at *http://firesafecigarettes.org/itemDetail.asp?categoryID=107&itemID=1512&URL=In+the+news%2FThe+New+York+Experience&utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+firesafecigarettes+%28Fire+Safe+Cigarettes%29,* accessed February 14, 2011.
147. Flynn, J.D., ''Characteristics of Home Fire Victims Fact Sheet,'' NFPA Fire Analysis and Research, March 2010.
148. U.S. Census Bureau, Statistics of U.S. Businesses (SUSB), Latest SUSB Annual Data, U.S., All Industries, 2007, available at *http://www.census.gov/econ/susb/* (accessed July 2010).
149. U.S. Census Bureau, 2005c, Product Lines: 2002, 2002 Economic Census, Accommodation and Food Services, Subject Series, available at *http://www.census.gov/prod/ec02/ec0272sllst.pdf.*
150. U.S. Census Bureau, 2005d, Product Lines: 2002, 2002 Economic Census, Retail Trade, Subject Series, available at *http://www.census.gov/prod/ec02/ec0244sllst.pdf.*
151. U.S. Census Bureau, Nonemployer Statistics, U.S., All Industries, 2008, Retail Trade, Accommodation and Food Services, available at *http://censtats.census.gov/cgi-bin/nonemployer/nonsect.pl* (accessed July 2010).
152. Muth, M.K., Gledhill, E.C., and Karns, S.A., ''FDA Labeling Cost Model,'' Research Triangle Park, NC: Research Triangle Institute (RTI), January 2003.
153. California Directory of Compliant Cigarettes and Roll-Your-Own Brand Families Listed by Manufacturer, available at *http://ag.ca.gov/tobacco/pdf/CompliantManufacturers.pdf* (accessed July 2, 2010).
154. Office of the Chief Financial Officer, ''District of Columbia Tobacco Directory,'' available at *http://cfo.dc.gov/cfo/cwp/view,A,1324,Q,616374.asp* (accessed Aug. 6, 2010).
155. State of Hawaii, Department of the Attorney General, Criminal Justice Division Tobacco Enforcement Unit ''Directory: Cigarettes and Roll-Your-Own Tobacco,'' available at *http://hawaii.gov/ag/tobacco.*
156. Nebraska Department of Revenue, ''Nebraska Directory of Certified Tobacco Product Manufacturers and Brands,'' August 2010.
157. State of South Carolina, Office of the Attorney General, ''South Carolina Tobacco Directory,'' November 1, 2010.
158. Utah State Tax Commission, ''Utah Approved Tobacco Manufacturers and Cigarette/RYO Brands,'' Utah State Tax Commission Publication 51, November 2010.
159. Braithwaite, R.S., Meltzer, D.O., King, J.T., *et al.,* ''What Does the Value of Modern Medicine Say About the $50,000 per Quality-Adjusted Life-Year Decision Rule?,'' *Medical Care,* 46(4); 349–56, April 2008.
160. U.S. Census Bureau, American FactFinder, ''2006 Annual Survey of Manufacturers,'' 2008, available at *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=AM0631GS101.*
161. U.S. Department of Agriculture, ''2007 Census of Agriculture: United States Summary and State Data: Volume 1, Geographic Area Series, Part 51,'' December 2009, available at *http://www.agcensus.usda.gov/Publications/2007/Full_Report/usv1.pdf.*
162. Chaloupka, F., and Warner, K, ''The Economics of Smoking,'' in A.J. Culyer and J.P. Newhouse (eds.), *Handbook of Health Economics,* vol. 1B, Amsterdam: Elsevier, 2000.
163. U.S. Bureau of Economic Analysis, National Economic Accounts, ''Table 3.5. Taxes on Production and Imports,'' available at *http://www.bea.gov/national/nipaweb/SelectTable.asp* (accessed October 13, 2010).
164. U.S. Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau, ''Federal Excise Tax Increase and Related Provisions,'' available at *http://www.ttb.gov/main_pages/schip-summary.shtml* (accessed August 18, 2010).
165. Tax Foundation, ''State Sales, Gasoline, Cigarette and Alcohol Tax Rates by State, 2000–2010,'' available at *http://www.taxfoundation.org/publications/show/245.html.*
166. Joint Committee on Taxation, ''Overview of Revenue Estimating Procedures and Methodologies Used by the Staff of the Joint Committee on Taxation,'' (JCX–1–05), February 2, 2005, available at *http://jct.gov/publications.html?func=startdown&id=1181.*
167. U.S. Department of the Treasury, Daily Treasury Long-Term Rate Data, Daily Treasury Real Long-Term Rates, available at *http://www.treasury.gov/resource-center/data-chart-center/interest-rates/Pages/default.aspx* (accessed February 11, 2011).
168. U.S. Department of Commerce, Bureau of Economic Analysis, 2010, National Income and Product Accounts Table 2.5.5, available at *http://www.bea.gov/national/nipaweb/TableView.asp?SelectedTable=74&Freq=Year&FirstYear=2008&LastYear=2009* (accessed August 26, 2010).
169. U.S. Census Bureau, 2010, International Trade Statistics.
170. U.S Department of Agriculture, Foreign Agricultural Service, Global Agricultural Trade System Online, available at *http://www.fas.usda.gov/ustrade/usthome.asp* (accessed August 9, 2010).
171. U.S. Small Business Administration, 2008, Table of Size Standards.
172. U.S. Census Bureau, 2005a, ''Establishment and Firm Size: 2002,'' 2002 Economic Census, Accommodation and Food Services, Subject Series, available at *http://www.census.gov/prod/ec02/ec0272ssszt.pdf.*
173. U.S. Census Bureau, 2005b, ''Establishment and Firm Size: 2002,'' 2002 Economic Census, Retail Trade, Subject Series, available at *http://www.census.gov/prod/ec02/ec0244ssszt.pdf.*
174. The Ontario Flue-Cured Tobacco Growers' Marketing Board, *Annual Report 2009,* Tillsonburg, ON: The Ontario Flue-Cured Tobacco Growers' Marketing Board, June 25, 2009, available at *http://www.ontarioflue-cured.com/uploads/General/2009AnnualReport.pdf.*
175. Statistics Canada, ''Population by year, by province and territory,'' 2010, available at *http://www40.statcan.gc.ca/l01/cst01/demo02a-eng.htm* (accessed February 7, 2011).
176. Bank of Canada, ''Consumer Price Index, 1995 to present,'' available at *http://www.bankofcanada.ca/en/cpi.html* (accessed February 7, 2011).
177. Centers for Disease Control and Prevention, State Tobacco Activities Tracking and Evaluation (STATE) System, State Comparison Report, available at *http://apps.nccd.cdc.gov/statesystem/ComparisonReport/ComparisonReports.aspx* (accessed February 7–8, 2011).
178. Jamison, N., *et al.,* ''Federal and State Cigarette Excise Taxes—United States, 1995–2009,'' *Morbidity and Mortality Weekly Report,* 58(19); 524–27, May 22, 2009.
179. U.S. Census Bureau Population Division, ''Table CO–EST2001–12–00—Time Series of Intercensal State Population Estimates: April 1, 1990 to April 1, 2000,'' April 11, 2002, available at *http://www.census.gov/popest/archives/2000s/vintage_2001/CO–EST2001–12/CO–EST2001–12–00.xls* (accessed February 8, 2011).
180. U.S. Census Bureau, Population Division, ''Table 1—Annual Estimates of the Resident Population for the United States, Regions, States and Puerto Rico: April 1, 2000 to July 1, 2009,'' (NST–

EST2009–01), December 2009, available at *http://www.census.gov/popest/states/tables/NST–EST2009–01.xls* (accessed February 7, 2011).
181. Weimer, D.L., Vining, A.R., and Thomas, R.K., ''Cost-Benefit Analysis Involving Addictive Goods: Contingent Valuation to Estimate Willingness-to-Pay for Smoking Cessation,'' *Health Economics,* 18; 181–202, 2009.
182. Gruber, J.H. and Mullainathan, S., ''Do Cigarette Taxes Make Smokers Happier?'' *Advances in Economic Analysis & Policy,* 5(1); Article 4, 2005.
183. Smith, V.K., Taylor, D.H., Jr., Sloan, F.A., *et al.,* ''Do Smokers Respond to Health Shocks?,'' *The Review of Economics and Statistics,* 83(4); 675–87, November 2001.

List of Subjects in 21 CFR Part 1141

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, and Smoking.

Therefore, under the Federal Cigarette Labeling and Advertising Act, the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended by adding part 1141 to subchapter K to read as follows:

PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS

Subpart A—General Provisions

Subpart B—Cigarette Package and Advertising Warnings

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

Authority: 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

(1) Contains a health warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) or this part, including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

(d) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings in an advertisement for cigarettes if the advertisement is not created by or on behalf of the retailer and the retailer is not otherwise responsible for the inclusion of the required warnings. This paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4(b) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)), this part, or section 4(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(c)), including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

§ 1141.3 Definitions.

For the purposes of this part,

Cigarette means:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Importer means any person who imports any cigarette that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Package means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Required warning means the combination of one of the textual warning statements and its accompanying color graphic, which are set forth in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term ''State'' includes any political division of any State.

Subpart B—Cigarette Package and Advertising Warnings

§ 1141.10 Required warnings.

(a) *Packages*—(1) It shall be unlawful for any person to manufacture, package,

sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings on the front and the rear panels.

(2) The required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings.''

(3) The required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.

(4) The required warning shall be located in the upper portion of the front and rear panels of the package and shall comprise at least the top 50 percent of these panels; *Provided, however,* that on cigarette cartons, the required warning shall be located on the left side of the front and rear panels of the carton and shall comprise at least the left 50 percent of these panels.

(5) The required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(b) *Advertisements*—(1) It shall be unlawful for any manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings.

(2) The text in each required warning shall be in the English language, except that:

(i) In the case of an advertisement that appears in a non-English publication, the text in the required warning shall appear in the predominant language of the publication whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning shall appear in the same language as that principally used in the advertisement.

(3) For English-language and Spanish-language warnings, each required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings.''

(4) For foreign-language warnings, except for Spanish-language warnings, each required warning shall be obtained from the electronic images contained in ''Cigarette Required Warnings,'' which is incorporated by reference at § 1141.12, and accurately reproduced as specified in ''Cigarette Required Warnings,'' including the insertion of a true and accurate translation of the textual warning. The inserted textual warning must comply with the requirements of section 4(b)(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)(2)).

(5) The required warning shall occupy at least 20 percent of the area of each advertisement, and shall be placed in accordance with the requirements in the Federal Cigarette Labeling and Advertising Act.

(c) *Irremovable or permanent warnings.* The required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. Such warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1141.12 Incorporation by reference of required warnings.

''Cigarette Required Warnings'' Edition 1.0 (June 2011), consisting of electronic files, U.S. Food and Drug Administration, referred to at § 1141.3, § 1141.10(a) and (b), and § 1141.16(a), is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, you may obtain a copy of the material by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373, or *cigarettewarningfiles@fda.hhs.gov.* You may also obtain the material at *http://www.fda.gov/cigarettewarningfiles.*

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

§ 1141.16 Disclosures regarding cessation.

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, ''Cigarette Required Warnings'' (incorporated by reference at § 1141.12).

(b) In meeting the smoking cessation needs of an individual caller, the smoking cessation assistance resource required to be referenced by paragraph (a) of this section must, as appropriate:

(1) Provide factual information about the harms to health associated with cigarette smoking and the health benefits of quitting smoking;

(2) Provide factual information about what smokers can expect when trying to quit;

(3) Provide practical advice (problem solving/skills training) about how to deal with common issues faced by smokers trying to quit;

(4) Provide evidence-based advice about how to formulate a plan to quit smoking;

(5) Provide evidence-based information about effective relapse prevention strategies;

(6) Provide factual information on smoking cessation treatments, including FDA-approved cessation medications; and

(7) Provide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation.

(c) The smoking cessation resource must:

(1) Other than as described in this section, not advertise or promote any particular product or service;

(2) Except to meet the particularized needs of an individual caller as determined in the context of individual counseling, not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories;

(3) Not provide or otherwise encourage the use of any drug or other medical product that FDA has not approved for tobacco cessation;

(4) Not encourage the use of any non-evidence-based smoking cessation practices;

(5) Ensure that staff providing smoking cessation information, advice, and support are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support; and

(6) Maintain appropriate controls to ensure the criteria described in paragraphs (b) and (c) of this section are met.

(d) If the Secretary of the Department of Health and Human Services (Secretary) determines that a part of the smoking cessation assistance resource referenced by paragraph (a) of this section does not meet the criteria described in paragraphs (b) and (c) of this section, the Secretary shall take appropriate steps to address the noncompliance.

Dated: June 9, 2011.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

Dated: June 9, 2011.

Kathleen Sebelius,

Secretary of Health and Human Services.

Note: The following Appendices will not appear in the Code of Federal Regulations.

Appendices

I. Technical Appendix X1: Smoking Rates

FDA's primary and secondary methods for estimating the reduction in smoking rates realized in Canada due to that country's introduction, in December 2000, of graphic warning labels both involve several steps. In both methods, the first step is to estimate the smoking rate trend for Canada in the years from 1991 up to and including 2000. (We perform a similar analysis for the United States, but this will be used only in the primary method.)

In response to comments on the Preliminary Regulatory Impact Analysis of the proposed rule, we refine our estimate of the Canadian smoking rate trend by accounting for tax changes at the Federal and provincial levels. The Ontario Flue-Cured Tobacco Growers' Marketing Board (Ref. 174) reports time series of cigarette taxes for Canadian provinces and territories. (Because these time series only extend back to 1991, we have had to estimate a shorter time trend than the one used in the analysis of the proposed rule.) We find average tax levels for all of Canada by weighting by provincial and territorial populations (using Ref. 175). We then adjust nominal cigarette taxes for general inflation using the broad Canadian CPI (Ref. 176). (Canada has estimated a GDP deflator only since 2002, so we use the Canadian CPI, even though consumer price indices tend to be characterized by slight upward biases in their estimates of inflation.) Our results, along with results from an analogous estimation for the United States, are reported in Table 42.

Table 42.--Smoking Rate Trends, Canada and United States[a]

	Regression Results, Canada[b]	Regression Results, United States[d]
Intercept	Intercept = 4.455	Intercept = 3.451
	Standard Error = 0.215[c]	Standard Error = 0.202[c]
	t-statistic = 20.715[c]	t-statistic = 17.084[c]
Time Trend = *ln(Year - 1985)*	Coefficient = -0.377	Coefficient = -0.115
	Standard Error = 0.063[c]	Standard Error = 0.074[c]
	t-statistic = -6.012[c]	t-statistic = -1.551[c]
Excise Tax (*ln*)	Coefficient = -0.215	Coefficient = -0.101
	Standard Error = 0.080[c]	Standard Error = 0.106[c]
	t-statistic = -2.688[c]	t-statistic = -0.950[c]
N	7	5

[a] Underlying smoking rate data appear in table 4 of this document.

[b] Regression equation: *ln(SmokingRate) = Intercept + Coefficient*ln(Year-1985) + Coefficient*ln(ExciseTax) + error.*

[c] Standard errors and t-statistics reported here are not adjusted for uncertainty introduced by the use of survey data.

[d] Regression equation: *ln(SmokingRate) = Intercept + Coefficient* ln(Year-1985) + Coefficient*ln(ExciseTax) + error.*

Using the estimated time trend, we forecast the Canadian smoking rate that would have been realized post-2000 had graphic warning labels not been introduced in that country. The difference between the smoking rate forecast and the actual Canadian smoking rate yields the portion of the smoking rate that is unexplained apart from the introduction of graphic warning labels. Calculating the difference in the average unexplained smoking rate between 1994–2000 and 2001–09 yields the estimate of the effect of graphic warning labels, 0.574 percentage points, that appears in part (a) of Technical Appendix X6.

Table 43.--Impact of Graphic Warning Labels on Canadian Smoking Rate

	Smoking Rate, Canada[a]	Time Trend Forecast Smoking Rate, Canada	Unexplained Smoking Rate, Canada[b]
1994-95	30.5	30.391	0.109
1996-97	28.6	28.172	0.428
1998-99	27.7	26.237	1.463
1999	25.2	25.855	-0.655
2000	24.4	25.099	-0.699
2001	21.7	24.088	-2.388
2002	21.4	22.247	-0.847
2003	20.9	20.274	0.626
2004	19.6	19.596	0.004
2005	18.7	19.242	-0.542
2006	18.6	18.950	-0.350
2007	19.2	18.607	0.593
2008	17.9	18.291	-0.391
2009	17.25	17.957	-0.707

[a] Source: Health Canada (Refs. 126 and 127).
[b] Mean for 1994-2000 is 0.129; mean for 2001-09 is -0.445; difference in means is 0.574.

In our preferred estimation method (see section XI.D.1, above), we use the U.S. experience as an additional control. We find the unexplained smoking rate in the United States using calculations analogous to those used for Canada and tax data from the Centers for Disease Control and Prevention (Ref. 177) and Jamison *et al.* (Ref. 178), population data from the U.S. Census Bureau (Refs. 179 and 180), and inflation data from the U.S. Bureau of Economic Analysis (Ref. 132). We then calculate the difference in unexplained smoking rates between the United States and Canada. Finally, we again subtract the average for 1994–2000 from the average for 2001–09; this produces the estimate that graphic warning labels decrease the national smoking rate by 0.088 percentage points. Details appear in Table 44.

Table 44.--Impact of Graphic Warning Labels on Difference Between Unexplained United States and Canadian Smoking Rates

	Smoking Rate, United States[a]	Standard Error, Smoking Rate, United States[a]	Time Trend Forecast Smoking Rate, United States	Unexplained Smoking Rate, United States	Difference in Unexplained Smoking Rates (United States-Canada)[c]
1994-95	24.6	[b]	24.742	-0.142	-0.251
1996-97	24.558	0.29	24.213	0.344	-0.083
1998	23.918	0.30	23.971	-0.053	-1.516
1999	23.302	0.32	23.564	-0.261	0.393
2000	23.065	0.32	23.005	0.060	0.759
2001	22.644	0.30	22.869	-0.226	2.162
2002	22.262	0.32	22.141	0.121	0.967
2003	21.310	0.30	21.945	-0.635	-1.261
2005	20.724	0.31	21.538	-0.814	-0.272
2006	20.564	0.35	21.447	-0.882	-0.533
2007	19.449	0.40	21.211	-1.762	-2.356
2008	20.409	0.38	20.948	-0.539	-0.148
2009	20.513	0.37	20.190	0.323	1.030

[a] Sources: National Center for Health Statistics (Ref. 129) and FDA analysis of National Health Interview Survey (Ref. 128).
[b] Not reported for 1994, but likely to be near the standard error of 0.3 found for years 2000-03.
[c] Mean for 1994-2000 is -0.140; mean for 2001-09 is -0.051; difference in means is 0.088.

II. Technical Appendix X2: Life-Years

In calculating expected life-years saved per dissuaded smoker, FDA relies heavily on the life tables developed by Sloan *et al.* (Ref. 116). The life tables are calculated from the perspective of 24-year-olds, so the calculation of rule-induced effects on males and females who turn 24 sometime after the rule takes effect is relatively straightforward. In the following example, we will show the calculation of expected rule-induced effects for 24-year-old females, under the assumption of a 3 percent discount rate; the calculations for males or for a 7 percent discount rate would be analogous.

The life tables show that, of one hundred thousand females who smoke at their 24th birthdays, 99,939 will survive to their 25th birthdays and 99,876 to their 26th birthdays. Of one hundred thousand 24-year-old female nonsmoking smokers, 99,946 will survive to their 25th birthdays and 99,889 to their 26th birthdays. These numbers imply that, for every one hundred thousand females who smoke at their 24th birthdays, smoking will cause seven deaths between birthdays 24 and 25 and six deaths between birthdays 25 and 26. The tables continue to show number of survivors in each category (and thus the smoking-related excess probability of dying) for every birthday up to age 100; the discontinuation of the tables at this point requires us to assume no survival in either category to the one-hundred-and-first birthday.

Someone who dies at the age of 24 loses all the life-years up to and including age 100. Without discounting, this would be a total of 77 years; with a 3 percent discount rate, however, the total is 29.9 years. Similarly, someone who dies at age 25 loses 76 undiscounted or 29.8 discounted life-years. By multiplying together the age-specific discounted life-year loss and the age-specific smoking-related excess probability of dying, then summing over all ages, we arrive at the overall expected number of life-years saved per dissuaded female smoker. Using a discount rate of 3 percent, this result is (7/100,000)*29.9 + (6/100,000)*29.8 + … = 0.524.

For individuals who are older than 24 at the time of the rule's implementation, we want to perform a similar calculation; however, direct application of the nonsmoking smoker life tables is inappropriate because the life expectancy effect of smoking cessation at a particular age is almost certainly different than the effect of having refrained from smoking since at least the age of 24. Thus, it is necessary to develop age-specific survival probabilities for former smokers.

There are four possible events that a 24-year-old smoker can experience between any two birthdays: staying alive and remaining a smoker, staying alive and becoming a former smoker, dying in the state of being a smoker, or dying in the state of being a former smoker. The percentage of former smokers who do not experience the last of these events is the former smoker survival probability that we seek to calculate. We will illustrate this calculation for 25-year-old females, under the assumption of a 3 percent discount rate; the calculation for males or other discount rates or age categories would be analogous.

We again consider one hundred thousand female smokers at their 24th birthdays. According to the National Health Interview Survey (Ref. 128), 3.4 percent of them will become former smokers by their 25th birthdays. Following Sloan *et al.,* we use the 1998 NHIS and define former smokers as individuals who quit at least 5 years in the past. Sloan *et al.*'s life tables indicate that another 61 of the original one hundred thousand will die before their 25th birthdays; all 61 die in the state of being smokers (because no time has elapsed since they were smokers at the definitional age of 24). This leaves 96,540 who are alive and still smoking and 3,399 who are living former smokers at the 25th birthday.

Sloan *et al.*'s typical smoker life table indicates that 63 of these 25-year-old survivors will die before their 26th birthdays; we must calculate how many of them die in the state of being smokers and how many in the state of being former smokers. To find death probabilities for those individuals who are still smoking at age 25, we look to Sloan *et al.*'s life table for *lifetime* smokers. Whereas the typical smoker life table shows survival patterns for individuals who smoke at age 24 and may quit sometime later in life, the lifetime smoker life table isolates survival patterns for individuals who smoke at age 24 and continue to a specific age. The lifetime smoker life table will begin to diverge from the typical life table at later ages, but for birthdays 25 and 26, the results are once again 99,939 and 99,876 survivors; therefore, the percentage of 25-year-old female smokers who survive to birthday 26 is 99,876/99,939. Multiplying this percentage by the 96,540 smokers alive at birthday 25 yields 61 deaths. Therefore, two (=63 − 61) deaths of former smokers are expected between birthdays 25 and 26, and the age-specific former smoker survival probability is 1 − (2/3,399) = 0.99937. (This technique for estimating former smoker survival probability does not distinguish between recent quitters and those who quit many years ago. Not making this distinction, which becomes increasingly important the further beyond age 25 we consider, will result in our estimates of cessation-related life expectancy benefits being too great for those who quit at an advanced age and too low for those who quit at an early age.)

To find the expected number of life-years gained for a female who quits smoking at age 25, we subtract from 0.99937 the survival probability for a smoker of the same age (calculated from Sloan *et al.*'s typical smoker life table), then multiply by the discounted number of life-years lost if death occurs at age 25 (previously found to be 29.8), and finally add the expected value of life-years gained by quitting at age 26, discounted 1 year. Because there is no extension of life brought about by quitting at age 100, this addition is feasible for age 99, and then for age 98, and so on back to age 25. The final result for females who quit smoking at age 25 is 0.081 discounted life-years saved.

For the year 2013, we multiply our estimated age-specific expected discounted life-years saved by the cohort sizes (for ages 18 and above) projected by the U.S. Census Bureau (Ref. 130). For years 2014–31, we multiply our estimated age-specific expected discounted life-years saved by the cohorts that would not have been included in our 2013 calculation, specifically new 24-year-olds and older individuals whose cohorts grow from one year to another (for example, if the projected number of 35-year-olds in 2014 is greater than the projected number of 34-year-olds in 2013, the difference is included in the 2014 calculation). Finally, we estimate effects for individuals who are 18–23 in the year 2031 by discounting the present value of benefits accruing to 24-year-olds by the number of years until each cohort reaches that age threshold. Results are further multiplied by FDA's estimate of the rule-induced reduction in the U.S. smoking rate to yield our final estimate of the number of life-years saved by the regulation.

III. Technical Appendix X3: Timing of Benefits

FDA's estimated benefits appear as undiscounted streams in Table 45, Parts 1 through 12. Benefits are realized as late as 2113 because we calculate effects over lifetimes extending to age 100 for

cohorts aged 18 and above during the first 20 years (2012 to 2031) of the final rule's implementation.

Because many of our sources report only present values of smoking-related effects, estimating the timing of those effects requires us to make various assumptions. Changing those assumptions would change the results appearing in Table 45. Similarly, because many of our sources report present values calculated only with a discount rate of 3 percent, changing our assumptions about the timing of effects would change the present values we have reported at the 7 percent discount rate (an important exception being the present value of reduced mortality for 24-year-olds because Sloan *et al.*'s life tables allow us to know the timing of those benefits).

BILLING CODE 4160–01–P

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	0.0	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.1	-0.2
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	10.4	20.9	31.3	41.7	52.0	62.2	72.2	82.1
Health Status, with VSLY = $212,615[a,c]	0.0	6.1	12.3	18.5	24.6	30.6	36.5	42.4	48.2
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	0.0	1.2	2.5	3.8	5.0	6.3	7.5	8.7	9.9
Medical Costs Reductions, Age > 24 in 2013[e]	0.0	21.7	21.7	21.7	21.7	21.7	21.7	21.6	21.6
Financial Effects[f]	0.0	1.1	1.6	2.1	2.6	3.1	3.6	4.1	4.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	0.0	4.9	4.9	5.0	5.1	5.2	5.2	5.3	5.4
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	0.0	2.8	2.9	2.9	3.0	3.0	3.1	3.1	3.2
Fire-Related Property Damage[i]	0.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.0
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	0.0	308.1	313.0	317.8	322.6	327.4	332.4	337.7	343.0
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	0.0	139.9	142.2	144.3	146.5	148.7	151.0	153.4	155.8

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	-0.2	-0.2	-0.1	-0.1	0.7	2.2	4.5	7.7	11.6
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	91.8	101.3	110.6	119.7	128.3	136.4	144.0	151.1	157.8
Health Status, with VSLY = $212,615[a,c]	53.9	59.6	65.3	71.1	77.1	83.2	89.3	95.4	101.6
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	11.0	12.2	13.4	14.6	15.8	17.0	18.3	19.5	20.8
Medical Costs Reductions, Age > 24 in 2013[e]	21.6	21.6	21.6	21.6	21.6	21.6	21.6	21.6	21.6
Financial Effects[f]	5.0	5.5	5.9	6.4	6.9	7.3	7.8	8.3	8.8
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.5	5.6	5.7	5.8	5.8	5.9	6.0	6.1	6.2
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.2	3.3	3.3	3.4	3.4	3.5	3.5	3.6	3.6
Fire-Related Property Damage[i]	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	348.4	353.9	359.4	365.1	370.8	376.6	382.6	388.7	394.8
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	158.2	160.7	163.3	165.8	168.4	171.1	173.8	176.5	179.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 3

	2030	2031	2032	2033	2034	2035	2036	2037	2038
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	16.5	22.2	29.0	36.7	45.4	55.7	67.5	81.0	96.4
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	163.9	169.5	174.6	179.2	183.3	186.8	189.6	191.8	193.4
Health Status, with VSLY = $212,615[a,c]	107.9	114.2	120.4	126.8	133.2	139.6	146.0	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	22.1	23.4	24.7	26.0	27.3	28.6	29.9	31.2	31.2
Medical Costs Reductions, Age > 24 in 2013[e]	21.5	21.5	21.4	21.2	21.1	21.0	20.8	20.6	20.5
Financial Effects[f]	9.4	9.9	10.4	11.0	11.6	12.2	12.8	13.5	13.9
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	6.3	6.4	6.3	6.3	6.2	6.1	6.1	6.0	6.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.7	3.7	3.7	3.7	3.6	3.6	3.5	3.5	3.5
Fire-Related Property Damage[i]	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	400.4	405.3	401.6	397.7	393.8	389.8	385.6	381.3	379.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	181.8	184.1	182.4	180.7	178.9	177.1	175.1	173.2	172.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 4

	2039	2040	2041	2042	2043	2044	2045	2046	2047
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	113.5	132.7	154.0	177.4	203.2	231.5	262.5	296.6	333.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	194.4	194.8	194.6	193.9	192.6	190.8	188.4	185.4	181.9
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	31.2	30.3	29.3	28.3	27.4	26.5	25.5	24.6	23.7
Medical Costs Reductions, Age > 24 in 2013[e]	20.3	20.1	19.9	19.7	19.4	19.2	18.9	18.7	18.4
Financial Effects[f]	14.4	15.0	15.5	16.1	16.8	17.5	18.3	19.1	20.0
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.9	5.9	5.9	5.8	5.8	5.7	5.7	5.6	5.6
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.5	3.4	3.4	3.4	3.4	3.4	3.3	3.3	3.3
Fire-Related Property Damage[i]	1.1	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	377.2	374.9	372.6	370.1	367.3	364.3	361.3	358.3	355.1
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	171.3	170.3	169.2	168.1	166.8	165.5	164.1	162.7	161.3

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 5

	2048	2049	2050	2051	2052	2053	2054	2055	2056
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	374.5	418.7	465.6	515.5	568.4	624.4	683.5	745.7	811.1
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	177.9	173.4	168.4	163.1	157.3	151.2	144.9	138.3	131.5
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	22.8	22.0	21.1	20.2	19.2	18.3	15.5	12.6	9.7
Medical Costs Reductions, Age > 24 in 2013[e]	18.1	17.7	17.4	17.0	16.6	16.3	15.9	15.5	15.0
Financial Effects[f]	21.0	22.1	23.3	24.5	25.8	27.2	28.6	30.0	31.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	5.5	5.5	5.4	5.3	5.3	5.2	5.1	5.0	5.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	3.2	3.2	3.2	3.1	3.1	3.0	3.0	2.9	2.9
Fire-Related Property Damage[i]	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	351.1	347.0	342.9	338.6	334.3	329.8	325.2	320.3	315.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	159.5	157.6	155.7	153.8	151.8	149.8	147.7	145.5	143.2

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 6

	2057	2058	2059	2060	2061	2062	2063	2064	2065
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	879.5	951.0	1,025.4	1,101.6	1,179.5	1,258.8	1,339.1	1,420.0	1,499.5
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	124.5	117.5	110.3	103.2	96.1	89.1	82.2	75.4	68.8
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	6.8	3.9	1.1	-1.7	-4.5	-7.3	-10.1	-12.9	-14.7
Medical Costs Reductions, Age > 24 in 2013[e]	14.6	14.2	13.7	13.3	12.8	12.3	11.9	11.4	10.9
Financial Effects [f]	33.2	35.0	36.8	38.6	40.5	42.5	44.5	46.5	48.4
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	4.9	4.8	4.7	4.6	4.5	4.5	4.4	4.3	4.2
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.9	2.8	2.8	2.7	2.7	2.6	2.6	2.5	2.5
Fire-Related Property Damage[i]	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.7
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	310.2	304.9	299.5	294.1	288.5	283.0	277.5	272.0	266.4
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	140.9	138.5	136.1	133.6	131.0	128.5	126.0	123.5	121.0

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 7

	2066	2067	2068	2069	2070	2071	2072	2073	2074
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	1,577.2	1,652.5	1,725.2	1,794.6	1,857.9	1,914.4	1,963.6	2,004.9	2,037.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	62.5	56.5	50.7	45.2	40.0	35.2	30.8	26.8	23.1
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-16.6	-18.5	-20.4	-22.3	-24.2	-26.2	-28.2	-30.1	-32.1
Medical Costs Reductions, Age > 24 in 2013[e]	10.5	10.0	9.6	9.2	8.8	8.3	7.9	7.5	7.1
Financial Effects[f]	50.4	52.3	54.1	55.8	57.4	58.8	60.0	61.0	61.7
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	4.1	4.0	4.0	3.9	3.8	3.7	3.6	3.5	3.5
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.4	2.4	2.3	2.3	2.2	2.2	2.1	2.1	2.0
Fire-Related Property Damage[i]	0.7	0.7	0.7	0.7	0.7	0.7	0.6	0.6	0.6
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	261.0	255.9	250.9	245.9	240.7	235.3	230.1	225.0	220.2
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	118.5	116.2	113.9	111.7	109.3	106.9	104.5	102.2	100.0

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 8

	2075	2076	2077	2078	2079	2080	2081	2082	2083
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	2,056.2	2,060.2	2,050.8	2,028.8	1,995.5	1,951.7	1,898.6	1,837.1	1,768.2
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	19.8	16.8	14.1	11.8	9.7	8.0	6.5	5.2	4.1
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4	152.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-34.1	-36.1	-38.1	-40.1	-40.1	-40.1	-40.1	-40.1	-40.1
Medical Costs Reductions, Age > 24 in 2013[e]	6.7	6.2	5.8	5.4	5.0	4.6	4.1	3.7	3.2
Financial Effects[f]	62.1	62.1	61.7	60.9	59.9	58.6	57.0	55.3	53.3
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	3.4	3.3	3.2	3.2	3.1	3.0	2.9	2.8	2.7
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	2.0	1.9	1.9	1.8	1.8	1.8	1.7	1.7	1.6
Fire-Related Property Damage[i]	0.6	0.6	0.6	0.6	0.5	0.5	0.5	0.5	0.5
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	215.4	210.6	205.7	200.9	195.8	190.7	185.3	179.8	174.3
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	97.9	95.6	93.5	91.2	89.0	86.6	84.1	81.7	79.2

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 9

	2084	2085	2086	2087	2088	2089	2090	2091	2092
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	1,692.7	1,611.9	1,526.4	1,436.4	1,342.4	1,245.4	1,147.1	1,047.9	948.1
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	3.3	2.6	2.0	1.5	1.1	0.9	0.8	0.6	0.5
Health Status, with VSLY = $212,615[a,c]	152.4	152.4	152.4	152.4	152.4	152.4	146.4	140.1	133.9
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-40.1	-40.1	-40.1	-40.1	-40.1	-40.1	-38.5	-36.9	-35.3
Medical Costs Reductions, Age > 24 in 2013[e]	2.8	2.3	1.8	1.4	0.9	0.4	0.4	0.4	0.3
Financial Effects[f]	51.1	48.8	46.3	43.8	41.1	38.3	35.4	32.5	29.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	2.7	2.6	2.5	2.4	2.3	2.2	2.9	2.8	2.7
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.6	1.5	1.5	1.4	1.3	1.3	1.7	1.7	1.6
Fire-Related Property Damage[i]	0.5	0.5	0.4	0.4	0.4	0.4	0.5	0.5	0.5
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	168.9	163.4	157.9	152.4	146.8	141.1	185.9	179.5	173.0
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	76.7	74.2	71.7	69.2	66.7	64.1	84.4	81.6	78.6

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 10

	2093	2094	2095	2096	2097	2098	2099	2100	2101
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	848.2	748.5	651.8	558.6	469.4	384.8	305.1	237.3	180.5
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.4	0.3	0.2	0.2	0.1	0.1	0.1	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	127.8	121.8	115.9	110.0	104.2	98.5	92.9	87.1	81.3
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-33.7	-32.1	-30.5	-29.0	-27.4	-25.9	-24.5	-22.9	-21.4
Medical Costs Reductions, Age > 24 in 2013[e]	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1	0.1
Financial Effects[f]	26.6	23.7	20.8	18.1	15.4	12.9	10.5	8.5	6.8
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	2.6	2.5	2.4	2.3	2.3	2.2	2.1	2.0	2.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.5	1.5	1.4	1.4	1.3	1.3	1.2	1.2	1.1
Fire-Related Property Damage[i]	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.3
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	166.5	160.3	154.4	149.0	143.7	138.6	133.8	129.0	124.2
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	75.6	72.8	70.1	67.7	65.3	63.0	60.8	58.6	56.4

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 11

	2102	2103	2104	2105	2106	2107	2108	2109	2110
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	133.8	96.4	67.2	45.0	28.7	17.2	9.5	4.7	1.9
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	75.3	69.3	63.2	57.0	50.8	44.5	38.3	32.0	25.6
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-19.8	-18.2	-16.6	-15.0	-13.4	-11.7	-10.1	-8.4	-6.8
Medical Costs Reductions, Age > 24 in 2013[e]	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financial Effects[f]	5.3	4.2	3.2	2.5	1.9	1.4	1.1	0.8	0.6
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	1.9	1.8	1.7	1.6	1.6	1.5	1.4	1.2	1.0
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	1.1	1.0	1.0	1.0	0.9	0.9	0.8	0.7	0.6
Fire-Related Property Damage[i]	0.3	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.2
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	119.1	113.9	108.8	103.8	98.7	93.6	88.0	74.5	60.9
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	54.1	51.8	49.4	47.1	44.8	42.5	40.0	33.8	27.6

Table 45.--Undiscounted Stream of Benefits and Consumer Surplus Costs ($ mil), Part 12

	2111	2112	2113
Mortality, Age = 18-24 during 2013-31, with VSLY = $212,615[a]	0.5	0.0	0.0
Mortality, Age > 24 in 2013, with VSLY = $212,615[a,b]	0.0	0.0	0.0
Health Status, with VSLY = $212,615[a,c]	19.3	12.9	6.4
Medical Costs Reductions, Age = 18-24 during 2013-31[d]	-5.1	-3.4	-1.7
Medical Costs Reductions, Age > 24 in 2013[e]	0.0	0.0	0.0
Financial Effects[f]	0.4	0.3	0.1
Fire-Related Mortality with 3% Disc. Rate and VSLY = $212,615[a,g]	0.7	0.5	0.3
Fire-Related Mortality with 7% Disc. Rate and VSLY = $212,615[a,h]	0.4	0.3	0.2
Fire-Related Property Damage[i]	0.1	0.1	0.1
Consumer Surplus with 3% Disc. Rate and VSLY = $212,615[i,j]	47.2	33.4	19.6
Consumer Surplus with 7% Disc. Rate and VSLY = $212,615[i,k]	21.4	15.2	8.9

[a] Numbers in this row may be multiplied by 0.5 to produce results for VSLY=$106,308 or by 1.5 to produce results for VSLY=$318,923.
[b] Also includes individuals who turn 24 between 2013 and 2031 but are first exposed to graphic warning labels at later ages due to immigration. Underlying assumptions discussed in detail in Technical Appendix X2.
[c] Underlying assumption: Sloan et al.'s present value of years with fair/poor health status distributed equally over ages 24 to 100. Result: this row shows benefits being accrued in a pattern somewhat less concentrated in the middle years of life than the likely reality. Because Sloan et al. report undiscounted effects of 2.69 years for females and 1.41 year for males, and discounting reduces the effects to 1.27 and 0.90 years, this concentration, on average, centers on females' forty-ninth birthdays and males' thirty-ninth birthdays.
[d] Underlying assumption: Sloan et al.'s medical cost present value distributed equally within age bins (24-50, 51-64 and 65+).
[e] Also includes individuals who turn 24 between 2013 and 2031 but are first exposed to graphic warning labels at later ages due to immigration. Underlying assumption: Sloan et al.'s medical costs present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and in lesser amounts than the likely reality for relatively young quitters and somewhat earlier and in greater amounts than the likely reality for relatively old quitters.
[f] Includes Social Security outlays, income taxes on Social Security-taxable earnings, defined benefit private pension outlays and life insurance outlays. Underlying assumption: net financial effect distributed over time in the same pattern as the sum of mortality, morbidity and medical cost effects.
[g] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality. Fire-related death loss is a present value, calculated at the time of death with a discount rate of 3 percent, of future VSLY.
[h] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality. Fire-related death loss is a present value, calculated at the time of death with a discount rate of 7 percent, of future VSLY.
[i] Underlying assumption for quitters aged 25 and above: Sloan et al.'s cigarette consumption present value distributed equally over ages 24 to 100. Result: this row shows benefits being accrued somewhat later and possibly in slightly greater amounts than the likely reality.
[j] Numbers in this row may be multiplied by approximately 0.496 to produce results for VSLY=$106,308 or by approximately 1.504 to produce results for VSLY=$318,923.
[k] Numbers in this row may be multiplied by approximately 0.520 to produce results for VSLY=$106,308 or by approximately 1.500 to produce results for VSLY=$318,923.

IV. Technical Appendix X4: Timing of Costs

Table 46.--Undiscounted Stream of Costs, Low Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	272.5								
Market Testing	1.5								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Subtotal	319.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	325.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6

Table 46.--Undiscounted Stream of Costs, Low Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Subtotal	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6

Table 47.--Undiscounted Stream of Costs, Medium Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	295.2								
Market Testing	2.1								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Subtotal	342.7	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	348.9	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8

Table 47.--Undiscounted Stream of Costs, Medium Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
		0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Subtotal	0.0	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	6.2	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8	6.8

Table 48.--Undiscounted Stream of Costs, High Estimate ($ mil), Part 1

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Private Sector									
Labeling Change	464.8								
Market Testing	8.2								
Point-of-Sale Advertising	45.4								
Continuing Admin and RK		0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Subtotal	518.4	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Government									
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	524.6	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1

Table 48.--Undiscounted Stream of Costs, High Estimate ($ mil), Part 2

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Private Sector											
Labeling Change											
Market Testing											
Point-of-Sale Advertising											
	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Subtotal	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Government											
FDA	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Other (Cessation Resource)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Subtotal	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
TOTAL	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1

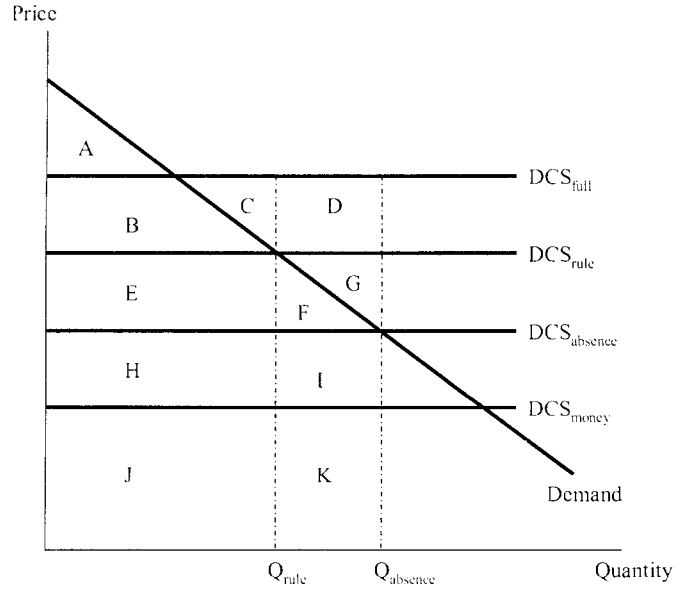
BILLING CODE 4160–01–C

V. Technical Appendix X5: Additional Diagrams on Benefits

Consumer Surplus Model. The benefits estimated in sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v overstate, all else held equal, the net internal (*i.e.,* intrapersonal) benefits (or costs, in the case of section XI.D.2.b.v) of reduced smoking because they include only the increased welfare from improved health and expected longevity (and decreased welfare due to subsidy loss) and do not account for any lost consumer surplus [21] associated with the activity of smoking. In the Preliminary Regulatory Impact Analysis (see page 75 FR 69524 at 69544), FDA adjusted benefits estimates with a 50 percent consumer surplus reduction, based on a model created by Cutler (Ref. 134). Several comments on the proposed rule expressed concern about the appropriateness of Cutler's assumptions, so FDA has revised the model to make it more applicable to the present analysis. Our revised model is illustrated in Figure E1.

[21] The difference between what a consumer would be willing to pay for a good or service and what that consumer actually has to pay.

Figure E1. The Market for Smoking, Before and After Rule Implementation



We begin with a downward-sloping demand for typical lifetime smoking. A negative relationship between price and consumption of cigarettes has been demonstrated empirically many times over (Chaloupka and Warner (Ref. 162) review this literature).

The height of line DCS_{full} marks the full cost, including the cost of adverse health and life expectancy effects, of typical lifetime smoking (thus, the ''Discounted Cost of Smoking'' or DCS), while the height of line DCS_{money} marks only the after-tax price of cigarettes. The height difference between these two lines is the sum of the per-person effects we calculated in sections XI.D.2.b.ii, XI.D.2.b.iii and XI.D.2.b.iv. Also belonging in DCS_{full} are the effects calculated in section XI.D.2.b.v because the concept of the full cost of smoking, as used in the model, is defined from the private perspective of the smoker (and thus it is irrelevant whether or not there is someone else in society who experiences an effect that offsets the cost or benefit experienced by the smoker—which is what distinguishes the entries in Tables 22 and 23 from the effects in sections XI.D.2.b.ii, XI.D.2.b.iii and XI.D.2.b.iv). While the elements in Tables 22 and 23 do contribute to DCS_{full}, we posit that they should not be thought of as included in DCS_{money} because they are intricately related to the mortality and morbidity effects of smoking that, unlike the after-tax price of cigarettes, are likely characterized by time inconsistency, incomplete information or other sources of market failure.

Society will be at the intersection of Demand and DCS_{money} if the health costs associated with smoking are not known or, if known, cannot be ''internalized'' and incorporated into consumption decisions. The current widespread awareness that smoking poses health risks and the significant decline in smoking rates over the past 50 years make it highly implausible that actual consumption is near that hypothetical level. The intersection of the Demand line and DCS_{full} represents the other extreme. At that hypothetical level, consumers are fully aware of all known risks and have internalized all health costs and incorporated them into consumption decisions. The economic models and empirical studies of addiction, self–control, and time inconsistency (which we discuss in detail in our response to comments on the preliminary analysis) strongly suggest that health costs are not fully internalized; the behaviors that lead to less-than-full internalization appear to be common. In surveys, many smokers express a desire to quit and report that they have tried to stop smoking. The demand for various aids to smoking cessation provides further evidence of less-than-full internalization. Moreover, the immature judgments, short time horizons and lack of self-control of most children and adolescents—who make up the vast majority of new smokers—suggest that policy interventions that prevent initiation and encourage cessation can increase social welfare.

For these reasons, we find it implausible that actual consumption is at the intersection of Demand and DCS_{full}. The number of current smokers is therefore found at the intersection of Demand with a line falling somewhere between DCS_{full} and DCS_{money}. We have drawn this as line $DCS_{absence}$. Our finding that the graphic warning label regulation will reduce smoking rates is represented by an upward shift of this line to DCS_{rule}. (This may seem less intuitive to some readers than shifting the demand curve—which is the approach taken by Weimer *et al.* (Ref. 181)—but the two analytic methods will produce equivalent results, as we illustrate below.) The intersections of $DCS_{absence}$ and DCS_{rule} with the demand curve show the number of smokers, $Q_{absence}$ and $Q_{rule,}$ in the absence and in the presence of the final rule.

In the absence of the final rule, total cost, including health costs, for smokers is shown by the sum of areas *B* through *K.* We reiterate that, even though consumers do not internalize all costs upfront, they do ultimately incur them. The gross value smokers place on cigarette consumption (known as willingness-to-pay) is the area under the demand curve as far right as $Q_{absence}$, or $A+B+E+F+H+I+J+K$. The net value to smokers of cigarette consumption is thus $(A+B+E+F+H+I+J+K) - (B+C+D+E+F+G+H+I+J+K) = A - (C+D+G)$.

In the presence of the final rule, total expenditure, including health costs, by smokers is $B+C+E+H+J$. Smokers' willingness-to-pay is the area under the demand curve as far right as Q_{rule}, or $A+B+E+H+J$. The net value to smokers of cigarette consumption is thus $(A+B+E+H+J) - (B+C+E+H+J) = A - C$. As a result, the effect of the rule is to increase net value by $(A - C) - [A - (C+D+G)] = D+G$.

The calculations appearing in sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v each consist of multiplying ($Q_{absence} - Q_{rule}$) by some portion of ($DCS_{full} - DCS_{money}$); therefore, summing the results of D2b.ii, D2b.iii, D2b.iv and D2b.v produces an estimate of (*D*+*F*+*G*+*I*). Because we have already established that the benefit of the rule is (*D*+*G*), reporting the unadjusted sum of results from sections XI.D.2.b.ii, XI.D.2.b.iii, XI.D.2.b.iv and XI.D.2.b.v would cause us to overestimate the benefits of the final rule by an amount equal to (*D*+*F*+*G*+*I*) − (*D*+*G*) = (*F*+*I*). As drawn in Figure E1, (*F*+*I*) is approximately 50 percent of the unadjusted estimate, (*D*+*F*+*G*+*I*). FDA does not claim that 50 percent is the correct ratio; the correct ratio of (*F*+*I*) to (*D*+*F*+*G*+*I*) is determined by the shape of the demand curve as it divides areas *F* and *G* and, more pertinently, by the relative height differences between DCS_{full} and DCS_{rule} and between $DCS_{absence}$ and DCS_{money}. ($DCS_{full} - DCS_{rule}$) may be much greater than ($DCS_{absence} - DCS_{money}$) or it may be much less, yielding a ratio that may be near zero or may be near 100 percent, depending on the starting height of $DCS_{absence}$ and the size of the policy-induced reduction in smoking.

We now parameterize this model using the literature on the economics of habits and addiction. (We note, however, that rigorous quantitative welfare analyses of tobacco control interventions are rare in published, peer-reviewed literature, so the estimates generated below should not be viewed as definitive.) First, the Robert Wood Johnson Foundation (Ref. 137) reports that, as of 2009, State and Federal taxes made up 40.4 percent of the total retail price of cigarettes. With the Federal cigarette excise tax being $1.01 per pack (Ref. 164) and the population-weighted average State tax being $1.33 per pack (Ref. 165, with population weights from Ref. 130), we estimate the average after-tax price of a pack of cigarettes, or the height of DCS_{money}, to be $5.78. FDA's analysis in section XI.D.2.b of the benefits of smoking reduction has produced an estimate of discounted internal health and financial effects (reduced mortality, morbidity, medical costs and implicit smoking subsidy) that ranges from $2.10 billion to $27.80 billion in total, or from $4.56 to $27.69 per pack; this range indicates the range of potential height differences between DCS_{full} and DCS_{money}. We can derive the heights of the remaining DCS curves from a simulation conducted by Gruber and Köszegi (Ref. 104), in which they estimate the tax rate that would allow time-inconsistent smokers to consume the quantity that would be optimal under perfect rationality. Because this quantity is found at the intersection of the demand curve and DCS_{full}, Gruber and Köszegi's tax result provides an estimate of $DCS_{full} - DCS_{absence}$. Gruber and Köszegi first estimate an internal health cost of $30.45 per pack. From this, they calculate an internality tax that ranges from $0.98 to $2.89 (depending on technical parameters of their model), with an average of $2.17. FDA's internal health and financial cost estimates differ from Gruber and Köszegi's in a number of respects, including discount rate and use of a VSLY rather than value of a statistical life approach. We therefore scale the $2.17 internality tax estimate according to the ratio between our internal health and financial cost estimates and the $30.45 result found by Gruber and Köszegi; this produces internality tax estimates ranging from $0.33 to $1.98. Subtracting these values from our estimates of DCS_{full} yields estimates of $DCS_{absence}$ ranging from $10.01 to $31.49. Knowing $DCS_{absence}$ and $Q_{absence}$, we can use a Gruber and Köszegi elasticity estimate, −0.803, to find the height of DCS_{rule}. This calculation yields estimates of the difference between DCS_{rule} and DCS_{full} that range from $0.27 to $1.81. If we assume a linear demand curve (in which case *F* will be 50 percent of the sum of *F* and *G*), this indicates that consumer surplus loss offsets roughly 93 percent of rule-induced internal health benefits. An analogous calculation using the $7.50 per pack tax suggested by Gruber (Ref. 133) indicates that consumer surplus loss offsets roughly 76 percent of rule-induced internal health benefits.

Figures E2 and E3 illustrate the underlying model for the benefits analysis and the uncertainty associated with the changes in consumer surplus resulting from the final rule and other tobacco control policies. The diagrams are elaborations on Figure E1, and lines and areas should be interpreted as discussed in the explanation of that figure. (Full internalization in Figure E2 corresponds to DCS_{full} in Figure E1; no internalization in Figure E2 corresponds to DCS_{money} in Figure E1.) Both of the diagrams below show the effects on lifetime smoking of differing degrees of average internalization of the full costs of smoking. Figure E2 shows a rise in the full price (equal to the money price plus the internalized cost), while Figure E3 shows a downward shift in demand equal to the level where all costs are internalized; both diagrams illustrate how the market evolves as it moves leftward from the no-internalization equilibrium to the full-internalization equilibrium. We note that the net internal benefits to smokers of smoking reductions, shown as shaded triangles or trapezoids above the full-internalization demand curve, are the same size in each diagram. Moreover, the area representing benefits decreases in size as the size of the smoking population decreases. We assume that the market is currently at some intermediate point given by the intersection of one of the dashed (partial internalization) price lines with the solid demand curve or the intersection of one of the dashed (partial internalization) demand curves with the solid money price line, but we are not able to definitively estimate where that point is today or where it will be after this final rule takes effect.

Figure E2. Smoking Market Illustrated with Shifting Full Cost Lines

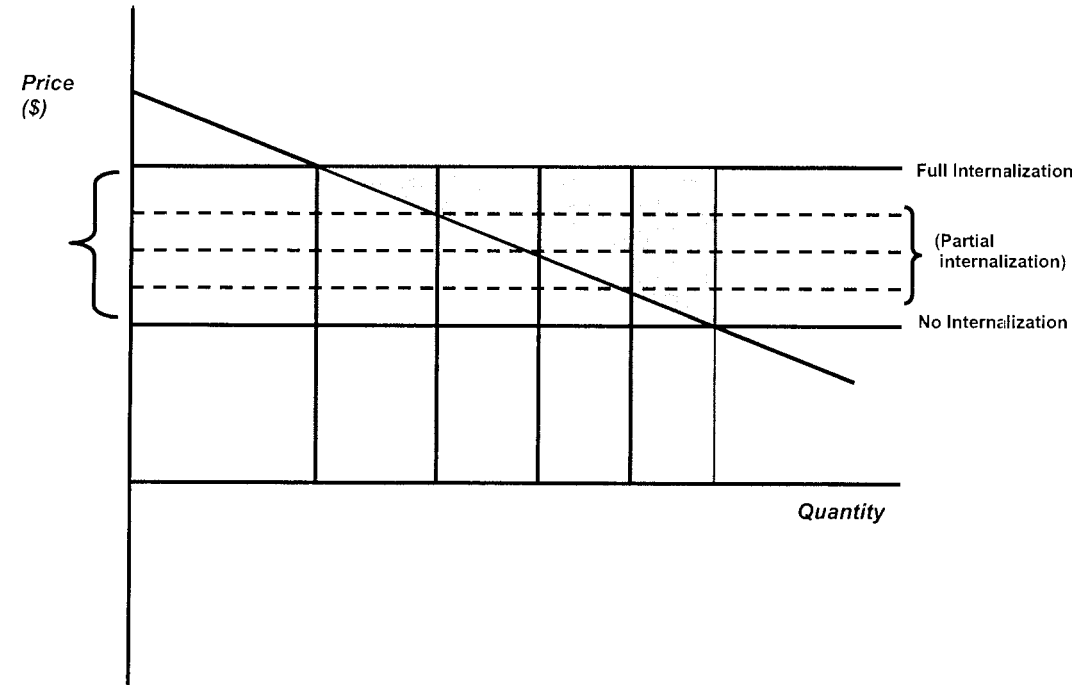
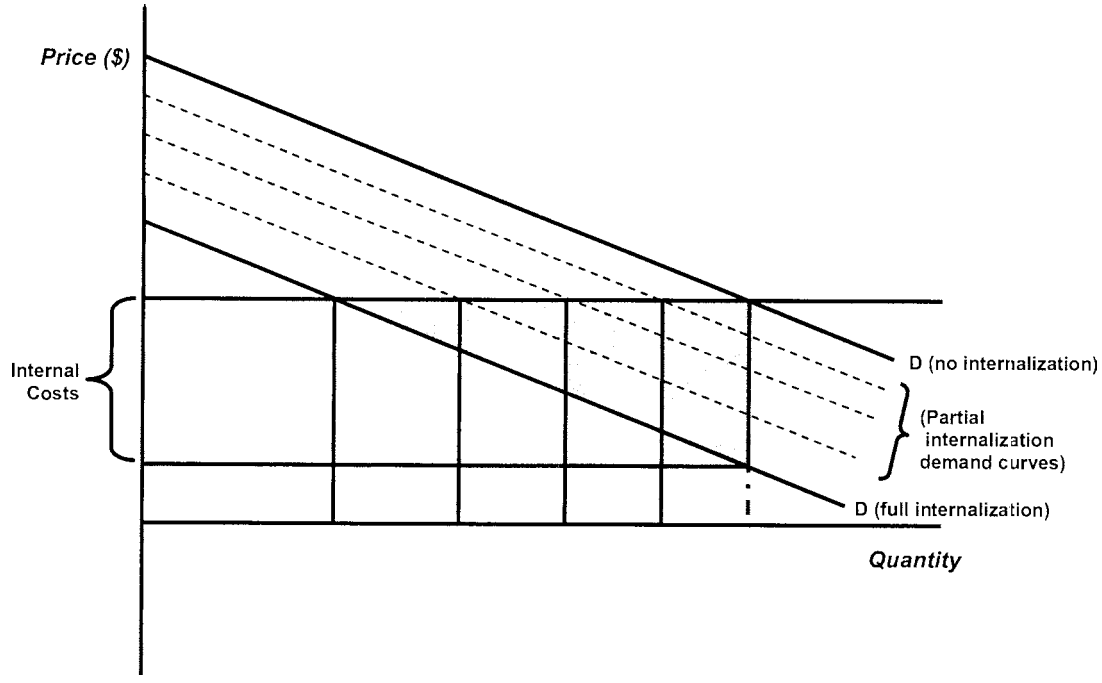


Figure E3. Smoking Market Illustrated with Shifting Demand Curves



VI. Technical Appendix X6: Uncertainty Analysis

Estimation of the effectiveness of the rule (on reducing the future U.S. smoking rate) is subject to a large uncertainty that is not fully reflected in the benefits estimates appearing in the preceding sections, which only reflect different estimates of the VSLY and different discount rates. In this section, we show the uncertainty associated with our estimate of the effectiveness of the rule.

A. Alternative Estimation of Smoking Rate Reduction

Our primary estimate, that the U.S. smoking rate will decrease by 0.088 percentage points, was calculated in the following steps. First, we found the decrease in Canadian smoking rates

since 1994 over and above what would have been expected using the pre-2001 trend and accounting for the effect of excise tax changes. We then subtracted the analogous unexplained decrease in the U.S. smoking rate over the same period. This second step was driven by the idea that the U.S. experience could proxy for recent social or policy changes (such as public smoking restrictions) that may have had effects on Canada's smoking rate and thus needed to be subtracted in order to isolate the effect of graphic warning labels. The last step was to calculate the difference between United States and Canadian unexplained decreases in smoking before and after graphic warning labels were introduced in Canada. We attributed the remaining unexplained difference to graphic warning labels.

However, the U.S. social and policy climate may have been so different from Canada's during the years 1994–2009 that this proxy is inappropriate. To account for this possibility, we calculate the unexplained difference in Canadian smoking rates before and after graphic warning labels were introduced, this time omitting any U.S. adjustments. We assume that antismoking policies and programs other than the graphic warning labels are incorporated in the pre-2001 trend, with no additional effects of these variables occurring after the introduction of graphic warning labels. This approach indicates that graphic warning labels may have been responsible for a 0.574 percentage point decrease in the Canadian smoking rate. If the rule were to achieve this effectiveness level in the United States, benefits would be approximately six times larger than those reported earlier in this analysis. For example, our benefits estimates calculated with a VSLY of $318,923 and a net-to-gross benefits ratio of 90 percent rise from $1,681.0 million with a 3 percent discount rate and $517.5 million with a 7 percent discount rate (see Table 9b) to $10,916.6 and $3,360.7 million. We use these last two numbers as global upper bounds in Table 1.

Although both of the estimation methods discussed thus far lead to the conclusion that graphic warning labels will reduce smoking rates, FDA has had access to very small data sets, so our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate. Therefore, the appropriate lower bound on benefits is zero. Ranges of benefits, representing the zero-effect case and the Canada-only modeling approach, appear in Table 49. The wide ranges shown in the table highlight the uncertainty inherent in our approach.

Table 49.--Ranges of Benefits ($ billion)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Present Value	[0 , 33.8]	[0 , 9.0]	[0 , 60.9]	[0 , 15.2]	[0 , 88.0]	[0 , 21.2]
Annualized Valuc (Over Twenty Years)	[0 , 2.3]	[0 , 0.8]	[0 , 4.1]	[0 , 1.4]	[0 , 5.9]	[0 , 2.0]

B. Monte Carlo Simulation

In addition to the uncertainty surrounding the effectiveness of graphic warning labels at reducing smoking rates, the other principal uncertainty in our benefits analysis is the value to smokers of cessation or avoided initiation. As discussed in section XI.D.2, we use two methods and several net-to-gross benefits ratios to produce a range of value estimates. For every percentage point reduction in the national smoking rate, these estimates become $4.2 to $281.6 billion (with a 3 percent discount rate) or $1.3 to $61.1 billion (with a 7 percent discount rate). Similarly, for every percentage point reduction in the national smoking rate, estimates of benefits accruing to the general public (including fire loss and financial effects) range from $6.1 to $14.7 billion (with a 3 percent discount rate) or $4.3 to $11.6 billion (with a 7 percent discount rate). Details appear in Table 50.

Table 50.--Benefits Ranges, Per Percentage Point Reduction in Smoking Rate ($ mil)

	3% Discount Rate			7% Discount Rate		
	VSLY= $106,308	VSLY= $212,615	VSLY= $318,923	VSLY= $106,308	VSLY= $212,615	VSLY= $318,923
Accruing to Dissuaded Smokers:						
Lower Bound	4,191.0	4,191.0	4,191.0	1,489.5	3,007.7	3,648.8
Upper Bound	96,196.9	188,907.5	281,618.1	22,386.4	42,260.2	62,134.0
Accruing to General Public:						
Lower Bound	6,097.1	6,982.8	7,868.6	2,017.9	2,257.9	2,497.9
Upper Bound	12,895.9	13,781.7	14,667.4	6,230.0	6,470.0	6,710.0

We estimate the 90th percentile range for the present and annualized values of total benefits with a Monte Carlo simulation. We model the distribution of the decline in smoking rates with a non-parametric bootstrap, in which we draw from discrete uniform distributions an individual year's United States-Canada adjusted smoking rate difference from the graphic warning label period (in Canada) and an individual year's difference from the pre-graphic warning label period. To account for uncertainty in the value to dissuaded smokers of cessation or avoided initiation, we use for each discount rate and VSLY a uniform distribution running from the lower

bound estimate to the upper bound estimate, as shown in Table 50. Benefits accruing to the general public are modeled analogously, with a uniform distribution bounded below and above by the values appearing in the table. We run 100,000 iterations for each simulation and report our results in Table 51. Both positive and negative results appear in the table because some paired-year United States-Canada differences show graphic warning labels decreasing the Canadian smoking rate and some paired-year differences show them increasing the smoking rate. (The second finding is almost certainly due to survey noise. More specifically, ordinary sampling variation will cause the percentage of smokers contained in a survey sample to change from one year or country to the next; this is separate from any underlying change in the true smoking rate. Depending on the sizes and directions of the relative changes, a comparison of country-year pairs can show the smoking rate increasing even when it has actually decreased, or vice versa. Because we expect this survey noise to overestimate the smoking rate change in some years and underestimate it in others, in our primary estimate, we take an average over all the years for which we have data in order to estimate as reliably as possible the true underlying change.) The wide differences in benefits shown in the table highlight the uncertainty inherent in our analysis.

Table 51.--Monte Carlo Simulation Ranges of Benefits ($ billion)

	VSLY=$106,308		VSLY=$212,615		VSLY=$318,923	
	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate	3% Discount Rate	7% Discount Rate
Present Value	[-54.0 , 69.4]	[-14.3 , 18.1]	[-100.3 , 127.1]	[-24.2 , 30.9]	[-144.5 , 185.3]	[-35.5 , 43.9]
Annualized Value (Over 20 Years)	[-3.6 , 4.7]	[-1.3 , 1.7]	[-6.7 , 8.5]	[-2.3 , 2.9]	[-9.7 , 12.5]	[-3.3 , 4.1]

[FR Doc. 2011–15337 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

December 2010

Experimental Study of Graphic Cigarette Warning Labels

Final Results Report

Contract No. HHSF-223-2009-10135G
Task Order 7

Prepared for

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

Prepared by

James Nonnemaker
Matthew Farrelly
Kian Kamyab
Andrew Busey
Nathan Mann
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0212305.007.003
OMB Control No. 0910-0668

RTI Project Number
0212305.007.003

Experimental Study of Graphic Cigarette Warning Labels

Final Results Report

Contract No. HHSF-223-2009-10135G
Task Order 7

December 2010

Prepared for

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

Prepared by

James Nonnemaker
Matthew Farrelly
Kian Kamyab
Andrew Busey
Nathan Mann
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

Contents

Figure

Number **Page**

Tables

1. INTRODUCTION

1.1 Background and Purpose of Report

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law, granting the Food and Drug Administration (FDA) new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act requires nine new health warning statements on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

The Act also requires FDA to issue "regulations that require color graphics depicting the negative health consequences of smoking to accompany the nine label statements."

The new graphic warning labels required on cigarette packs must cover at least 50% of the front and back of the pack. In addition, the new graphic warning labels required in cigarette advertisements must cover at least 20% of the area of the ad. The Act permits FDA, after notice and an opportunity for the public to comment, to adjust the format, type size, color graphics, and text of any health warning statement if such change would promote greater public understanding of the risks associated with the use of tobacco products. Similarly, FDA may adjust the type size, text, and format of the warning statements as FDA determines appropriate so that both the textual warning statements and the accompanying color graphics are clear, conspicuous, legible, and appear within the specified area.

The objective of this project is to develop graphic images to accompany the nine warning statements and to conduct a series of studies to assess the relative efficacy of the graphic warning labels (i.e., warning statements plus images) at conveying information about various health risks of smoking and at encouraging smoking cessation and discouraging smoking initiation.

This report presents the results from the experimental study. Throughout the report, we use the term "warning statement" to refer to the nine statements above, "image" to refer to the images that accompany the warning statements, and "graphic warning label" to refer to the warning statement plus image. In the remainder of this section, we give an overview of the experimental design. Section 2 briefly outlines the study methods, describing in particular the measures and statistical analyses. Section 3 summarizes the results for each warning statement and warning images for a subset of key outcomes. Conclusions and limitations are discussed in Section 4.

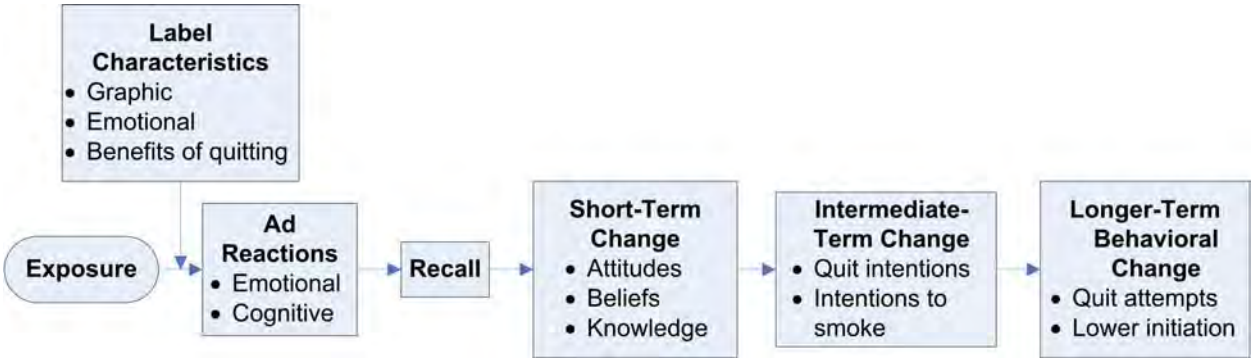
1.2 Overview of Design

Images were designed and created for each of the nine warning statements. The experimental study's purpose was to

- measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels (i.e., warning statement plus image);
- evaluate the relative efficacy of various graphic images associated with each of the nine warning statements specified in the Tobacco Control Act for achieving each of the communication goals; and
- determine whether consumer responses to graphic warning labels differ across the target groups based on age or other demographic variables.

Figure 1-1 illustrates a simple conceptual model to guide the analyses presented in this report. This conceptual model is consistent with several theories of message processing (e.g., Lang, 2000; Petty & Cacioppo, 1986) and health behavior change (Azjen, 1991; Fishbein & Azjen, 1975). This model illustrates possible short- and long-term responses to the graphic cigarette warning labels, beginning with emotional (e.g., worried, disgusted, hopeful) and cognitive (e.g., informative, worth remembering) responses. Eliciting strong emotional and cognitive reactions to the graphic cigarette warning label enhances recall and processing of the health warning, which helps ensure that the warning is better processed, understood, and remembered. Thus, these responses potentially enhance the effectiveness of the health warning. These immediate responses in turn influence short-term outcomes, such as later recall of the message and changes in knowledge, attitudes, and beliefs related to the dangers of tobacco use and exposure to secondhand smoke. As attitudes and beliefs change, they eventually lead to changes in intentions to quit/start smoking and then later to lower smoking initiation and successful cessation. The time scale on which this behavior change process occurs is largely unknown in the context of the impact of exposure to graphic warning labels on smoking behaviors, but the effects on behavior change are unlikely to be immediate or short-term. In the context of the current experiment, respondents in the treatment conditions are exposed to one graphic warning label once. Consequently, the ability of the experiment to discriminate across warning labels in terms of longer-term outcomes is limited.

Figure 1-1. Illustrative Conceptual Model of Message Processing, Reactions, and Outcomes



The respondent universe for the experimental study is (1) current smokers aged 25 or older, (2) young adult smokers aged 18 to 24, and (3) youth aged 13 to 17 who are current smokers or who may be susceptible to initiation of smoking. Because the new graphic warning labels will be required on all advertisements for cigarettes, we also tested the effect of the labels on adult responses to a cigarette advertisement. The four separate samples were selected from Research Now's e-Rewards online member panel, a national opt-in e-mail list sample.

The experimental study tested two to seven warning images per warning statement with a control group for each warning. The control group viewed a hypothetical pack of cigarettes with no warning image but just the warning statement presented in the style or format of the current standard warning. The treatment groups (exposed to warning images) viewed a hypothetical pack of cigarettes that included the graphic warning label. Each group viewed several different screen shots of the pack and were able to view the images for as long as they wanted. However, once they moved to the next image, they could not go back and view the previous image again. Thus, for each outcome, the experiment tested the relative efficacy of each warning image within a warning statement relative to the control for that warning statement.

After being shown the cigarette package with a graphic warning label (treatment group) or warning statement (control group), respondents answered questions about their reactions to the cigarette package, related attitudes and beliefs, and intentions to quit (young adults and adults) or start smoking (youth). At the end of the survey, subjects were asked to recall which warning statement and image they saw earlier in the survey to assess the accuracy of recall. In addition, 1 week after completing this survey, subjects were re-contacted and asked to recall the warning statement and image to which they were exposed.

The analyses presented below contrast the various outcomes illustrated in Figure 1-1 between each of the treatment groups exposed to an individual graphic warning label and the control group and among the treatment groups to assess the relative efficacy of each graphic warning label.

2. METHODS

In this section, we briefly outline the study methods. The survey instruments used for the study are presented in Appendix A, and additional details about the study methodology, including the coding of specific outcomes for analyses, are provided in Appendix B.

2.1 Measures

2.1.1 Key Outcomes

The following key outcomes were measured post exposure and/or at 1-week follow-up:

- Emotional and cognitive reactions to the warning statements and warning labels (i.e., warning statement plus image)
- Emotional and cognitive reactions to the print ad (adult sample viewing print ad)
- Recall of the nine warning statements
- Recall of the warning images
- Recall of the print ad (adult sample viewing print ad)
- Beliefs about the health risks of smoking and secondhand smoke
- Quit intentions (self-reported likelihood of quitting within the next 30 days)
- Self-reported likelihood of smoking 1 year from now (youth)

2.1.2 Covariates and Controls

We included the following control variables in our regression models: age, gender, race/ethnicity, socioeconomic status (income and education), and quit intentions.

2.1.3 Data Reduction/Scale Creation

As a data reduction strategy, we explored the creation of several possible measurement scales. Our approach was to use factor analysis to see if the items loaded on a single factor and, if so, to assess the alpha reliability of the scaled items. In each case where we created a scale, we found a single eigenvalue greater than 1 (typically a factor is indicated for each eigenvalue over 1). We did not use specific cut-off criteria in terms of factor loadings or alpha reliability; however, for the scales we created, factor loadings for individual items generally were greater than 0.6 and alpha reliabilities generally were greater than 0.7. In particular, we investigated the scaling of survey questions D1 (emotional reactions to the labels), D2 (cognitive reactions to the labels), D3 (beliefs about the risks of smoking), D4 (beliefs about the risks of secondhand smoke exposure), E5 (beliefs about the risks of smoking and exposure to secondhand smoke), and E6 (attitudes about smoking; only asked of youth and young adults). Based on the results from the factor analyses (conducted by warning statement), we were able to scale D1 (emotional reaction scale), D2 (cognitive

reaction scale), D3 (belief scale: health risks of smoking to smoker), and D4 (belief scale: health risks of secondhand smoke exposure to nonsmokers). The items from E5 and E6 did not scale. See Appendix B for additional information on scale creation.

2.2 Regression Analyses

We assessed the relative efficacy of the warning images using regression analyses. Regressions for each outcome were estimate separately for each warning statement.

The regression models were of the following general form:

$$\text{outcome} = f(I_i, \text{age, gender, race/ethnicity, education, income, Internet connection, plans to quit}),$$

where I_i are indicators for treatment conditions (exposure to warning images) with control group as the referent category. Thus, we are interested in the parameter estimates or beta coefficients on the image exposure indicators because these estimates represent the effect of exposure to the image compared with the effect of the exposure the controls received. The number of treatment indicators ranges from 2 to 7.

We used logistic regression for dichotomous outcomes. Ordinal outcomes were dichotomized collapsing the top two categories (e.g., agree and strongly agree). For scaled outcomes, we used ordinary least squares regression. Note that when we estimate the regression with the indicator for correct recall of the warning image, we exclude the control group respondents (because they did not view an image) and specify one of the treatment groups (warning images) as the referent category (image). Because there was no variation in the Internet connection measure, we dropped it as a control. Also note that the measures of plans to quit, education, and income were not included in the models for the youth sample: plans to quit was not included in the models for the youth sample because the measure is not meaningful for youth susceptible to smoking but not yet smoking and less salient for youth who are relatively new smokers; education was not included for youth because grade is similar to age; and income was not included because it is difficult to get valid and reliable estimates of income from youth.

In linear or ordinary least squares regression, when the outcome is continuous, the estimates of interest are the beta coefficients on each warning image indicator variable. A higher value on this coefficient indicates that exposure to the warning image is associated with a greater value on the outcome variable (e.g., a higher score on the emotional reaction scale) compared to the value of the outcome for control participants.

When using logistic regression for dichotomous outcomes, we converted the coefficient obtained from the regression for each warning image indicator into an odds ratio (OR). An OR greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR

less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

In this report, we summarize the results from the regression analyses, focusing on a set of key outcomes. Descriptive statistics and a comprehensive set of regression results are provided in Appendix C.

3. RESULTS

In this section, we present results from the experimental study described in Section 1.2. Only statistically significant results ($p < 0.05$) are discussed.

3.1 Sociodemographic Description of the Samples

Table 3-1 summarizes the sociodemographic characteristics of the four samples: adult (pack), adult (ad), young adult, and youth. All four sample sizes were over 4,500, ranging from 4,584 young adults to 4,890 adults in the pack study. The average age of adults was 43.5 and 44.7 years in the pack and ad studies, respectively. The average age was 21.6 years for young adults and 15.7 years for youth. Gender distribution was roughly even for all samples—the adult ad study was the most unbalanced at 56.1% female. White was the predominant race in all four study samples, ranging from 65.2% for young adults to 82.4% for adults in the ad study. The distribution of education levels varied across the four samples, with expected differences considering the age ranges of each study. Income differences between the adult and young adult samples were again expected given age differences. Youth were not asked about their household income. Additional details about the samples are provided in Appendix B.

Table 3-1. Summary of the Sociodemographic Characteristics of the Four Samples

Characteristic	Adult Pack	Young Adult	Youth	Adult Ad
N	4,890	4,584	4,600	4,685
Age (average)	43.5	21.6	15.7	44.7
Gender				
Male	49.4%	53.8%	52.7%	43.9%
Female	50.6%	46.2%	47.3%	56.1%
Race/Ethnicity				
White	77.9%	65.2%	68.7%	82.4%
Black	6.5%	2.8%	5.4%	4.3%
Hispanic	9.3%	17.1%	14.1%	6.4%
Other	6.4%	14.9%	11.9%	6.9%
Education Level				
Elementary or middle school	0.2%	0.2%	10.3%	0.4%
High school	0.9%	0.8%	86.9%	1.1%
High school graduate	13.0%	11.9%	2.8%	12.8%
Some college	32.4%	56.3%	—	34.0%
College graduate or more	53.4%	30.8%	—	51.6%
Income				
Less than $25,000	11.2%	32.4%	—	8.9%
Between $25,000 and $49,999	24.9%	32.4%	—	26.1%
Between $50,000 and $74,999	27.2%	17.5%	—	26.6%
More than $75,000	36.7%	17.7%	—	38.5%

3.2 Warning Statement 1: Cigarettes are Addictive

Cigarette Injection

Red Puppet


Hole in Throat


Woman in Rain

3.2.1 Emotional and Cognitive Reactions

Cigarette Injection, Red Puppet, and Hole in Throat consistently elicited higher scores on the emotional reaction scale (e.g., disgusted, worried) from adults, young adults, and youth compared with the control group who did not view the images (see Table 3-2, presented at the end of this section). Woman in Rain elicited higher scores on this scale from adults and young adults compared with controls.

Similarly, Cigarette Injection, Red Puppet, and Hole in Throat elicited higher scores on the cognitive reaction scale (e.g., informative, worth remembering) from adults, young adults, and youth compared with controls. Woman in Rain elicited a higher score on this scale only from youth.

Cigarette Injection, Hole in Throat, and Woman in Rain elicited a stronger response (i.e., higher odds of agreeing that the pack was difficult to look at) from adults and young adults compared with controls. Among youth, only Hole in Throat evoked a stronger response compared with the control condition.

3.2.2 Recall of Warning Statements and Images at Baseline and Follow-up

At baseline, Cigarette Injection prompted higher correct recall of the warning statement for adults and young adults compared with the control condition (Table 3-2). At 1-week follow-up, Red Puppet elicited higher correct recall for young adults compared with the control condition. In contrast, Hole in Throat elicited relatively lower correct recall at follow-up for young adults compared with the control condition. Cigarette Injection, Red Puppet, and Hole in Throat were more likely to elicit correct recall of the warning image at baseline and follow-up than the referent image (Woman in Rain).

3.2.3 Influences on Beliefs

Cigarette Injection, Hole in Throat, and Woman in Rain elicited stronger beliefs (i.e., higher scale scores) about the health risks of smoking (e.g., more likely to believe that regular smokers will get cancer, have fatal lung disease) compared with the control condition for adults (Table 3-3).

Hole in Throat evoked stronger beliefs about the health risks of exposure to secondhand smoke to nonsmokers (e.g., more likely to believe that nonsmokers will get cancer, heart disease) compared with the control condition for adults.

3.2.4 Behavioral Responses

Cigarette Injection was associated with higher intentions to quit in the next 30 days compared with the control condition for young adults (Table 3-3).

3.2.5 Adult Advertisement Study

In the adult advertisement study, all of the warning images except Red Puppet received higher scores on the emotional reaction scale (e.g., disgusted, worried) compared with the control condition (see Table 3-2). Cigarette Injection, Red Puppet, and Hole in Throat elicited higher scores on the cognitive reaction scale (e.g., informative, worth remembering) compared with the control condition. All warning images were reported as difficult to look at relative to controls.

Hole in Throat prompted lower correct recall of the warning statement at follow-up compared with the control condition. Red Puppet was more likely to evoke correct recall of the warning image at baseline and follow-up compared with the referent image. As noted in Section 2 (Methods), we excluded the control group respondents from this analysis because they did not view an image. Thus, when we estimated the regression with the indicator for correct recall of the warning image, we specified one of the treatment groups (warning images) as the referent category (image). In this case, Woman in Rain is the referent image.

Cigarette Injection elicited a less favorable response (i.e., lower score) on the health risks of smoking beliefs scale (e.g., less likely to believe that regular smokers will get cancer, have fatal lung disease) compared with the control condition (see Table 3-3).

Table 3-2. Emotional and Cognitive Reactions and Recall for Warning Statement 1

Sample / image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Cigarette injection	4.022***	(0.000)	1.893**	(0.001)	4.190***	(0.001)	2.125*	(0.049)	0.944	(0.879)	9.892***	(0.000)	10.798***	(0.000)
Red puppet	3.046***	(0.000)	1.790**	(0.002)	3.033**	(0.009)	1.361	(0.387)	1.506	(0.297)	5.034***	(0.000)	6.035***	(0.000)
Hole in throat	5.233***	(0.000)	2.664***	(0.000)	5.380***	(0.000)	0.831	(0.576)	0.745	(0.424)	4.134***	(0.000)	5.125***	(0.000)
Woman in rain	1.877**	(0.005)	0.955	(0.098)	2.392*	(0.045)	0.998	(0.994)	0.994	(0.987)	Ref.	Ref.	Ref.	Ref.
Observations	539		539		539		539		394		433		316	
Young Adult														
Cigarette injection	3.933***	(0.000)	3.326***	(0.000)	2.590*	(0.014)	2.083*	(0.042)	2.135	(0.109)	12.936***	(0.000)	16.736***	(0.000)
Red puppet	2.282**	(0.001)	1.748**	(0.006)	1.640	(0.227)	1.327	(0.396)	4.288**	(0.009)	5.266***	(0.000)	15.425***	(0.000)
Hole in throat	5.485***	(0.000)	2.352***	(0.000)	5.446***	(0.000)	0.697	(0.247)	0.367*	(0.010)	5.881***	(0.000)	5.957***	(0.000)
Woman in rain	2.423***	(0.000)	0.542	(0.388)	2.750**	(0.009)	1.181	(0.609)	1.666	(0.247)	Ref.	Ref.	Ref.	Ref.
Observations	507		507		507		507		342		404		268	
Youth														
Cigarette injection	2.706***	(0.000)	4.888***	(0.000)	1.151	(0.716)	1.103	(0.840)	2.421	(0.083)	14.152***	(0.000)	22.280***	(0.000)
Red puppet	1.557*	(0.018)	3.326***	(0.000)	1.317	(0.468)	1.129	(0.803)	2.049	(0.145)	5.388***	(0.000)	4.221***	(0.001)
Hole in throat	3.932***	(0.000)	4.036***	(0.000)	4.180***	(0.000)	0.627	(0.295)	0.772	(0.536)	7.786***	(0.000)	7.985***	(0.000)
Woman in rain	1.273	(0.053)	1.833**	(0.003)	1.413	(0.360)	0.515	(0.124)	1.354	(0.495)	Ref.	Ref.	Ref.	Ref.
Observations	511		512		512		512		300		410		239	
Adult Ad														
Cigarette injection	3.462***	(0.000)	1.912**	(0.003)	13.255***	(0.001)	1.385	(0.464)	0.824	(0.682)	1.865	(0.113)	1.674	(0.180)
Red puppet	0.922	(0.153)	1.305*	(0.043)	8.287**	(0.007)	0.583	(0.160)	0.821	(0.682)	4.431**	(0.002)	3.139**	(0.009)
Hole in throat	5.042***	(0.000)	3.442***	(0.000)	31.437***	(0.000)	0.568	(0.136)	0.259**	(0.002)	1.337	(0.422)	2.091	(0.071)
Woman in rain	1.942**	(0.003)	0.838	(0.193)	8.524**	(0.006)	0.748	(0.458)	0.562	(0.203)	Ref.	Ref.	Ref.	Ref.
Observations	517		517		517		517		402		413		329	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-3. Influences on Beliefs and Behavior for Warning Statement 1

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Cigarette injection	2.039***	(0.001)	0.892	(0.101)	1.215	(0.577)
Red puppet	0.670	(0.273)	0.284	(0.598)	0.763	(0.444)
Hole in throat	1.544*	(0.013)	1.099*	(0.044)	1.060	(0.869)
Woman in rain	1.489*	(0.015)	0.559	(0.300)	0.946	(0.873)
Observations	539		539		539	
Young Adult						
Cigarette injection	0.027	(0.967)	0.789	(0.169)	2.011*	(0.044)
Red puppet	−0.464	(0.469)	−0.029	(0.960)	1.149	(0.696)
Hole in throat	0.344	(0.590)	0.965	(0.095)	1.108	(0.773)
Woman in rain	−0.906	(0.154)	−0.133	(0.816)	0.835	(0.609)
Observations	507		507		506	
Youth						
Cigarette injection	0.159	(0.794)	0.001	(0.999)	0.927	(0.812)
Red puppet	0.337	(0.582)	−0.032	(0.955)	1.085	(0.800)
Hole in throat	0.300	(0.624)	−0.272	(0.631)	1.220	(0.545)
Woman in rain	0.474	(0.442)	−0.024	(0.966)	0.894	(0.722)
Observations	512		512		512	
Adult Ad						
Cigarette injection	−1.514**	(0.010)	−0.404	(0.458)	1.587	(0.178)
Red puppet	−0.370	(0.527)	0.160	(0.770)	1.262	(0.508)
Hole in throat	−0.333	(0.566)	−0.244	(0.652)	0.865	(0.687)
Woman in rain	−0.645	(0.270)	−0.070	(0.898)	0.538	(0.097)
Observations	517		517		517	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.3 Warning Statement 2: Tobacco Smoke Can Harm Your Children

Smoke at Toddler

Girl Crying

Girl in Oxygen Mask

Smoke at Baby

Smoke Approaching Baby

Warning in Child Lettering

3.3.1 Emotional and Cognitive Reactions

All six warning images elicited higher scores on the emotional reaction scale (e.g., disgusted, worried) compared with the control condition for adults, young adults, and youth (see Table 3-4 at the end of this section).

All six warning images also received higher scores on the cognitive reaction scale (e.g., informative, worth remembering) from adults, young adults, and youth compared with the control condition (see Table 3-4 at the end of this section).

Smoke at Toddler, Girl Crying, Girl in Oxygen Mask, and Smoke Approaching Baby elicited a stronger response (i.e., higher odds of agreeing) to the reaction item "the pack was difficult to look at" compared with the control condition for adults, young adults, and youth. Smoke at Baby evoked a stronger response from adults and youth compared with the control condition.

3.3.2 Recall of Warning Statements and Images at Baseline and Follow-up

Girl Crying, Smoke Approaching Baby, and Warning in Child Lettering elicited higher correct recall of the warning statement at baseline compared with the control condition for adults (see Table 3-4). Warning in Child Lettering prompted higher correct recall of the warning statement at baseline for young adults compared with controls, and Smoke Approaching Baby prompted higher correct recall for youth. Girl Crying, Smoke at Baby, and Warning in Child Lettering elicited higher correct recall of the warning statement at follow-up compared with the control group for adults and young adults. In addition, Smoke Approaching Baby prompted higher correct recall at follow-up for young adults. Warning in Child Lettering elicited higher correct recall of the warning statement at follow-up for youth compared with the control condition.

Compared with the referent image (Girl Crying), Warning in Child Lettering elicited lower correct recall of the warning image at baseline and follow-up for adults, young adults, and youth.

3.3.3 Influences on Beliefs

Among young adults and youth, none of the warning images were significantly associated with beliefs about the health risks of smoking or of secondhand smoke exposure compared with the control condition (see Table 3-4 at the end of this section). Among adults, Girl Crying and Girl in Oxygen Mask were negatively associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers (i.e., less likely to believe that nonsmokers will get cancer, heart disease).

3.3.4 Behavioral Responses

None of the warning images were significantly associated with quit intentions among adults and young adults compared with controls (see Table 3-5). However, Girl Crying and Smoke Approaching Baby were positively associated with the likelihood of smoking 1 year from now for youth (i.e., respondents who viewed these images were more likely than controls to report being moderately to extremely likely to be smoking 1 year from now).

3.3.5 Adult Advertisement Study

Consistent with the results above, all warning images in the adult ad study received higher scores on the emotional and cognitive reaction scales compared with the control condition (see Table 3-4). Furthermore, all images evoked a stronger response (i.e., more likely to agree) to the reaction item “the ad was difficult to look at” compared with the control group.

Warning in Child Lettering prompted higher correct recall of the warning statement at baseline only compared with the control condition. Smoke at Toddler elicited lower correct recall of the warning image at baseline and follow-up compared with the referent image Girl Crying. Furthermore, Smoke at Baby prompted lower correct recall at baseline compared with Girl Crying. Finally, Smoke at Baby was associated with lower quit intentions in the next 30 days compared with the control condition for adults in the ad study (see Table 3-5).

Table 3-4. Emotional and Cognitive Reactions and Recall for Warning Statement 2

Sample / image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Smoke at toddler	4.764***	(0.000)	1.900**	(0.003)	6.593***	(0.000)	1.767	(0.094)	1.700	(0.174)	0.430	(0.091)	0.682	(0.441)
Girl crying	4.007***	(0.000)	1.593*	(0.013)	6.515***	(0.000)	5.132***	(0.000)	3.424**	(0.005)	Ref.	Ref.	Ref.	Ref.
Girl in oxygen mask	4.855***	(0.000)	2.556***	(0.000)	13.478***	(0.000)	1.172	(0.626)	1.099	(0.799)	0.745	(0.592)	1.439	(0.531)
Smoke approaching baby	3.888***	(0.000)	2.715***	(0.000)	5.158***	(0.000)	2.012*	(0.045)	1.654	(0.188)	0.908	(0.865)	1.300	(0.626)
Smoke at baby	4.173***	(0.000)	2.258***	(0.000)	5.484***	(0.000)	1.538	(0.201)	2.668*	(0.023)	0.524	(0.212)	1.277	(0.672)
Warning in child lettering	2.827***	(0.000)	1.742**	(0.007)	1.156	(0.766)	2.343*	(0.021)	2.665*	(0.020)	0.047***	(0.000)	0.076***	(0.000)
Observations	748		748		748		748		534		641		454	
Young Adult														
Smoke at toddler	3.863***	(0.000)	2.293***	(0.000)	2.364**	(0.009)	1.176	(0.661)	1.683	(0.202)	0.464	(0.227)	2.057	(0.420)
Girl crying	4.919***	(0.000)	2.660***	(0.000)	5.922***	(0.000)	2.112	(0.079)	3.111*	(0.021)	Ref.	Ref.	Ref.	Ref.
Girl in oxygen mask	4.297***	(0.000)	3.075***	(0.000)	4.900***	(0.000)	0.866	(0.684)	1.262	(0.562)	0.614	(0.464)	0.974	(0.971)
Smoke approaching baby	2.138**	(0.005)	3.012***	(0.000)	2.145*	(0.023)	1.627	(0.221)	3.217*	(0.023)	0.998	(0.997)	4.328	(0.200)
Smoke at baby	2.736***	(0.000)	2.426***	(0.000)	1.477	(0.259)	1.509	(0.294)	2.649*	(0.040)	0.962	(0.957)	3.931	(0.230)
Warning in child lettering	1.733*	(0.023)	1.933***	(0.000)	1.279	(0.487)	3.232*	(0.013)	2.677*	(0.037)	0.038***	(0.000)	0.083***	(0.000)
Observations	709		709		709		709		500		607		425	
Youth														
Smoke at toddler	4.427***	(0.000)	2.317***	(0.000)	5.620***	(0.000)	0.894	(0.758)	2.395	(0.079)	0.376	(0.110)	0.130	(0.062)
Girl crying	3.994***	(0.000)	3.230***	(0.000)	9.399***	(0.000)	1.446	(0.352)	1.330	(0.530)	Ref.	Ref.	Ref.	Ref.
Girl in oxygen mask	4.101***	(0.000)	4.098***	(0.000)	5.418***	(0.000)	0.746	(0.408)	0.646	(0.305)	0.667	(0.543)	0.323	(0.338)
Smoke approaching baby	4.431***	(0.000)	3.738***	(0.000)	5.737***	(0.000)	2.543*	(0.039)	1.906	(0.175)	0.562	(0.371)	.	.
Smoke at baby	3.448***	(0.000)	2.532***	(0.000)	3.647**	(0.002)	0.827	(0.597)	0.798	(0.593)	0.661	(0.531)	0.258	(0.234)
Warning in child lettering	2.040**	(0.004)	1.821***	(0.000)	2.014	(0.116)	1.211	(0.617)	3.193*	(0.029)	0.026***	(0.000)	0.015***	(0.000)
Observations	713		714		714		714		378		612		273	
Adult Ad														
Smoke at toddler	3.542***	(0.000)	2.769***	(0.000)	9.341***	(0.000)	1.964	(0.091)	1.170	(0.721)	0.125***	(0.000)	0.409*	(0.043)
Girl crying	4.027***	(0.000)	1.752**	(0.006)	18.947***	(0.000)	1.828	(0.110)	2.515	(0.065)	Ref.	Ref.	Ref.	Ref.
Girl in oxygen mask	3.609***	(0.000)	3.085***	(0.000)	9.542***	(0.000)	0.770	(0.450)	1.082	(0.856)	0.565	(0.367)	0.890	(0.812)
Smoke approaching baby	3.155***	(0.000)	2.892***	(0.000)	5.178**	(0.004)	1.870	(0.109)	1.235	(0.632)	0.480	(0.228)	1.026	(0.958)
Smoke at baby	4.046***	(0.000)	2.385***	(0.000)	8.720***	(0.000)	1.096	(0.796)	0.624	(0.241)	0.311*	(0.044)	1.171	(0.753)
Warning in child lettering	3.424***	(0.000)	3.027***	(0.000)	3.686*	(0.028)	3.677**	(0.005)	1.735	(0.226)	1.380	(0.672)	0.817	(0.666)
Observations	727		727		727		727		567		624		483	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-5. Influences on Beliefs and Behavior for Warning Statement 2

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Smoke at toddler	0.049	(0.935)	−0.599	(0.274)	1.000	(0.999)
Girl crying	0.280	(0.645)	−1.249*	(0.024)	1.556	(0.221)
Girl in oxygen mask	−0.816	(0.177)	−1.533**	(0.005)	1.495	(0.262)
Smoke approaching baby	0.362	(0.548)	−1.025	(0.062)	1.352	(0.405)
Smoke at baby	0.271	(0.653)	−0.388	(0.479)	1.199	(0.620)
Warning in child lettering	0.602	(0.322)	−0.053	(0.924)	1.964	(0.057)
Observations	748		748		748	
Young Adult						
Smoke at toddler	0.545	(0.368)	−0.545	(0.361)	1.391	(0.319)
Girl crying	0.188	(0.756)	0.399	(0.504)	0.741	(0.375)
Girl in oxygen mask	0.305	(0.611)	0.451	(0.445)	1.165	(0.644)
Smoke approaching baby	0.198	(0.744)	0.298	(0.619)	1.187	(0.607)
Smoke at baby	0.522	(0.390)	0.035	(0.954)	0.836	(0.593)
Warning in child lettering	0.168	(0.783)	0.009	(0.988)	1.112	(0.750)
Observations	709		709		709	
Youth						
Smoke at toddler	−0.893	(0.153)	0.470	(0.426)	1.514	(0.160)
Girl crying	−0.320	(0.609)	1.036	(0.080)	1.823*	(0.045)
Girl in oxygen mask	−0.711	(0.256)	0.336	(0.570)	1.710	(0.072)
Smoke approaching baby	−0.079	(0.900)	0.832	(0.158)	1.990*	(0.023)
Smoke at baby	−0.331	(0.596)	0.586	(0.321)	1.615	(0.105)
Warning in child lettering	−0.638	(0.307)	0.462	(0.434)	1.693	(0.075)
Observations	714		714		714	
Adult Ad						
Smoke at toddler	0.594	(0.316)	0.295	(0.585)	0.916	(0.804)
Girl crying	0.192	(0.744)	0.339	(0.529)	0.978	(0.949)
Girl in oxygen mask	−0.143	(0.810)	−0.598	(0.270)	0.766	(0.461)
Smoke approaching baby	0.151	(0.798)	0.084	(0.877)	0.871	(0.698)
Smoke at baby	−0.859	(0.146)	−0.118	(0.826)	0.479*	(0.047)
Warning in child lettering	−0.374	(0.528)	0.021	(0.969)	0.866	(0.686)
Observations	727		727		727	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.4 Warning Statement 3: Cigarettes Cause Fatal Lung Disease

Toe Tag

Healthy/Diseased Lungs

Lungs Full of Cigarettes

Dr. with X-ray

3.4.1 Emotional and Cognitive Reactions

All four warning images received higher scores on the emotional and cognitive reaction scales from adults, young adults, and youth compared with the control group (see Table 3-6 at the end of this section).

All four images evoked a stronger response (i.e., more likely to agree) to the reaction item "the ad was difficult to look at" from adults and youth compared with the control group. Among young adults, all images except for Dr. with X-ray evoked a stronger response to this item compared with the control group.

3.4.2 Recall of Warning Statements and Images at Baseline and Follow-up

Lungs Full of Cigarettes and Dr. with X-ray prompted higher correct recall of the warning statement at baseline and follow-up among young adults. Among youth, Toe Tag prompted lower correct recall of the warning statement at baseline, whereas Dr. with X-ray prompted higher correct recall at follow-up. Healthy/Diseased Lungs and Lungs Full of Cigarettes elicited higher correct recall of the warning image at baseline and follow-up among adults and youth than the referent image (Dr. with X-Ray). Lung Full of Cigarettes elicited higher correct recall of the warning image at baseline only than Dr. with X-ray for young adults.

3.4.3 Influences on Beliefs

None of the warning images were significantly associated with beliefs about health risks to regular smokers for adults, young adults, or youth compared with the control group (see Table 3-7 at the end of this section). Among young adults, Dr. with X-ray was negatively associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers (i.e., less likely to believe that nonsmokers will get lung cancer, heart disease).

3.4.4 Behavioral Responses

None of the warning images were significantly associated with the likelihood of quitting in the next 30 days (among adults and young adults) or the likelihood of smoking 1 year from now (among youth) compared with the control group (see Table 3-7).

3.4.5 Adult Advertisement Study

All four warning images elicited higher scores on the emotional and cognitive reaction scales (see Table 3-6). Toe Tag, Healthy/Diseased Lungs, and Lungs Full of Cigarettes were reported as “difficult to look at” relative to controls.

At follow-up, Dr. with X-ray elicited higher correct recall of the warning statement compared with the control group. Lungs Full of Cigarettes elicited higher correct recall of the warning image at follow-up than Dr. with X-ray (the referent image) among adults exposed to warning images.

Dr. with X-ray was also negatively associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers. None of the four images were significantly associated with quit intentions relative to controls (see Table 3-7).

Table 3-6. Emotional and Cognitive Reactions and Recall for Warning Statement 3

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Toe tag	2.116**	(0.003)	2.214***	(0.000)	3.999**	(0.001)	0.684	(0.334)	0.963	(0.921)	0.884	(0.668)	0.909	(0.769)
Healthy/diseased lungs	4.929***	(0.000)	3.640***	(0.000)	12.232***	(0.000)	0.530	(0.087)	1.071	(0.854)	2.608**	(0.002)	2.342*	(0.016)
Lungs full of cigarettes	3.638***	(0.000)	2.343***	(0.000)	5.279***	(0.000)	1.148	(0.740)	2.136	(0.081)	5.148***	(0.000)	4.523***	(0.000)
Dr. with X-ray	2.877***	(0.000)	2.890***	(0.000)	3.839**	(0.001)	0.597	(0.177)	1.011	(0.978)	Ref.	Ref.	Ref.	Ref.
Observations	543		543		543		543		415		434		328	
Young Adult														
Toe tag	2.856***	(0.000)	2.321***	(0.000)	2.758**	(0.003)	1.348	(0.406)	1.167	(0.718)	0.711	(0.302)	0.643	(0.282)
Healthy/diseased lungs	4.758***	(0.000)	3.756***	(0.000)	4.682***	(0.000)	1.388	(0.362)	2.291	(0.074)	2.004	(0.066)	1.625	(0.291)
Lungs full of cigarettes	4.328***	(0.000)	2.534***	(0.000)	3.568***	(0.000)	2.684*	(0.016)	2.675*	(0.045)	2.397*	(0.028)	1.664	(0.301)
Dr. with X-ray	2.587***	(0.000)	1.596**	(0.006)	1.777	(0.104)	2.257*	(0.033)	4.271**	(0.004)	Ref.	Ref.	Ref.	Ref.
Observations	511		512		512		512		340		408		280	
Youth														
Toe tag	2.872***	(0.000)	3.652***	(0.000)	3.207**	(0.004)	0.441*	(0.026)	1.000	(1.000)	1.055	(0.860)	0.583	(0.200)
Healthy/diseased lungs	3.644***	(0.000)	6.128***	(0.000)	7.721***	(0.000)	0.931	(0.860)	1.549	(0.423)	4.084***	(0.000)	2.976*	(0.044)
Lungs full of cigarettes	3.333***	(0.000)	5.381***	(0.000)	3.703**	(0.001)	1.049	(0.909)	12.181*	(0.022)	3.696***	(0.001)	3.266*	(0.037)
Dr. with X-ray	1.773*	(0.010)	3.492***	(0.000)	2.507*	(0.026)	1.944	(0.158)	1.290	(0.625)	Ref.	Ref.	Ref.	Ref.
Observations	511		511		511		511		271		409		217	
Adult Ad														
Toe tag	3.214***	(0.000)	2.469***	(0.000)	3.678**	(0.002)	0.734	(0.481)	0.844	(0.667)	0.582	(0.196)	0.753	(0.489)
Healthy/diseased lungs	5.666***	(0.000)	4.253***	(0.000)	12.871***	(0.000)	0.531	(0.136)	2.316	(0.080)	1.628	(0.318)	1.671	(0.258)
Lungs full of cigarettes	4.069***	(0.000)	2.662***	(0.000)	3.544**	(0.003)	0.563	(0.176)	1.878	(0.149)	1.861	(0.234)	3.322*	(0.016)
Dr. with X-ray	2.793***	(0.000)	2.337***	(0.000)	1.706	(0.250)	1.249	(0.640)	2.885*	(0.033)	Ref.	Ref.	Ref.	Ref.
Observations	515		515		515		515		386		412		310	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-7. Influences on Beliefs and Behavior for Warning Statement 3

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Toe tag	0.004	(0.994)	−0.818	(0.118)	1.360	(0.383)
Healthy/diseased lungs	0.245	(0.686)	−0.876	(0.092)	1.943	(0.054)
Lungs full of cigarettes	0.768	(0.205)	−0.096	(0.853)	0.982	(0.959)
Dr. with X-ray	0.175	(0.774)	−0.096	(0.855)	1.306	(0.450)
Observations	543		543		543	
Young Adult						
Toe tag	−0.612	(0.313)	−0.296	(0.591)	1.147	(0.671)
Healthy/diseased lungs	−0.534	(0.377)	−0.392	(0.476)	0.862	(0.650)
Lungs full of cigarettes	0.119	(0.847)	−0.424	(0.448)	1.697	(0.111)
Dr. with X-ray	−0.212	(0.726)	−1.282*	(0.020)	1.034	(0.919)
Observations	512		512		512	
Youth						
Toe tag	−0.267	(0.639)	0.786	(0.159)	1.031	(0.917)
Healthy/diseased lungs	−0.577	(0.310)	−0.177	(0.751)	0.878	(0.657)
Lungs full of cigarettes	0.731	(0.199)	0.618	(0.268)	1.840	(0.053)
Dr. with X-ray	−0.099	(0.862)	0.320	(0.566)	1.322	(0.358)
Observations	511		511		511	
Adult Ad						
Toe tag	−0.470	(0.443)	−0.987	(0.074)	0.746	(0.445)
Healthy/diseased lungs	−0.561	(0.364)	−0.915	(0.100)	1.160	(0.684)
Lungs full of cigarettes	−0.936	(0.131)	−0.807	(0.148)	0.638	(0.242)
Dr. with X-ray	−0.139	(0.822)	−1.132*	(0.042)	0.875	(0.722)
Observations	515		515		515	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$, ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a greater value on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.5 Warning Statement 4: Cigarettes Cause Cancer

Deathly Ill Woman

Red Cigarette Burning

White Cigarette Burning

Cancerous Lesion on Lip

3.5.1 Emotional and Cognitive Reactions

Deathly Ill Woman, Red Cigarette Burning, White Cigarette Burning, and Cancerous Lesion on Lip elicited higher scores on the emotional and cognitive reaction scales from adults, young adults, and youth compared with the control group (see Table 3-8). Among adults, all four warning images elicited stronger responses (i.e., higher odds of agreeing) to the reaction item "the pack was difficult to look at" compared with the control condition. For young adults and youth, Deathly Ill Woman, Red Cigarette Burning, and Cancerous Lesion on Lip were reported as difficult to look at relative to controls.

3.5.2 Recall of Warning Statements and Images at Baseline and Follow-up

Deathly Ill Woman and Red Cigarette Burning prompted higher correct recall of the warning statement at baseline for adults compared with the control group (see Table 3-8). At follow-up, all images except for White Cigarette Burning elicited higher correct recall of the warning statement for adults compared with the control group. For young adults and youth, only recall of Red Cigarette Burning was significantly higher at baseline and follow-up compared with the control group. Additionally, White Cigarette Burning prompted higher correct recall of the warning statement at baseline for youth compared with the control group. Red Cigarette Burning elicited lower correct recall of the warning image at baseline and follow-up than Cancerous Lesion on Lip (the referent image) for adults, young adults, and youth. Adults and young adults exposed to White Cigarette Burning were less likely to recall the correct warning image at baseline and follow-up than those exposed to Cancerous Lesion on Lip. Youth exposed to White Cigarette Burning were less likely to recall the correct warning image at baseline only than those exposed to Cancerous Lesion on Lip.

3.5.3 Influences on Beliefs

None of the four warning images were significantly associated with beliefs about the health risks of smoking to regular smokers or beliefs about the health risks of secondhand smoke exposure to nonsmokers (see Table 3-9 at the end of this section).

3.5.4 Behavioral Responses

Red Cigarette Burning was significantly associated with the likelihood of smoking 1 year from now for youth compared with the control group (see Table 3-9). Specifically, youth who viewed this warning image were more likely to report that they will be smoking 1 year from now.

3.5.5 Adult Advertisement Study

In the adult advertisement study, all four warning images elicited higher scores on the emotional reaction scale compared with the control group (see Table 3-8). All images except for White Cigarette Burning elicited higher scores on the cognitive reaction scale. All four images evoked a stronger response (i.e., more likely to agree) to the reaction item "the pack was difficult to look at" compared with the control group.

Red Cigarette Burning prompted lower correct recall of the warning statement at baseline and follow-up compared with the control group. Those exposed to Deathly Ill Woman were significantly less likely than the control group to correctly recall the warning statement at baseline. White Cigarette Burning elicited lower correct recall of the warning image than Cancerous Lesion on Lip (the referent image).

Cancerous Lesion on Lip was positively associated with beliefs about the health risks to regular smokers (i.e., more likely than controls to believe that a regular smoker would get cancer, have fatal lung disease, etc.) and beliefs about the health risks of secondhand smoke exposure to nonsmokers compared with the control condition (i.e., more likely than controls to believe that regularly breathing secondhand smoke would cause nonsmokers to get cancer, have fatal lung disease, etc.) (see Table 3-9). None of the images were significantly associated with quit intentions for adults and young adults or the likelihood of smoking 1 year from now for youth.

Table 3-8. Emotional and Cognitive Reactions and Recall for Warning Statement 4

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Deathly ill woman	6.109***	(0.000)	3.369***	(0.000)	10.402***	(0.000)	0.475*	(0.045)	0.338**	(0.009)	0.962	(0.911)	0.839	(0.669)
Red cigarette burning	3.719***	(0.000)	3.591***	(0.000)	2.426*	(0.016)	0.139***	(0.000)	0.190***	(0.000)	0.231***	(0.000)	0.314**	(0.002)
White cigarette burning	4.840***	(0.000)	3.821***	(0.000)	2.754**	(0.005)	2.076	(0.133)	1.193	(0.698)	0.267***	(0.000)	0.315**	(0.002)
Cancerous lesion on lip	6.291***	(0.000)	3.169***	(0.000)	7.591***	(0.000)	0.641	(0.247)	0.366*	(0.015)	Ref.	Ref.	Ref.	Ref.
Observations	538		539		539		539		407		430		334	
Young Adult														
Deathly ill woman	6.570***	(0.000)	3.860***	(0.000)	9.997***	(0.000)	0.588	(0.168)	0.820	(0.619)	1.169	(0.776)	0.827	(0.779)
Red cigarette burning	3.436***	(0.000)	3.567***	(0.000)	2.042*	(0.041)	0.238***	(0.000)	0.354**	(0.007)	0.241**	(0.001)	0.277*	(0.024)
White cigarette burning	3.276***	(0.000)	3.881***	(0.000)	1.568	(0.212)	2.432	(0.085)	2.133	(0.102)	0.192***	(0.000)	0.278*	(0.025)
Cancerous lesion on lip	6.906***	(0.000)	3.998***	(0.000)	8.171***	(0.000)	0.576	(0.157)	0.906	(0.808)	Ref.	Ref.	Ref.	Ref.
Observations	505		505		505		505		366		402		294	
Youth														
Deathly ill woman	5.000***	(0.000)	6.060***	(0.000)	16.889***	(0.000)	1.152	(0.705)	1.810	(0.262)	0.888	(0.808)	1.515	(0.545)
Red cigarette burning	3.357***	(0.000)	6.089***	(0.000)	2.295*	(0.048)	0.342**	(0.001)	0.281**	(0.002)	0.193***	(0.000)	0.327*	(0.035)
White cigarette burning	2.403***	(0.001)	5.631***	(0.000)	1.446	(0.408)	2.788*	(0.023)	1.295	(0.599)	0.150***	(0.000)	0.414	(0.109)
Cancerous lesion on lip	6.195***	(0.000)	6.473***	(0.000)	15.205***	(0.000)	0.566	(0.093)	0.559	(0.183)	Ref.	Ref.	Ref.	Ref.
Observations	511		511		511		511		289		409		218	
Adult Ad														
Deathly ill woman	6.078***	(0.000)	3.501***	(0.000)	57.334***	(0.000)	0.463*	(0.038)	0.473	(0.068)	1.013	(0.980)	0.853	(0.736)
Red cigarette burning	3.981***	(0.000)	2.723***	(0.000)	16.565***	(0.000)	0.157***	(0.000)	0.222***	(0.000)	0.837	(0.712)	0.609	(0.264)
White cigarette burning	1.602*	(0.019)	0.593	(0.369)	7.199*	(0.011)	1.048	(0.911)	0.824	(0.662)	0.438	(0.071)	0.367*	(0.022)
Cancerous lesion on lip	6.966***	(0.000)	4.503***	(0.000)	87.765***	(0.000)	0.759	(0.474)	0.557	(0.155)	Ref.	Ref.	Ref.	Ref.
Observations	518		518		518		518		391		414		310	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-9. Influences on Beliefs and Behavior for Warning Statement 4

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Deathly ill woman	0.780	(0.181)	0.267	(0.628)	1.366	(0.396)
Red cigarette burning	−0.395	(0.500)	−0.175	(0.752)	1.663	(0.171)
White cigarette burning	0.420	(0.467)	0.215	(0.695)	1.385	(0.374)
Cancerous lesion on lip	0.192	(0.741)	−0.398	(0.470)	1.355	(0.406)
Observations	539		539		539	
Young Adult						
Deathly ill woman	0.158	(0.785)	−0.546	(0.319)	1.302	(0.417)
Red cigarette burning	−0.751	(0.196)	−0.021	(0.970)	1.528	(0.200)
White cigarette burning	−0.480	(0.408)	0.023	(0.966)	1.076	(0.826)
Cancerous lesion on lip	−0.776	(0.180)	−0.704	(0.199)	1.297	(0.432)
Observations	505		505		505	
Youth						
Deathly ill woman	0.090	(0.881)	0.043	(0.938)	1.258	(0.492)
Red cigarette burning	−0.695	(0.247)	−0.596	(0.277)	0.503*	(0.025)
White cigarette burning	−0.399	(0.505)	−0.494	(0.365)	1.027	(0.934)
Cancerous lesion on lip	0.089	(0.882)	0.309	(0.571)	0.890	(0.712)
Observations	511		511		511	
Adult Ad						
Deathly ill woman	−0.682	(0.257)	−0.129	(0.804)	0.532	(0.097)
Red cigarette burning	0.828	(0.163)	0.722	(0.160)	1.155	(0.686)
White cigarette burning	−0.133	(0.825)	0.286	(0.583)	0.926	(0.830)
Cancerous lesion on lip	1.363*	(0.022)	1.402**	(0.007)	0.890	(0.744)
Observations	518		518		518	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.6 Warning Statement 5: Cigarettes Cause Strokes and Heart Disease

Red Lightning with Heart

Hand with Oxygen Mask

Man in Pain with Hand on Chest

Oxygen Mask on Man's Face

3.6.1 Emotional and Cognitive Reactions

All four warning images elicited higher scores on the emotional reaction scale for adults, young adults, and youth (see Table 3-10). For young adults and youth, all four warning images consistently elicited higher scores on the cognitive reaction scale compared with the control group (see Table 3-10). For adults, all images except Man in Pain with Hand on Chest elicited higher scores on the cognitive reaction scale compared with controls.

For the reaction item "the pack was difficult to look at," all warning images except Man in Pain with Hand on Chest elicited a stronger response (i.e., higher odds of agreeing that the pack was difficult to look at) from young adults compared with controls. For youth, all images except Red Lightning with Heart elicited a stronger response to the reaction item compared with controls.

3.6.2 Recall of Warning Statements and Images at Baseline and Follow-up

For adults and young adults, Red Lightning with Heart elicited higher correct recall of the warning statement at follow-up compared with controls (see Table 3-10). For youth, Red Lightning with Heart and Man in Pain with Hand on Chest elicited higher correct recall of the warning statement at follow-up compared with the control group. Man in Pain with Hand on Chest elicited lower correct recall of the warning image at baseline for adults than Oxygen Mask on Man's Face (referent image). Among youth, Red Lightning with Heart prompted lower correct recall of the warning image at baseline and follow-up than Oxygen Mask on Man's Face. Moreover, youth exposed to Hand with Oxygen Mask were less likely to recall the correct image at baseline only in comparison with those exposed to Oxygen Mask on Man's Face.

3.6.3 Influences on Beliefs

None of the warning images were associated with either belief scale compared with the control group (see Table 3-11).

3.6.4 Behavioral Responses

Hand with Oxygen Mask was associated with significantly lower likelihood of quitting within the next month for adults compared with the control group (see Table 3-11). None of the warning images were associated with quit intentions for young adults or the likelihood of smoking 1 year from now for youth compared with the control group.

3.6.5 Adult Advertisement Study

In the adult advertisement study, all four warning images consistently elicited higher scores on the emotional and cognitive reaction scales compared with the control group (see Table 3-10). Only Oxygen Mask on Man's Face evoked a stronger response to the reaction item "the pack was difficult to look at" compared with the control group. Red Lightning with Heart elicited higher correct recall of the warning statement at baseline compared with the control group. Hand with Oxygen Mask elicited lower correct recall of the warning image at follow-up than Oxygen Mask on Man's Face (the referent image).

None of the warning images were associated with either belief scale (see Table 3-11). Likewise, the warning images were not significantly associated with quit intentions for adults and young adults or the likelihood of smoking 1 year from now for youth.

Table 3-10. Emotional and Cognitive Reactions and Recall for Warning Statement 5

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	**ß**		**ß**		**OR**		**OR**		**OR**		**OR**		**OR**	
Red lightning w/heart	3.698***	(0.000)	1.832**	(0.003)	3.915**	(0.003)	1.251	(0.513)	2.565*	(0.029)	0.612	(0.146)	0.788	(0.549)
Hand w/oxygen mask	3.269***	(0.000)	2.522***	(0.000)	6.885***	(0.000)	0.723	(0.313)	1.004	(0.992)	0.628	(0.173)	0.855	(0.695)
Man in pain with hand on chest	2.139**	(0.001)	0.580	(0.335)	4.301**	(0.001)	1.272	(0.483)	1.358	(0.419)	0.457*	(0.019)	0.531	(0.108)
Oxygen mask on man's face	4.870***	(0.000)	2.281***	(0.000)	11.338***	(0.000)	0.593	(0.100)	0.793	(0.535)	Ref.	Ref.	Ref.	Ref.
Observations	541		541		541		541		403		434		331	
Young Adult														
Red lightning w/heart	3.330***	(0.000)	4.084***	(0.000)	2.928**	(0.001)	1.728	(0.185)	3.082*	(0.038)	0.855	(0.681)	0.973	(0.955)
Hand w/oxygen mask	4.603***	(0.000)	4.404***	(0.000)	2.384**	(0.009)	0.593	(0.137)	0.668	(0.338)	1.042	(0.916)	1.946	(0.213)
Man in pain with hand on chest	3.974***	(0.000)	3.026***	(0.000)	1.633	(0.157)	0.782	(0.493)	1.844	(0.193)	1.151	(0.719)	1.179	(0.731)
Oxygen mask on man's face	4.771***	(0.000)	3.093***	(0.000)	4.449***	(0.000)	0.526	(0.062)	0.866	(0.729)	Ref.	Ref.	Ref.	Ref.
Observations	504		504		504		504		344		404		279	
Youth														
Red lightning w/heart	2.305***	(0.001)	4.401***	(0.000)	2.190	(0.088)	1.472	(0.303)	2.699*	(0.036)	0.219***	(0.000)	0.259*	(0.012)
Hand w/oxygen mask	3.524***	(0.000)	5.690***	(0.000)	5.123***	(0.000)	0.685	(0.260)	1.826	(0.168)	0.424*	(0.045)	0.609	(0.401)
Man in pain with hand on chest	3.353***	(0.000)	4.398***	(0.000)	4.185***	(0.001)	1.588	(0.225)	2.940*	(0.026)	0.540	(0.158)	0.660	(0.479)
Oxygen mask on man's face	5.138***	(0.000)	5.427***	(0.000)	15.514***	(0.000)	0.894	(0.744)	1.471	(0.355)	Ref.	Ref.	Ref.	Ref.
Observations	511		511		511		511		292		409		236	
Adult Ad														
Red lightning w/heart	1.885**	(0.005)	1.893**	(0.002)	1.944	(0.109)	2.354*	(0.042)	2.711	(0.077)	1.642	(0.367)	0.564	(0.235)
Hand w/oxygen mask	1.948**	(0.004)	1.227*	(0.046)	1.131	(0.779)	0.588	(0.120)	1.172	(0.736)	0.725	(0.508)	0.340*	(0.026)
Man in pain with hand on chest	1.911**	(0.005)	1.337*	(0.029)	1.841	(0.150)	2.028	(0.086)	1.013	(0.977)	0.891	(0.810)	0.708	(0.488)
Oxygen mask on man's face	4.847***	(0.000)	3.220***	(0.000)	7.741***	(0.000)	0.705	(0.312)	0.506	(0.105)	Ref.	Ref.	Ref.	Ref.
Observations	517		517		517		517		399		413		314	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-11. Influences on Beliefs and Behavior for Warning Statement 5

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Red lightning w/heart	0.745	(0.189)	−0.193	(0.712)	0.694	(0.269)
Hand w/oxygen mask	0.041	(0.942)	−0.085	(0.871)	0.325**	(0.002)
Man in pain with hand on chest	−0.510	(0.368)	−0.869	(0.096)	0.635	(0.173)
Man w/mask and bag	−0.116	(0.838)	−0.512	(0.328)	0.653	(0.199)
Observations	541		541		541	
Young Adult						
Red lightning w/heart	0.210	(0.739)	0.565	(0.347)	1.036	(0.917)
Hand w/oxygen mask	−0.214	(0.733)	−0.095	(0.873)	1.174	(0.626)
Man in pain with hand on chest	−0.227	(0.720)	0.959	(0.110)	0.635	(0.186)
Man w/mask and bag	0.644	(0.301)	0.883	(0.136)	0.830	(0.569)
Observations	504		504		504	
Youth						
Red lightning w/heart	−0.887	(0.142)	−0.605	(0.288)	0.864	(0.619)
Hand w/oxygen mask	1.025	(0.090)	0.178	(0.754)	1.342	(0.330)
Man in pain with hand on chest	0.202	(0.738)	0.181	(0.750)	1.596	(0.127)
Man w/mask and bag	0.493	(0.413)	0.860	(0.130)	1.532	(0.162)
Observations	511		511		511	
Adult Ad						
Red lightning w/heart	−0.356	(0.535)	−0.945	(0.073)	1.124	(0.755)
Hand w/oxygen mask	−0.280	(0.628)	−0.433	(0.417)	1.192	(0.633)
Man in pain with hand on chest	0.528	(0.360)	−0.562	(0.290)	1.454	(0.308)
Man w/mask and bag	0.054	(0.925)	−0.605	(0.254)	0.669	(0.312)
Observations	517		517		517	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.7 Warning Statement 6: Smoking during Pregnancy Can Harm Your Baby

Pacifier & Ashtray

Baby in Incubator

3.7.1 Emotional and Cognitive Reactions

Pacifier & Ashtray and Baby in Incubator received higher scores on the emotional and cognitive reaction scales from adults, young adults, and youth relative to the control group (see Table 3-12). Results for the reaction item "the pack was difficult to look at" diverged somewhat across study populations. In the adult pack study population, respondents viewing either image were significantly more likely than the control group to agree or strongly agree that the pack was difficult to look at. Among young adults and youth, however, only Baby in Incubator evoked stronger responses to this reaction item.

3.7.2 Recall of Warning Statements and Images at Baseline and Follow-up

At baseline, Baby in Incubator elicited higher correct recall of the warning statement by youth, and Pacifier & Ashtray elicited higher correct recall by young adults compared with the control group (see Table 3-12). At follow-up, Pacifier & Ashtray and Baby in Incubator elicited higher correct recall of the warning statement by young adults. Pacifier & Ashtray prompted lower correct recall of the warning image than Baby in Incubator (the referent image) at baseline and follow-up among adults, young adults, and youth compared with controls.

3.7.3 Influences on Beliefs

Among adults, Pacifier & Ashtray and Baby in Incubator elicited stronger beliefs (i.e., higher scale scores) about the health risks of smoking (e.g., more likely to believe that regular smokers will get cancer, have fatal lung disease) compared with the control condition (see Table 3-13). In contrast, Baby in Incubator was negatively associated with beliefs about the health risks of smoking for youth compared with the control condition. None of the images were associated with beliefs about the health risks of secondhand smoke exposure to nonsmokers.

3.7.4 Behavioral Responses

Neither warning image was significantly associated with quit intentions (for adults and young adults) or the likelihood of smoking 1 year from now (for youth) compared with the control condition (see Table 3-13).

3.7.5 Adult Advertisement Study

In the adult advertisement study, both images elicited significantly higher scores on the emotional and cognitive reaction scales from respondents compared with controls (see Table 3-12). Only Baby in Incubator was reported as “difficult to look at” relative to controls. Pacifier & Ashtray elicited significantly lower recall of the correct image at baseline than Baby in Incubator. Neither image was significantly associated with beliefs about the health risks of smoking or secondhand smoke exposure or with quit intentions (see Table 3-13).

Table 3-12. Emotional and Cognitive Reactions and Recall for Warning Statement 6

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Pacifier & ashtray	2.786***	(0.000)	2.038**	(0.001)	4.008**	(0.005)	1.741	(0.204)	1.705	(0.284)	0.074***	(0.000)	0.063***	(0.000)
Baby in Incubator	5.397***	(0.000)	2.306***	(0.000)	9.931***	(0.000)	2.027	(0.123)	2.086	(0.145)	Ref.	Ref.	Ref.	Ref.
Observations	321		321		321		321		229		213		159	
Young Adult														
Pacifier & ashtray	2.978***	(0.000)	2.926***	(0.000)	1.340	(0.430)	5.612**	(0.004)	3.612*	(0.020)	0.235**	(0.001)	0.168**	(0.006)
Baby in Incubator	5.355***	(0.000)	3.426***	(0.000)	3.514***	(0.000)	2.048	(0.139)	4.083*	(0.010)	Ref.	Ref.	Ref.	Ref.
Observations	303		303		300		303		209		200		141	
Youth														
Pacifier & ashtray	1.883**	(0.005)	4.648***	(0.000)	2.839*	(0.029)	1.770	(0.210)	1.061	(0.926)	0.130***	(0.000)	0.290*	(0.011)
Baby in Incubator	4.258***	(0.000)	5.661***	(0.000)	10.658***	(0.000)	4.670*	(0.010)	0.626	(0.443)	Ref.	Ref.	Ref.	Ref.
Observations	306		306		306		306		175		204		120	
Adult Ad														
Pacifier & ashtray	1.547*	(0.019)	1.720**	(0.006)	2.351	(0.058)	1.894	(0.289)	0.645	(0.517)	0.207**	(0.002)	0.417	(0.059)
Baby in Incubator	4.350***	(0.000)	2.896***	(0.000)	5.123***	(0.000)	1.443	(0.517)	0.565	(0.386)	Ref.	Ref.	Ref.	Ref.
Observations	310		310		310		310		243		199		155	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-13. Influences on Beliefs and Behavior for Warning Statement 6

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Pacifier & ashtray	1.222*	(0.037)	−0.195	(0.714)	0.560	(0.130)
Baby in Incubator	1.508*	(0.011)	0.576	(0.282)	0.876	(0.716)
Observations	321		321		321	
Young Adult						
Pacifier & ashtray	0.173	(0.779)	−0.438	(0.434)	1.668	(0.121)
Baby in Incubator	−0.447	(0.475)	−0.358	(0.529)	1.812	(0.078)
Observations	303		303		303	
Youth						
Pacifier & ashtray	−1.029	(0.107)	−0.270	(0.637)	0.598	(0.093)
Baby in Incubator	−1.546*	(0.017)	−0.858	(0.139)	0.619	(0.119)
Observations	306		306		306	
Adult Ad						
Pacifier & ashtray	0.088	(0.876)	−0.603	(0.264)	0.987	(0.969)
Baby in Incubator	0.015	(0.979)	0.152	(0.778)	0.877	(0.705)
Observations	310		310		310	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.8 Warning Statement 7: Smoking Can Kill You

Man in Casket

Man with Chest Staples

Red Coffin with Body in Black

Cigarettes = RIP

3.8.1 Emotional and Cognitive Reactions

All four images elicited higher scores on the emotional reaction scale for adults and youth compared with the control condition (see Table 3-14). Among young adults, Man with Chest Staples and Cigarettes = RIP received higher scores on the emotional reaction scale relative to controls.

All four images also received significantly higher scores on the cognitive reaction scale for adults, young adults, and youth compared with controls (see Table 3-14).

All four images evoked a stronger response to the reaction item "this pack was difficult to look at" (i.e., higher odds of agreeing that the pack was difficult to look at) from adults and youth compared with controls. However, among young adults, only Man with Chest Staples elicited a stronger response compared with the control condition.

3.8.2 Recall of Warning Statements and Images at Baseline and Follow-up

Among adults, Red Coffin with Body in Black and Cigarettes = RIP prompted higher correct recall of the warning statement at baseline compared with the control group (see Table 3-14). Among youth, Man in Casket elicited higher correct recall of the warning statement at baseline compared with the control group. In contrast, Man in Casket and Man with Chest Staples elicited lower correct recall of the warning statement at baseline among young adults, as did Man with Chest Staples at follow-up. Man with Chest Staples elicited higher correct recall of the warning image at follow-up than Cigarettes = RIP (the referent image).

3.8.3 Influences on Beliefs

None of the warning images were significantly associated with either belief scale for adults, young adults, or youth (see Table 3-15).

3.8.4 Behavioral Responses

Man with Chest Staples was significantly associated with quit intentions among adults in the pack sample (see Table 3-15).

3.8.5 Adult Advertisement Study

In the adult advertisement study, all four images elicited higher scores on the emotional reaction scale (see Table 3-14). Man in Casket, Man with Chest Staples, and Cigarettes = RIP also elicited higher scores on the cognitive reaction scale. All four images evoked stronger responses to the reaction item, “the pack was difficult to look at” compared with the control group. Man in Casket, Red Coffin with Body in Black, and Cigarettes = RIP all elicited stronger beliefs (i.e., higher scale scores) about the health risks of smoking compared with the control group (see Table 3-15). None of the four images were significantly associated with quit intentions.

Table 3-14. Emotional and Cognitive Reactions and Recall for Warning Statement 7

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Man in casket	3.592***	(0.000)	1.641**	(0.007)	3.668**	(0.001)	1.652	(0.228)	1.891	(0.166)	1.422	(0.344)	0.841	(0.676)
Man w/chest staples	5.920***	(0.000)	2.926***	(0.000)	7.658***	(0.000)	1.683	(0.205)	1.067	(0.881)	1.910	(0.098)	0.981	(0.964)
Red coffin w/body in black	4.040***	(0.000)	2.783***	(0.000)	4.139***	(0.000)	9.027***	(0.001)	2.093	(0.107)	1.123	(0.740)	1.678	(0.241)
Cigarettes = RIP	3.842***	(0.000)	3.035***	(0.000)	4.024***	(0.001)	2.553*	(0.034)	2.532	(0.059)	Ref.	Ref.	Ref.	Ref.
Observations	539		539		539		540		407		432		332	
Young Adult														
Man in casket	1.284	(0.066)	2.452***	(0.000)	1.368	(0.369)	0.352*	(0.021)	1.093	(0.886)	0.782	(0.587)	1.663	(0.376)
Man w/chest staples	4.251***	(0.000)	3.386***	(0.000)	4.083***	(0.000)	0.256**	(0.002)	0.335*	(0.040)	1.768	(0.277)	4.484*	(0.035)
Red coffin w/body in black	1.160	(0.101)	1.537*	(0.020)	1.505	(0.241)	0.573	(0.245)	0.770	(0.652)	0.523	(0.132)	0.650	(0.390)
Cigarettes = RIP	2.073**	(0.003)	2.082**	(0.002)	1.471	(0.271)	0.738	(0.547)	0.672	(0.490)	Ref.	Ref.	Ref.	Ref.
Observations	508		508		508		508		354		405		286	
Youth														
Man in casket	2.529***	(0.000)	2.758***	(0.000)	7.067***	(0.000)	3.270*	(0.022)	0.543	(0.358)	1.939	(0.136)	1.848	(0.330)
Man w/chest staples	4.189***	(0.000)	4.385***	(0.000)	16.268***	(0.000)	1.388	(0.443)	0.456	(0.218)	2.520	(0.056)	1.714	(0.392)
Red coffin w/body in black	2.316***	(0.001)	3.205***	(0.000)	6.395***	(0.000)	2.321	(0.085)	4.988	(0.159)	1.336	(0.487)	1.886	(0.345)
Cigarettes = RIP	1.705*	(0.015)	3.056***	(0.000)	2.997*	(0.046)	2.393	(0.065)	1.361	(0.701)	Ref.	Ref.	Ref.	Ref.
Observations	511		511		511		511		264		409		219	
Adult Ad														
Man in casket	3.682***	(0.000)	2.657***	(0.000)	4.338**	(0.002)	1.061	(0.907)	0.610	(0.405)	0.143	(0.075)	0.570	(0.335)
Man w/chest staples	4.747***	(0.000)	1.723**	(0.009)	11.938***	(0.000)	0.932	(0.886)	0.500	(0.233)	0.164	(0.102)	1.275	(0.707)
Red coffin w/body in black	2.351***	(0.000)	1.097	(0.097)	3.708**	(0.005)	0.856	(0.747)	0.800	(0.717)	0.120	(0.050)	0.605	(0.375)
Cigarettes = RIP	2.512***	(0.000)	1.776**	(0.007)	2.633*	(0.044)	1.221	(0.699)	1.185	(0.809)	Ref.	Ref.	Ref.	Ref.
Observations	516		516		516		501		402		414		324	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-15. Influences on Beliefs and Behavior for Warning Statement 7

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Man in casket	0.357	(0.543)	0.702	(0.198)	1.539	(0.237)
Man w/chest staples	0.882	(0.133)	0.314	(0.564)	2.428*	(0.012)
Red coffin w/body in black	0.029	(0.960)	0.255	(0.637)	1.901	(0.070)
Cigarettes = RIP	0.011	(0.986)	0.341	(0.534)	1.567	(0.213)
Observations	540		540		540	
Young Adult						
Man in casket	−0.248	(0.687)	−0.324	(0.575)	1.275	(0.451)
Man w/chest staples	0.355	(0.567)	−0.239	(0.681)	0.892	(0.727)
Red coffin w/body in black	−1.030	(0.099)	−0.805	(0.171)	0.768	(0.426)
Cigarettes = RIP	−1.087	(0.082)	−0.801	(0.172)	1.363	(0.345)
Observations	508		507		508	
Youth						
Man in casket	0.821	(0.186)	0.683	(0.247)	0.666	(0.174)
Man w/chest staples	1.221	(0.051)	0.505	(0.394)	0.892	(0.709)
Red coffin w/body in black	1.090	(0.080)	0.317	(0.591)	0.837	(0.559)
Cigarettes = RIP	1.073	(0.085)	0.613	(0.300)	0.676	(0.192)
Observations	511		511		511	
Adult Ad						
Man in casket	1.492**	(0.009)	0.892	(0.096)	1.218	(0.590)
Man w/chest staples	0.270	(0.632)	0.163	(0.759)	1.312	(0.457)
Red coffin w/body in black	1.303*	(0.022)	0.775	(0.148)	1.072	(0.850)
Cigarettes = RIP	1.544**	(0.007)	0.779	(0.146)	1.822	(0.099)
Observations	516		516		516	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.9 Warning Statement 8: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers

Man Smoke at Woman

Woman Smoke at Man

Woman Crying

Graveyard

Man Hands Up & Smoke

3.9.1 Emotional and Cognitive Reactions

All five warning images elicited higher scores on the emotional reaction scale from adults, young adults, and youth compared with the control group (see Table 3-16). In the adult pack sample, only Man Smoke at Woman and Woman Crying elicited higher scores on the cognitive scale compared with the control group.

Man Smoke at Woman, Woman Smoke at Man, Woman Crying, and Graveyard evoked stronger responses to the reaction item “the pack was difficult to look at” from youth compared with the control group. Woman Crying and Man Smoke at Woman elicited stronger responses to this item from young adults, and Woman Smoke at Man and Woman Crying elicited stronger responses from adults.

3.9.2 Recall of Warning Statements and Images at Baseline and Follow-up

Graveyard elicited lower correct recall of the warning statement at baseline by adults and at follow-up by young adults compared with the control group. In contrast, Woman Smoke at Man elicited higher correct recall of the warning statement at follow-up by adults compared with the control group. Woman Smoke at Man, Woman Crying, and Graveyard prompted lower correct recall of the warning statement at baseline by youth compared with the control group.

Woman Crying elicited higher correct recall of the warning image at baseline and follow-up than Man Hands Up & Smoke (the referent image) by adults, young adults, and youth. In contrast, Man Smoke at Woman and Woman Smoke at Man elicited lower correct recall of the warning image at baseline than Man Hands Up & Smoke by adults.

3.9.3 Influences on Beliefs

Man Smoke at Woman, Woman Crying, and Graveyard were positively associated with beliefs that regular smokers are at risk for various health consequences of smoking for young adults compared with controls (see Table 3-17).

3.9.4 Behavioral Responses

Woman Smoke at Man was significantly associated with quit intentions for young adults compared with the control group (see Table 3-17).

3.9.5 Adult Advertisement Study

In the adult ad sample, Woman Crying, Graveyard, and Man Hands Up & Smoke all received higher scores on the emotional reaction scale. Woman Crying and Graveyard also received higher scores on the cognitive reaction scale. Those who viewed Woman Crying and Man Smoke at Woman were more likely than controls to report that the pack was difficult to look at (see Table 3-16).

Woman Smoke at Man elicited higher correct recall of the warning statement at follow-up compared with the control group. Woman Crying prompted higher correct recall of the warning image at baseline than Man Hands Up & Smoke (the referent image).

None of the warning images were significantly associated with belief scales or quit intentions in the adult ad sample (see Table 3-17).

Table 3-16. Emotional and Cognitive Reactions and Recall for Warning Statement 8

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	**ß**		**ß**		**OR**		**OR**		**OR**		**OR**		**OR**	
Man smoke at woman	2.134**	(0.001)	1.202*	(0.047)	1.465	(0.320)	1.048	(0.867)	1.488	(0.246)	0.532*	(0.030)	1.623	(0.169)
Woman Smoke at Man	2.682***	(0.000)	0.659	(0.277)	2.885**	(0.003)	0.868	(0.610)	2.260*	(0.024)	0.283***	(0.000)	0.513	(0.054)
Woman crying	3.465***	(0.000)	1.384*	(0.023)	2.848**	(0.004)	1.061	(0.835)	1.241	(0.532)	2.627**	(0.006)	3.241**	(0.004)
Graveyard	2.061**	(0.002)	0.502	(0.412)	0.983	(0.965)	0.503*	(0.014)	0.684	(0.269)	0.749	(0.335)	1.438	(0.317)
Man hands up & smoke	1.473*	(0.027)	0.366	(0.545)	1.668	(0.169)	1.052	(0.857)	1.508	(0.234)	Ref.	Ref.	Ref.	Ref.
Observations	649		650		650		650		450		541		378	
Young Adult														
Man smoke at woman	2.698***	(0.000)	N/A	N/A	2.249*	(0.028)	1.381	(0.278)	1.336	(0.443)	1.395	(0.333)	1.002	(0.996)
Woman Smoke at Man	2.694***	(0.000)	N/A	N/A	2.050	(0.052)	1.300	(0.375)	1.352	(0.407)	0.753	(0.380)	0.716	(0.413)
Woman crying	3.798***	(0.000)	N/A	N/A	5.290***	(0.000)	0.672	(0.166)	0.568	(0.113)	4.942***	(0.000)	6.007**	(0.007)
Graveyard	1.933**	(0.007)	N/A	N/A	1.371	(0.412)	0.700	(0.219)	0.482*	(0.039)	0.942	(0.855)	0.618	(0.225)
Man hands up & smoke	1.901**	(0.008)	N/A	N/A	1.462	(0.323)	0.943	(0.841)	0.864	(0.684)	Ref.	Ref.	Ref.	Ref.
Observations	612		N/A	N/A	612		612		424		509		355	
Youth														
Man smoke at woman	1.958**	(0.003)	N/A	N/A	3.264*	(0.017)	0.883	(0.679)	1.003	(0.995)	1.075	(0.823)	1.090	(0.851)
Woman Smoke at Man	2.164**	(0.001)	N/A	N/A	2.956*	(0.031)	0.553*	(0.045)	1.179	(0.694)	0.620	(0.118)	0.643	(0.327)
Woman crying	3.563***	(0.000)	N/A	N/A	12.106***	(0.000)	0.476*	(0.012)	0.628	(0.242)	2.726**	(0.009)	8.667**	(0.006)
Graveyard	2.363***	(0.000)	N/A	N/A	5.600***	(0.000)	0.525*	(0.029)	0.634	(0.253)	0.862	(0.640)	1.042	(0.930)
Man hands up & smoke	1.580*	(0.016)	N/A	N/A	2.492	(0.075)	0.608	(0.093)	0.835	(0.651)	Ref.	Ref.	Ref.	Ref.
Observations	612		N/A	N/A	612		612		329		509		272	
Adult Ad														
Man smoke at woman	1.266	(0.055)	1.000	(0.103)	4.948**	(0.001)	0.919	(0.790)	1.116	(0.763)	0.916	(0.824)	1.040	(0.928)
Woman Smoke at Man	0.929	(0.155)	0.774	(0.202)	1.750	(0.300)	0.728	(0.306)	2.403*	(0.027)	1.432	(0.396)	0.793	(0.567)
Woman crying	2.840***	(0.000)	1.709**	(0.005)	9.107***	(0.000)	0.705	(0.259)	0.752	(0.408)	2.641*	(0.046)	1.604	(0.299)
Graveyard	2.674***	(0.000)	2.640***	(0.000)	2.702	(0.051)	0.616	(0.115)	0.681	(0.276)	1.054	(0.895)	0.951	(0.906)
Man hands up & smoke	1.713**	(0.009)	0.651	(0.282)	1.724	(0.312)	0.674	(0.197)	1.155	(0.687)	Ref.	Ref.	Ref.	Ref.
Observations	618		619		619		619		483		517		406	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-17. Influences on Beliefs and Behavior for Warning Statement 8

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Man smoke at woman	−0.016	(0.978)	0.402	(0.456)	0.866	(0.695)
Woman Smoke at Man	0.395	(0.487)	0.069	(0.899)	1.056	(0.880)
Woman crying	0.243	(0.671)	0.738	(0.175)	1.222	(0.572)
Graveyard	0.464	(0.419)	0.527	(0.335)	1.071	(0.849)
Man hands up & smoke	0.463	(0.414)	0.337	(0.532)	1.057	(0.874)
Observations	650		650		650	
Young Adult						
Man smoke at woman	1.301*	(0.043)	0.228	(0.695)	1.704	(0.111)
Woman Smoke at Man	0.923	(0.149)	−0.006	(0.992)	1.995*	(0.039)
Woman crying	1.290*	(0.042)	0.234	(0.684)	1.871	(0.059)
Graveyard	1.301*	(0.042)	0.927	(0.111)	1.779	(0.082)
Man hands up & smoke	−0.051	(0.936)	0.041	(0.944)	1.501	(0.224)
Observations	612		612		612	
Youth						
Man smoke at woman	−0.579	(0.327)	−0.328	(0.557)	0.907	(0.743)
Woman Smoke at Man	−0.613	(0.301)	−0.097	(0.862)	0.892	(0.702)
Woman crying	0.513	(0.386)	0.896	(0.109)	1.184	(0.578)
Graveyard	−0.031	(0.958)	0.551	(0.325)	0.949	(0.862)
Man hands up & smoke	−0.362	(0.540)	−0.037	(0.947)	0.979	(0.943)
Observations	612		612		612	
Adult Ad						
Man smoke at woman	−0.053	(0.927)	0.752	(0.161)	1.142	(0.704)
Woman Smoke at Man	0.204	(0.721)	0.574	(0.281)	0.963	(0.915)
Woman crying	−0.115	(0.842)	0.939	(0.079)	1.214	(0.579)
Graveyard	0.673	(0.241)	0.922	(0.084)	0.816	(0.573)
Man hands up & smoke	0.315	(0.582)	0.622	(0.242)	1.085	(0.818)
Observations	619		619		619	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

3.10 Warning Statement 9: Quitting Smoking Now Greatly Reduces Serious Risk to Your Health

Man I Quit T-shirt

Woman Blowing Bubble

Cigarettes in Toilet Bowl

3.10.1 Emotional and Cognitive Reactions

Cigarettes in Toilet Bowl elicited higher scores on the emotional reaction scale from adults and young adults compared with the control group (see Table 3-18). Among young adults, Man I Quit T-Shirt elicited higher emotional scale scores than controls.

Cigarettes in Toilet Bowl and Man I Quit T-shirt elicited higher scores on the cognitive reaction scale from adults, young adults, and youth compared with controls. Among youth, Woman Blowing Bubble also elicited higher scores on the cognitive reaction scale compared with the control group. None of the warning images were rated as difficult to look at compared to controls.

3.10.2 Recall of Warning Statements and Images at Baseline and Follow-up

Cigarettes in Toilet Bowl elicited higher correct recall of the warning statement at follow-up for youth compared with controls (see Table 3-18). Man I Quit T-shirt and Woman Blowing Bubble prompted higher correct recall of the warning image at baseline and follow-up compared with Cigarettes in Toilet Bowl (the referent image) for adults, young adults, and youth.

3.10.3 Influences on Beliefs

Cigarettes in Toilet Bowl was positively associated with beliefs about the health risks of smoking to regular smokers compared with controls among young adults (see Table 3-19). Among youth, Woman Blowing Bubble was negatively associated with beliefs about the health risks of smoking to both smokers and nonsmokers (e.g., less like to believe that smokers and nonsmokers exposed to secondhand smoke will get lung cancer, heart disease).

3.10.4 Behavioral Responses

None of the warning images were significantly associated with quit intentions (for adults and young adults) or the likelihood of smoking 1 year from now (for youth) compared with the control group (see Table 3-19).

3.10.5 Adult Advertisement Study

Cigarettes in Toilet Bowl elicited significantly higher scores on the cognitive reaction scale compared with controls (see Table 3-18). Man I Quit T-shirt elicited higher correct recall of the warning image at baseline than Cigarettes in Toilet Bowl (the referent image). Woman Blowing Bubble was negatively associated with quit intentions for adults and young adults compared with the control group (i.e., respondents exposed to Woman Blowing Bubble were less likely than the control group to express intentions to quit smoking in the next 30 days) (see Table 3-19).

Table 3-18. Emotional and Cognitive Reactions and Recall for Warning Statement 9

Sample/image	Emotional reaction scale		Cognitive reaction scale		The pack was difficult to look at		Recall of correct warning statement		Recall of correct warning statement (Follow-up)		Recall of correct image		Recall of correct image (Follow-up)	
Adult Pack	ß		ß		OR		OR		OR		OR		OR	
Man I quit T-shirt	0.920	(0.097)	1.310*	(0.023)	1.594	(0.287)	1.465	(0.279)	1.282	(0.497)	12.504***	(0.000)	20.319***	(0.000)
Woman blowing bubble	0.587	(0.290)	0.207	(0.719)	1.077	(0.872)	1.308	(0.441)	2.083	(0.063)	2.083*	(0.011)	4.945***	(0.000)
Cigarettes in toilet bowl	1.376*	(0.014)	2.189***	(0.000)	1.982	(0.110)	1.017	(0.960)	1.727	(0.159)	Ref.	Ref.	Ref.	Ref.
Observations	430		430		430		430		322		323		236	
Young Adult														
Man I quit T-shirt	1.643*	(0.010)	1.633**	(0.005)	1.460	(0.301)	1.386	(0.398)	0.676	(0.354)	13.515***	(0.000)	15.469***	(0.000)
Woman blowing bubble	−0.077	(0.903)	−0.110	(0.847)	1.219	(0.596)	1.308	(0.484)	0.785	(0.576)	4.757***	(0.000)	4.246**	(0.001)
Cigarettes in toilet bowl	1.471*	(0.020)	2.065***	(0.000)	0.785	(0.536)	1.833	(0.130)	1.735	(0.237)	Ref.	Ref.	Ref.	Ref.
Observations	405		405		393		393		285		305		215	
Youth														
Man I quit T-shirt	0.043	(0.942)	2.323***	(0.000)	1.258	(0.570)	1.173	(0.690)	1.340	(0.459)	16.420***	(0.000)	15.964***	(0.000)
Woman blowing bubble	−0.168	(0.779)	1.546**	(0.004)	1.024	(0.956)	0.855	(0.684)	1.828	(0.168)	2.372**	(0.003)	7.335***	(0.000)
Cigarettes in toilet bowl	0.087	(0.885)	3.223***	(0.000)	1.185	(0.680)	1.126	(0.767)	3.067*	(0.023)	Ref.	Ref.	Ref.	Ref.
Observations	409		409		409		409		234		306		170	
Adult Ad														
Man I quit T-shirt	−0.207	(0.690)	0.593	(0.321)	1.385	(0.629)	0.699	(0.289)	0.450	(0.067)	3.797**	(0.008)	1.788	(0.167)
Woman blowing bubble	0.049	(0.925)	0.364	(0.542)	2.594	(0.125)	1.235	(0.559)	0.723	(0.487)	1.122	(0.765)	0.987	(0.974)
Cigarettes in toilet bowl	0.989	(0.059)	1.275*	(0.034)	1.549	(0.513)	1.541	(0.253)	0.880	(0.783)	Ref.	Ref.	Ref.	Ref.
Observations	409		409		389		409		314		305		241	

Notes: Ref = referent image; p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

Table 3-19. Influences on Beliefs and Behavior for Warning Statement 9

Sample/image	Beliefs about health risks to regular smokers (scale)		Beliefs about health risks of secondhand smoke exposure to nonsmokers (scale)		How likely do you think it is that you will try to quit smoking within the next 30 days (adults/young adults)/… be smoking 1 year from now (youth)	
Adult Pack	**ß**		**ß**		**OR**	
Man I quit T-shirt	0.476	(0.423)	0.229	(0.664)	1.234	(0.555)
Woman blowing bubble	0.807	(0.175)	0.431	(0.415)	1.544	(0.223)
Cigarettes in toilet bowl	−0.108	(0.856)	−0.413	(0.437)	1.319	(0.439)
Observations	430		430		430	
Young Adult						
Man I quit T-shirt	0.808	(0.194)	0.352	(0.549)	1.277	(0.466)
Woman blowing bubble	−0.443	(0.471)	−0.564	(0.332)	1.217	(0.555)
Cigarettes in toilet bowl	1.350*	(0.028)	0.974	(0.094)	1.209	(0.573)
Observations	405		405		405	
Youth						
Man I quit T-shirt	−0.599	(0.319)	−0.187	(0.736)	0.985	(0.959)
Woman blowing bubble	−1.331*	(0.028)	−1.172*	(0.037)	0.969	(0.917)
Cigarettes in toilet bowl	0.062	(0.919)	0.547	(0.330)	1.130	(0.689)
Observations	409		409		409	
Adult Ad						
Man I quit T-shirt	0.190	(0.747)	0.239	(0.672)	0.814	(0.562)
Woman blowing bubble	0.333	(0.573)	0.173	(0.759)	0.476*	(0.049)
Cigarettes in toilet bowl	0.872	(0.142)	−0.055	(0.923)	1.273	(0.498)
Observations	409		409		409	

Notes: p value in parentheses; *Significant at $p < 0.05$; **Significant at $p < 0.01$; ***Significant at $p < 0.001$.

A higher value on ß indicates that exposure to the warning image is associated with a higher score on the outcome variable (e.g., higher score on the emotional reaction scale) compared with the value of the outcome for control participants.

An odds ratio (OR) greater than 1 indicates that those exposed to the warning image were more likely to have experienced the outcome (have a 1 on the outcome) than control participants. An OR less than 1 means that those exposed to the warning image were less likely to have experienced the outcome (less likely to have a 1 on the outcome) than control participants.

4. DISCUSSION

This report highlights results of an experiment to assess the relative efficacy of graphic cigarette warning labels created for each of nine warning statements required by the Tobacco Control Act. This was accomplished by randomly selecting study participants to be exposed to a cigarette package with either one of the nine warning statements with a corresponding warning image (treatment group) or only the warning statement similar to the current standard warning statement (control group). The outcomes we examined to assess relative efficacy were selected based on theories of message processing and health behavior change. These theories suggest that immediate emotional and cognitive reactions to and recall of messages are part of a process that eventually leads to changes in beliefs and intentions and ultimately behavior change. The specific measures of beliefs and intentions were selected to assess the relative effectiveness of the graphic warning labels at conveying information about the various health risks of smoking and at encouraging smoking cessation and discouraging smoking initiation. We report a set of outcomes intended to gauge whether these warning statements and images might meet those goals.

4.1 Emotional and Cognitive Reactions

Most of the warning images elicited strong emotional and cognitive responses compared with controls. This is significant because the literature suggests that such responses are likely to be related to behavior change (Dillard, Weber, & Vail, 2007).

Given that most warning images elicited strong emotional and cognitive responses in all samples, those images that did not elicit strong reactions in some samples are worth noting:

- Warning 1: Woman in Rain
- Warning 4: White Cigarette Burning
- Warning 5: Man with Hand on Chest
- Warning 7: Man in Casket, Red Coffin with Body in Black
- Warning 8: Man Blowing Smoke at Woman, Woman Blowing Smoke at Worker, Graveyard, and Man Hands Up & Smoke
- Warning 9: Man I Quit T-shirt, Woman Blowing Bubble, and Cigarettes in Toilet Bowl

It is possible that the reaction items are less salient for warning statement 9, which focuses on the benefits of quitting versus the risks of smoking. Perhaps images associated with such a statement are less likely to elicit strong emotional reactions. It is not clear whether to expect a strong reaction on the cognitive scale for such a statement, although one would expect that items related to meaningfulness or how informative this warning statement is would be salient. Thus, it is not surprising that the images for warning statement 9 have

relatively low scores on the emotional reaction scale and that the scores on the cognitive reaction scale are higher.

Consistent with evidence from research on smoking cessation advertisements (Biener et al., 2000; Durkin, Biener, & Wakefield, 2009; Durkin & Wakefield, 2009) and an emerging literature examining graphic warning labels (e.g., Hammond et al., 2004, 2006; Leshner, Bolls, & Thomas, 2009), our results suggest that cigarette warning labels that are most graphic (e.g., Hole in Throat, Healthy/Diseased Lungs) or emotional (e.g., Girl Crying or Woman Crying) elicit the strongest emotional reactions. These same graphic warning labels also are more likely to be rated as difficult to look at compared to the control groups. The literature also suggests that images that evoke the strongest graphic or emotional responses are likely to be most effective in promoting increased awareness of the warnings of the health risks of smoking and in turn promoting behavior change (e.g., Hammond et al., 2004) although there remains debate about this (e.g., Biener & Taylor, 2002; Hastings & MacFadyen, 2002).

Also, with the exception of warning statement 9, there is more differentiation across cigarette warning labels on the emotional scale than the cognitive scale.

4.2 Recall

Recall is another important measure because if a graphic warning label is not remembered, then it is unlikely to have a lasting impact. Recall of warning statements and images at baseline (immediate) and at the 1-week follow-up were relatively high. For most warning statements and images, recall was above 70% even at the 1-week follow-up. The following warning images were associated with an increased likelihood of correct recall of warning statements at follow-up relative to controls in at least one sample (i.e., adult pack, adult advertisement, young adult, or youth):

- Warning 1: Red Puppet, Hole in Throat
- Warning 2: Girl Crying, Smoke at Baby, Warning in Child Lettering
- Warning 3: Lungs Full of Cigarettes, Dr. with X-ray
- Warning 5: Red Lightning with Heart, Man with Hand on Chest
- Warning 6: Pacifier & Ashtray, Baby in Incubator
- Warning 8: Woman Smoke at Man, Woman Crying
- Warning 9: Cigarettes in Toilet Bowl

The following warning images were associated with lower correct recall of warning statements at follow-up relative to controls in at least one sample:

- Warning 4: Deathly Ill Woman, Red Cigarette Burning, and Cancerous Lesion on Lip
- Warning 7: Man with Chest Staples

4.3 Communicate Health Risks of Smoking

A number of warning images had a significant impact on beliefs about the health risks of smoking to regular smokers and in some cases on beliefs about the health risks of secondhand smoke exposure to nonsmokers relative to no image (control condition).

The following warning images elicited higher ratings about the health risks of smoking compared with no image (control condition) as measured by the belief scales in at least one sample:

- Warning 1: Cigarette Injection (smoking risks), Hole in Throat (smoking and secondhand smoke risks), Woman in Rain (smoking risks)
- Warning 4: Cancerous Lesion on Lip (smoking and secondhand smoke risks)
- Warning 6: Pacifier & Ashtray (smoking risks), Baby in Incubator (smoking risks)
- Warning 7: Man in Casket (smoking risks), Red Coffin with Body in Black (smoking risks), Cigarettes = RIP (smoking risks) (significant results in the adult ad sample)
- Warning 8: Man Smoke at Woman (smoking risks), Woman Crying (smoking risks), Graveyard (smoking risks)
- Warning 9: Cigarettes in Toilet Bowl (smoking risks)

The following warning images elicited lower ratings about the health risks of smoking compared with no image (control condition) as measured by the belief scales in at least one sample:

- Warning 2: Girl Crying (secondhand smoke risks), Girl with Oxygen Mask (secondhand smoke risks)
- Warning 3: Dr. with X-ray (secondhand smoke risks)
- Warning 6: Baby in Incubator (smoking risks: negative in youth sample)
- Warning 9: Woman Blowing Bubble (smoking and secondhand smoke risks)

4.4 Encourage Smoking Cessation and Discourage Youth Smoking

To assess the impact on cessation, we used a measure of intentions to quit: “How likely do you think it is that you will try to quit in the next month?” We do not find strong evidence that the warning labels tested in this experiment had much of an impact on this measure of cessation.

The following warning images were positively associated with quit intentions in at least one sample:

- Warning 1: Cigarette Injection
- Warning 7: Man with Staples in Chest
- Warning 8: Woman Smoke at Man

The following warning images were negatively associated with quit intentions in at least one sample:

- Warning 2: Smoke at Baby
- Warning 5: Hand with Oxygen
- Warning 9: Woman Blowing Bubble

For youth, we used a measure of how likely the youth felt they were to be smoking 1 year from now as a measure of the impact of viewing the warning images on potential initiation. We did not find much evidence for an impact of the warning labels on this outcome.

The following warning images were associated with youth reporting being less likely to be smoking 1 year from now:

- Warning 2: Girl Crying, Smoke Approaching Baby

The following warning images were associated with youth reporting being more likely to be smoking 1 year from now:

- Warning 4: Red Cigarette Burning

The graphic cigarette warning labels did not elicit strong responses in terms of intentions related to cessation or initiation. One possibility is that the observation period is too short to see any change in these types of outcomes. In a model of behavior change, exposure to a stimulus is posited to elicit an initial reaction and recall, which then results in changes in attitudes and beliefs followed by changes in intentions and then eventually behaviors (see Section 1.2). However, the time-scale on which this process occurs as well as the relative importance of each step in the process is not well-known.

Another possibility is that the "dose" is simply too small (Hornik, 2002). We do not know the dose required to elicit a response in intentions or behavior. The results do suggest that our dose was sufficient to elicit emotional and cognitive responses and some beliefs.

Responses vary somewhat by the age of the sample, suggesting that a one size fits all strategy for the graphic warning labels might not be optimal: what works best for one group might not be best for other groups.

4.5 Limitations

Measuring health behaviors and attitudes and beliefs related to smoking is an inexact science. The same is true, maybe even more so, for measuring emotional and cognitive reactions to warning images. There is also much uncertainty about how these shorter-term outcomes are related to the longer-term outcomes that are of most interest.

Given the time limitations of the research, we exposed participants to a single viewing of the graphic warning labels, which may not have been sufficient to elicit behavior changes

compared to controls. This design also does not allow for assessment of the effect that repetitive viewing of the graphic warning labels may have on recall or other outcomes. Once these graphic warning labels are on packs of cigarettes in the market, exposure will be more extensive. Time constraints prevented us from designing a longitudinal experiment involving repeated exposures and testing for dosing differences.

Small sample sizes for populations of interest (e.g., African Americans, Latinos, lower income or lower educational status) prevented us from obtaining precise parameter estimates for these populations, making it difficult to assess differences in efficacy of the warning labels across these groups. Time constraints prevented us from attempting to recruit additional members of some populations of interest. To increase the representation for these groups would have involved sending reminders to those who initially refused to participate (which has a slower response rate) or sending invites to potential respondents within these groups who had not answered the smoking interest question. The qualifying rate in this context would thus be much lower than originally assumed for the study. The time frame available for this study simply did not allow for such efforts to recruit additional members of these groups.

REFERENCES

Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes*, *50*, 179–211.

Biener, L., McCallum-Keeler, G., & Nyman, A. L. (2000). Adults' response to Massachusetts anti-tobacco television advertisements: impact of viewer and advertisement characteristics. *Tobacco Control*, *9*, 401–407.

Biener, L., & Taylor, T. M. (2002). The continuing importance of emotion in tobacco control media campaigns: a response to Hastings and MacFadyen. *Tobacco Control*, *11*, 75–77

Dillard, J. P., Weber, K. M., & Vail, R. G. (2007). The relationship between the perceived and actual effectiveness of persuasive messages: A meta-analysis with implications for formative campaign research. *Journal of Communication*, *57*(4), 613–631.

Durkin, S., Biener, L., & Wakefield, M. (2009). Effects of different types of antismoking ads on reducing disparities in smoking cessation among socioeconomic subgroups. *American Journal of Public Health*, *99*, 2217–2223.

Durkin, S., & Wakefield, M. (2009). Comparative responses to radio and television anti-smoking advertisements to encourage smoking cessation. *Health Promotion International*, Oct 24[Epub ahead of print].

Fishbein, M. G., & Azjen, I. (1975). *Belief, attitude, intention, and behavior: An introduction to theory and research*. Reading, MA: Addison-Welsey.

Hammond, D., Fong, G. T., McDonald, P. W., Brown, K. S., & Cameron, R. (2004). Graphic Canadian cigarette warning labels and adverse outcomes: evidence from Canadian smokers. *American Journal of Public Health*, *94*, 1442–1445.

Hammond, D., Fong, G. T., McNeill, A., Borland, R., & Cummings, K. M. (2006). Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four country Survey. *Tobacco Control*, *15*(suppl III), iii19–iii25.

Hastings, G., & MacFadyen, L. (2002). The limitations of fear messages. *Tobacco Control*, *11*, 73–75.

Hornik, R. C. (2002). *Public health communication: evidence for behavior change*. Mahwah, NJ: Lawrence Erlbaum.

Lang, A. (2000). The limited capacity model of mediated message processing. *Journal of Communication*, *50*, 46–70.

Leshner, G., Bolls, P., & Thomas, E. (2009). Scare' em or disgust 'em: the effects of graphic health promotion messages. *Health Communication*, *24*, 447–458.

Petty, R. E., & Cacioppo, J. T. (1986). *The elaboration likelihood model of persuasion*. New York, NY: Academic Press.

APPENDIX A:
QUESTIONNAIRES FOR EXPERIMENTAL STUDY

APPENDIX B:
METHODOLOGY REPORT

APPENDIX C:
ADDITIONAL ANALYSES

C.1 Descriptive Tables

C.2 Regression Results

Appendix 2

Press Releases

Government briefs tobacco trade on proposal to amend health warnings on tobacco product packets and retail containers

****

The Food and Health Bureau (FHB) and the Tobacco Control Office of the Department of Health today (November 23) held a briefing for the tobacco trade to further explain the Government's proposal to amend health warnings on packets and retail containers of tobacco products as well as technical issues related to implementation of the proposal.

The Government's proposed amendments are as follows:

The area of the graphic health warning shall be of a size that covers at least 85% of the two largest surfaces of the packet or the retail container;
Increase the number of forms of health warning from six to 12;
Incorporate the following health warning messages together with the existing "HKSAR GOVERNMENT WARNING"-"QUIT SMOKING FOR FUTURE GENERATIONS" and "QUITLINE: 1833 183" .

The Government plans to provide the trade with a six-month adaptation period from the date of the publication of the amendment proposal on the Gazette.

A spokesman for the FHB said, "Having studied overseas experience and considering the recommendations of the World Health Organization (WHO), the Government proposes to amend the prescribed forms (including specifications) of health warnings, the size and number of health warnings and messages on packet or retail container of cigarettes and tobacco products under the Smoking (Public Health) (Notices) Order, with a view to maintaining the salience and enhancing the impact of health warnings and messages.

"Overseas experience suggests that the increase in the size of health warning on packet or retail container of cigarettes and tobacco products helps reduce smoking prevalence, remind the public of the risk of smoking, as well as increase attempts to quit. Some countries have also banned display of tobacco products at point-of-sale.

"In fact, the WHO has urged its members to prepare for adopting plain packaging (standardised packaging) for tobacco products. Expanding the size of health warnings and messages is the international trend."

The major views expressed by the representatives of the tobacco trade who participated in the briefing include the six-month adaptation period was inadequate; the requirement of indication of tar and nicotine yields should be removed; the graphic files of the health warning forms should be provided as early as possible to facilitate the trade's preparation and ensure technical feasibility of the proposal, etc.

During the briefing, the Government representatives responded in detail to questions on implementation of the proposal at the briefing and noted the trade's views concerning the adaptation period and other technical issues. The Government would consider how best to facilitate the trade in preparing for the amendment proposal. The Government would report in details to the Panel on Health Services of the Legislative Council in December regarding the details of the proposal and the views collected. The Government plans to submit the amendment order to the Legislative Council in the first quarter of next year.

Ends/Wednesday, November 23, 2016
Issued at HKT 23:51
NNNN

Appendix B

The Status and Legal Effect of the WHO Framework Convention on Tobacco Control ("FCTC") in International Law

Prof. Dr. Jan Wouters

TABLE OF CONTENTS

Credentials

Jan Wouters is Full Professor of International Law and International Organizations, Jean Monnet Chair *ad personam* EU and Global Governance and founding Director of the Leuven Centre for Global Governance Studies and of the Institute for International Law at the University of Leuven (KU Leuven). As Visiting Professor at Sciences Po (Paris) and the College of Europe (Bruges), he teaches on the external relations of the European Union.

He has over 25 years of academic scholarship and more than two decades of practical experience in most areas of international law, from general international law to international criminal law, international economic law, international humanitarian law, international human rights law, international investment law, the law of international organizations (in particular the United Nations, UN specialized agencies and the World Trade Organization) and the law of outer space, as well as in the law of the European Union, corporate law and banking and financial law and global governance. He brings a strong insight in the multifaceted interactions between legal norms at international, European and national levels.

He is a Member of the Royal Academy of Belgium for Sciences and Arts. He taught at the Universities of Antwerp and Maastricht, and was Visiting Professor at Liège and Kyushu Universities and *Référendaire* at the European Court of Justice (1991-1994). He is Editor of the *International Encyclopedia of Intergovernmental Organizations*, Deputy Director of the *Revue belge de droit international*, Editor-in-Chief of the International Law book series with Intersentia Publishers and of the Leuven Global Governance book series with Edward Elgar Publishers, and editorial board member in eleven international journals. He has published widely. Recently he published *inter alia* a handbook on international law (2005), on *The World Trade Organization* (2007) and on *The Law of EU External Relations* (2013), and co-edited *The European Union and Conflict Prevention* (2004), *Legal Instruments in the Fight Against International Terrorism* (2004), *The United Nations and the European Union* (2006), *Multilevel Regulation and the EU* (2008), *The Europeanisation of International Law* (2008), *European Constitutionalism Beyond Lisbon* (2009), *Belgium in the Security Council* (2009), *Accountability for Human Rights Violations by International Organizations* (2010), *Upgrading the EU's Role as Global Actor* (2011), *The European Union and Multilateral Governance* (2012), *International Prosecutors* (2012), *Informal International Lawmaking* (2012), *Private Standards and Global Governance* (2012), *China, the European Union and Global Governance* (2012), *The EU's Role in Global Governance* (2013), *National Human Rights Institutions in Europe* (2013) and *China, the EU and the Developing World* (2015).

Educational Qualifications

- PhD in Law, K.U.Leuven (1996)
- Visiting Researcher, Harvard Law School (1990-91)
- Master of Laws, Yale University (1990)
- Lic. Juris, Antwerp University (1987)
- Bachelor of Philosophy, Antwerp University (1984)

Positions Currently Held

- Jean Monnet Chair *ad personam* EU and Global Governance, KU Leuven
- Full Professor of International Law and the Law of International Organizations, KU Leuven; courses on European and International Law, Public International Law, Law of International Organizations, Law of the World Trade Organization, Humanitarian and Security Law from a European Perspective, Space Law and Policy, Seminar/Master Thesis/Practical Exercises International Law and International Organizations
- Director of the Leuven Centre for Global Governance Studies and Institute for International Law, KU Leuven
- Visiting Professor, College of Europe, Bruges, and Sciences Po, Paris

- Expert, Indicative List for Panels of the World Trade Organization

Former Positions

1994-2006	Professor of Corporate Law (mergers and acquisitions), Catholic University of Brussels (postgraduate programme K.U.Leuven-K.U.B in corporate law)
1997-2003	Professor of European Banking and Securities Law, Maastricht University
1997-1998	Senior Lecturer on European, Economic and Financial Law, Antwerp University
1993-1998	Lecturer and Senior Lecturer in European and International Law, Maastricht University
1991-1994	Law Clerk (référendaire), European Court of Justice, Luxembourg
1989	Legal Adviser to the Belgian Minister of Finance, Brussels
1987-1989	Assistant in Financial, Economic and Commercial Law, Antwerp University

Honours and Distinctions

- Member, Advisory Board, Centre for Multilevel Federalism, Delhi, India, since January 2015
- Senior Visiting Fellow, the Graduate Institute, Geneva, Spring 2014
- International Chair, Luiss University, Rome, Spring 2014
- Visiting Professor, Université Nice Sophia Antipolis, Spring 2014
- Senior Visiting Fellow, Institute of Advanced Studies, University of Bologna, 2013
- Course Holder of the course « *Le statut juridique des standards publics et privés dans les relations économiques internationales* », Hague Academy of International Law, 29 July - 2 August 2013, The Hague
- Visiting Professor, Faculty of Law, Pontificia Universidad Católica de Chile, November 2012
- Visiting Scholar, Centre d'Etudes européennes, SciencesPo, Paris, 2012
- Senior Visiting Fellow, European Union Institute for Security Studies, Paris, 2012
- Fellow, Netherlands Institute for Advanced Study in the Humanities and Social Sciences (NIAS), 2010
- Honorary President, United Nations Association Flanders – Belgium (*Vereniging voor de Verenigde Naties)*, since June 2009
- Jean Monnet Chair *ad personam* European Union and Global Governance granted by European Commission (2009)
- Member of the Royal Flemish Academy of Belgium for Sciences and Arts (since 2008)
- Fernand Braudel Fellow, European University Institute, 2008
- Honorary Member, Association of International Relations ("Kring Internationale Betrekkingen," Leuven), since 2002
- Stibbe Prize, 1997
- Walter Leën Prize for Social Law, 1996
- Rotary Foundation Fellow, 1990-91
- Francqui Fellow, Belgian American Educational Foundation, 1989-90

Other Professional Activities

- Visiting professorships: Master of Laws in International Economic Law and Policy (LL.M. IELPO), University of Barcelona (since 2010); European Master's Degree in Human Rights and Democratisation (EMA), Venice (since 2009); Executive Master of European and International Business Law M.B.L.-HSG, University of Sankt-Gallen (since 2001); Leiden University (International Tax Programme, since 2003); University of Kyushu (Master of Laws Programme, 2007); Ghent University (Master of Laws Programme, 2003-2009); Liège University (D.E.A./D.E.S., 1996-1998); Université Libre de Bruxelles (European Programme in International Economic Law, EPIEL, 2005-2006)

- Membership international and national expert bodies: Expert, Indicative List for Panels of the World Trade Organization; Member, Group of Independent Experts on the European Charter of Local Self-Government,

Council of Europe; Panel Member, European Research Council (ERC) 2013 and 2014 Consolidator Grants; Panel Member, panel law and criminology, Research Foundation Flanders (FWO), Belgium.

- Coordination and membership of academic networks: co-chair, Community of Practice on Human Rights and Development (Global Forum on Law, Justice and Development), since October 2014; convener and coordinator of international research network on 'Global governance versus global government: global democracy and the G20' (Scientific Research Community, funded by Fund for Scientific Research Flanders, FWO, 2012-2016); member of coordinating team, international research network on 'Business and Human Rights Innovation Platform: Connecting Law and Management for Human Rights (BHRIP)' (Scientific Research Community, funded by Fund for Scientific Research Flanders, FWO, 2014-2018); programme director, research programme 'constitutional processes in the international legal order', Ius Commune Research School, Section Public Law (research alliance between KU Leuven, Maastricht University, Utrecht University and Amsterdam University); coordinator, Belgian National Point of Contact, European Centre for Space Law; member Scientific Research Community on Globalisation, Regionalisation and Social and Economic Inequality (with Antwerp and Ghent Universities and UNU-CRIS); member Board of LASA (Leuven Centre for Aero and Space Science, Technology and Applications)

- Other academic affiliations / representations: member, Executive Committee, Association for Human Rights Institutes (AHRI); member, Scientific Advisory Board of United Nations University – Comparative Regional Integration Studies (UNU-CRIS); member, Board of Administration of the Royal Dutch Association for International Law (*Koninklijke Nederlandse Vereniging voor Internationaal Recht*); Director of Studies, Belgian Branch, International Law Association; Member, Board of Administration of the Belgian Society for International Law (*Belgisch Genootschap voor Internationaal Recht*); member, Scientific Board, *Centre d'Etude de Droit Militaire et de Droit de la Guerre*, Brussels; member, International Advisory Board, Centro de Estudos sobre o Direito da Integração Regional da SADC (CEDIR), Eduardo Mondlane University (Maputo, Mozambique)

- Membership academic journals: Deputy Director, *Revue Belge de Droit International*; member, Editorial Board: *International Journal of Public Law and Policy; Journal of International Economic Law; Human Rights and International Legal Discourse; European* Business *Law Review; Zeitschrift für Öffentliches Recht – Austrian Journal of Public and International Law*; member, Editorial Advisory Board: *Asia Europe Journal; International Organizations Law Review*; *Maastricht Journal of European and Comparative Law*; *Legal Issues of Economic Integration*; *European Business Organization Law Review*; editorial member for European and international law, *Rechtskundig Weekblad*; external reviewer, *European Law Journal, European Law Review, Journal of Common Market Studies.*

- Membership of professional organizations: Academic Council on the United Nations System (ACUNS); American Society of International Law; Belgian Society of International Law; European Law Institute; European Society of International Law; Harvard Club Belgium; International Law Association and Belgian Branch of International Law Association; International Society for Military Law and Law of War; Royal Dutch Society of International Law.

- Membership of jury of scientific prizes: Fernand Collin Prize (most prestigious scientific price for Dutch-speaking legal scholarship in Belgium), Odissea Prize (scientific price granted by Belgian Senate to academic studies on space); Euro-Atlantic Prize of the Belgian Minister of Foreign Affairs.

6 July 2015

Prof. Dr. Jan Wouters **Date**

Executive Summary

This Report addresses three related questions concerning the framework nature and the legal effect of the World Health Organization's Framework Convention on Tobacco Control ("FCTC") under international law, including the relevance of the FCTC's references to domestic and international law and its relationship with other international agreements, like the agreements of the World Trade Organization ("WTO"). Based on the analysis of these three questions, the conclusion is that the FCTC constitutes an international treaty that sets forth a number of minimum obligations, the general objectives of the Parties and the institutional mechanisms (including legal instruments, i.e. protocols) by which such aims will subsequently be negotiated, developed and implemented. The 'framework' nature of this treaty implies that it is an agreement that sets forth certain broad objectives rather than specific legal obligations, with the exception of a limited set of obligations that are expressly included "as a minimum." The rationale for such an umbrella treaty is to express agreement on certain objectives and to create the institutions and mechanisms through which specific legal obligations may subsequently be negotiated and imposed. To interpret the broadly worded principles of a framework convention as comprehensive and specific legal obligations would fail to give due account to the intent of the drafters and render redundant the need to develop specific obligations through the institutions and mechanisms created by the framework convention.

In addition, the FCTC's generally worded obligations and frequent instances of deference to national law and constitutional principles highlight the fact that the FCTC's objectives and obligations are subject to limitations imposed by each Party's national law. They signify an element of 'subsidiarity,' taking into account the great diversity of national legal systems, and thereby leaving flexibility to the Parties to determine the manner in which they intend to meet their obligations. The minimum requirements that the Parties to the FCTC are to implement are subject to compliance with domestic and constitutional law, thus further highlighting the limited nature of the international legal obligations that are imposed.

As a matter of public international law, because of the aforementioned features of the FCTC, it is unlikely that there can be a conflict between the FCTC and the WTO agreements. Furthermore, as stated very clearly in Article 2(1) of the FCTC, measures that go beyond the minimum requirements of the FCTC must be in accordance with international law, reflecting the principle of *pacta sunt servanda*. In the unlikely event of overlapping obligations between the FCTC and the WTO agreements, the international law principle of harmonious interpretation provides that the conflict must so far as possible be avoided and the country must comply with both international legal obligations.

From the perspective of a WTO panel, which has a limited mandate to examine the consistency of measures with the WTO's covered agreements only and not with public international law more generally, the WTO agreements prevail. The FCTC may play only a limited role given that the WTO agreements are not to be read in clinical isolation from public international law.

Introduction

The WHO Framework Convention on Tobacco Control ("FCTC" or "Convention") sets forth broad objectives and certain generally worded obligations of the Parties to the FCTC in respect of tobacco control. Moreover, the FCTC itself as well as the Guidelines developed under it frequently defer to domestic (constitutional) law or international law.

This Report investigates the following questions:

(i) What is the legal status and effect of a 'framework' convention like the FCTC in public international law? In particular, what is the relevance of the 'framework' nature of the Convention on the characterization of the legal obligations contained in the FCTC?

(ii) Given the deference to domestic and international law, what is the 'international obligation' that is actually imposed by the FCTC, in particular under Articles 11 and 13 of the Convention relating to packaging, labelling and advertising?

(iii) More in particular, as to the two aforementioned provisions, how do the obligations in question relate to the legally binding obligations imposed by the agreements of the World Trade Organization ("WTO") relating to, for example, trademarks and technical packaging and labelling regulations?

The first set of questions is studied in Part I on the legal status of the FCTC as a framework convention. This part inquires about the notion of a 'framework convention' in international law, the criteria for, and characteristics of, the 'framework' nature of a convention, and the legal effects of these characteristics viz. nature, after which the insights obtained will be applied to the FCTC.

The second set of questions relating to the meaning of the multiple references to domestic and international law in the FCTC is examined in Part II. The various references to domestic law and to international law and their meaning will be discussed. On this basis, the Report attempts to elucidate the legal obligations emanating from the Convention in general and Articles 11 and 13 in particular, given that these are the provisions that have been most frequently referred to in the context of the adoption of ever larger and non-textual health warnings on the packaging of tobacco products and in the context of plain packaging requirements.

Finally, Part III tackles the relationship of the international legal obligations flowing from the FCTC and those emanating from the WTO agreements.

A conclusion summarizes the main findings.

Part I. Legal Status and Effect of the FCTC as a Framework Convention

1. The notion of 'framework convention' in international law

The notion of a 'framework convention' or 'framework agreement' (in French: *'convention-cadre'*) is a relatively recent concept in international law and legal practice. Although it appears particularly popular as an instrument in areas such as international environmental law[1] and transboundary cooperation on protected areas,[2] there are also examples of framework conventions in the fields of international economic law,[3] human rights law,[4] and, as the FCTC shows, international health law.

Kiss has developed the following synthetic definition:

> "*A framework treaty is a treaty instrument which sets out principles that must serve as the basis for cooperation between State Parties in a given field, while leaving them to define, through separate agreements, the terms and arrangements of the cooperation, in some cases by providing one or a number of institutions for this purpose."*[5]

Daillier and Pellet elaborate on this definition by further specifying that:

> *"[a] framework agreement is thus the basis for a later treaty or institutional activity which may be translated into implementing agreements, either through the adoption of protocols which specify and 'harden' the contents of the principles set out in the former agreement, or*

[1] Already in 1993, Kiss estimated that there were around 20 multilateral framework treaties in the area of international environmental law: see A.C. Kiss, "Les traités-cadres: une technique juridique caractéristique du droit international de l'environnement," *Annuaire français de droit international* 1993, 792, at 794.

[2] See J. Fall, "Designing Framework Conventions to Promote and Support Transboundary Protected Areas: Theory and Practice from the Carpathian Convention," in G. Tamburelli (ed.), *Biodiversity Conservation and Protected Areas: the Italian and Ukrainian Legislation,* Giuffrè, 2007, 101-117.

[3] An example is the 1995 Interregional Framework Cooperation Agreement between the European Community and its Member States, of the one part, and the Southern Common Market and its Party States, of the other part – Joint Declaration on political dialogue between the European Union and Mercosur.

[4] See the 1995 Framework Convention for the Protection of National Minorities of the Council of Europe.

[5] Emphasis added. Unofficial English translation of A.C. Kiss, "Les traités-cadres: une technique juridique caractéristique du droit international de l'environnement," *Annuaire français de droit international* 1993, 792, at 793: "Un traité-cadre est un instrument conventionnel qui énonce des principes devant server de fondement à la coopération entre les Etats parties dans un domaine déterminé, tout en leur laissant le soin de définir, par des accords séparés, les modalités et les détails de la coopération, en prévoyant, s'il y a lieu, une ou des institutions adéquates à cet effet." Compare the definition of J. Salmon, *Dictionnaire de droit international public,* Bruylant, 2001, at 1089: "Treaty defining the general principles of a legal regime, to be completed and further specified by later agreements" ("*Traité définissant les lignes générales d'un régime juridique, destiné à être complété et précisé par des accords ultérieurs").*

through a regulation (in the form of resolutions that are generally not binding) emanating from the institutional mechanism that it has put in place."[6]

In sum, a 'framework convention' is a legally binding treaty or agreement under international law. However, the 'framework' nature of this treaty implies that it is an agreement that sets forth certain broad objectives rather than specific legal obligations, with the exception of a limited set of obligations that are expressly included "as a minimum" (see also *infra,* 4., for the FCTC). The rationale for such an umbrella treaty is to express agreement on certain objectives and to create the institutions and mechanisms through which specific legal obligations may subsequently be negotiated and imposed. To interpret the broadly worded principles of a framework convention as comprehensive and specific legal obligations would fail to give due account to the intent of the drafters and render redundant the need to develop specific obligations through the institutions and mechanisms created by the framework convention.

2. Criteria for / characteristics of the 'framework' nature of a convention

As practice shows, the design of framework conventions very much depends on what the drafters of the treaty concerned have in mind regarding the shaping of the legal regime in question, but also on the political feasibility and the level and depth of the consensus prevailing at the time of negotiating the agreement.

Some framework conventions mainly provide for an institutional and/or procedural framework, leaving it to the thus created institutions or procedures to work out substantive rules. An illustration thereof is the Bonn Convention on the Conservation of Migratory Species of Wild Animals.[7] Other framework conventions provide for (at least a number of) detailed substantive rules while leaving the regulation of more specific issues to the adoption of protocols. This is the case, for example, with the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, which sets forth the rules on transboundary movement of waste, but leaves the question of liability to a subsequent protocol.[8] Still other framework agreements, like the 1995 Framework Convention for the Protection of National Minorities of the Council of Europe ("FCNM"), contain substantive provisions but leave the definition of the core notion of 'national minority' to national law

[6] Unofficial English translation of P. Daillier and A. Pellet, *Droit international public,* L.G.D.J., 7th edition, 2002, p. 1284, para. 739: "*Le traité-cadre est donc à l'origine d'une activité conventionnelle ou institutionnelle ultérieure qui peut se traduire soit par des accords de mise en oeuvre, soit par l'adoption de protocoles précisant et "durcissant" le contenu des principes qu'il a énoncés, soit par une réglementation (sous forme de résolutions en général non obligatoires) émanant du méchanisme institutionnel qu'il a mis en place."*

[7] Available at http://www.cms.int/sites/default/files/instrument/CMS-text.en_.PDF.

[8] N. Matz-Lück, "Framework Agreements," para. 3.

in the absence of a definition that the Council of Europe Member States could commonly agree on. Moreover, the term 'framework' in the title of the latter convention "highlights the scope for Member States to translate the Convention's provisions to their specific country situation through national legislation and appropriate governmental policies."[9]

The easiest way to recognize a framework convention is when the drafters of the treaty have chosen to mention 'framework' in the title of the instrument. This is, for instance, the case for the 1992 United Nations Framework Convention on Climate Change ("UNFCCC"), the FCNM and the FCTC. But a treaty does not need the word 'framework' in its title to be regarded, in whole or in part, as a framework agreement. For instance, as is known, the 1982 United Nations Convention on the Law of the Sea ("UNCLOS") contains many detailed rules on the law of the sea, but it operates rather as a framework agreement with regard to the protection of the marine environment. Thus, the regulation of straddling and highly migratory fish stocks was left to a further agreement, which came about in 1995 with the United Nations Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks. Another example is the 1985 Vienna Convention for the Protection of the Ozone Layer, which provides for the adoption of protocols, among which is the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer.

The common core element in all these framework agreements is what Kiss refers to as "a spreading out over time in the creation of norms" ("*un échellonement dans le temps de la création des normes"*). Or, in the words of Daillier and Pellet:

> *"We are far away from the traditional treaty-making technique: a framework convention is less the basis of specific obligations to be borne by the Contracting States, than a process of continuous negotiation which imposes on them the obligation to participate in good faith in further stages of negotiation (it is more a* pactum de negociando *than a* pactum de contrahendo)."[10]

This is in essence also captured in the note "Elements of a WHO framework convention for tobacco control" prepared by the WHO Secretariat for the first meeting of the Working Group for the FCTC:

---

[9] See http://www.coe.int/en/web/minorities/fcnm-factsheet.

[10] Emphasis added. Unofficial translation of P. Daillier and A. Pellet, *Droit international public,* p. 1284, para. 739: "On est loin ici de la technique conventionnelle traditionnelle: la convention-cadre est moins à l'origine d'obligations précises de faire à la charge des Etats parties, que d'un processus de négociation continue qui impose à ceux-ci l'obligation de participer de bonne foi aux étapes suivantes de la négociation (il s'agit cependant d'avantage d'un pactum de negociando que d'un pactum de contrahendo)."

"There is no single style or length for a framework convention. Some are detailed, others less so. Their general characteristic is that they set out few substantive obligations for the States Parties […] leaving most of those obligations to be established by individual protocols. The value of the framework convention and protocol approach is that it allows lawmaking to proceed incrementally. Topics on which there is widespread consensus among the negotiating States can be included in the convention itself. Topics on which many but not all States can agree may be included in concurrent protocols. Issues on which there is considerable debate can be addressed in protocols at some point in the future as consensus develops."[11]

3. Legal effect

There are no specific legal consequences flowing from the 'framework' nature of a convention. As Aust notes in the quotation above, as a multilateral agreement its legal effects are no different from those of any other international treaty. Also Matz-Lück observes that "[w]ith regard to their legal effect, i.e. the establishment of binding obligations for the parties, 'framework' treaties are no different from other multilateral agreements."[12] They are treaties in the full sense of the word and are therefore legally binding for the states that have expressed their consent to be bound by them and for whom they have entered into force.

The fact that the 'framework convention' is legally binding does not answer the question of substance: what is the nature and degree of the legal obligations imposed by the framework convention?

As noted above, a 'framework convention' typically limits itself to the formulation of broad principles and objectives and leaves the elaboration of more detailed substantive rules to later steps (at international or domestic level). Therefore, the substantive *degree* of its binding character will depend on the specific language of each such convention. But it is clear that the actual framework created, in particular the principles and objectives, does have a legal impact on the further implementing work. At least, by setting the general principles and objectives, "it gives guidance for the application and interpretation"[13] of the implementing protocols.

The legal effects of a 'framework convention' are also seen through their impact on the governance system it brings about. The institutional framework and processes laid down in the framework

[11] World Health Organization, *Elements of a WHO framework convention for tobacco control*, A/FCTC/WG1/6, 8 September 1999, p. 3, para. 3. (emphasis added)

[12] N. Matz-Lück, "Framework Agreements," in *Max Planck Encyclopedia of Public International Law* , 2011, para. 6.

[13] Idem.

convention will guide the later elaboration of norms. As Matz-Lück notes "[i]n essence, the framework agreement functions as an umbrella, under which the development of the treaty regime takes place and upon which it has significant influence."[14]

4. Application to the FCTC

The FCTC presents itself definitely as a 'framework' convention that seeks to develop certain broadly stated goals and principles for tobacco control and that creates instruments ("protocols") that are to subsequently embody the more specific obligations (the framework convention/protocol approach). From the outset, it has been the intention to develop an international legal instrument based on the example of the content and structure of international environmental agreements.[15] Moreover, the genesis of the Convention, in particular the steps preceding its negotiation as decided by the World Health Assembly ("WHA"),[16] points to a stated preference to take an incremental approach. As explained by Crow:

> *"The WHA's decision to adopt a framework convention, which typically establishes broadly stated goals, resulted primarily from the formidable political obstacles that could have prevented a global consensus on the more onerous commitments normally embodied in a conventional treaty."*[17]

The framework nature of the FCTC is also very clear in Article 3, which provides:

> *"The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and*

[14] N. Matz-Lück, "Framework Agreements," in *Max Planck Encyclopedia of Public International Law*, 2011, para. 8.

[15] See the detailed references to framework treaties in the environmental sphere as a source of inspiration for the to-be-established FCTC in World Health Organization, *Elements of a WHO framework convention for tobacco control*, A/FCTC/WG1/6, 8 September 1999, p. 3, para. 3.

[16] See in particular WHA, Resolution 49.17 "International framework convention for tobacco control" and Resolution 52.18 "Towards a WHO framework convention on tobacco control." But one can go back much earlier, in particular to the relevant considerations in favour of a "framework convention-protocol approach" as outlined in A.L. Taylor and R. Roemer, "International Strategy for Tobacco Control," WHO/PSA/96.6, pp. 16-17, paras 61-67. See already TAYLOR 295-296

[17] M.E. Crow, "Smokescreens and State Responsibility: Using Human Rights Strategies to Promote Global Tobacco Control," 29 *Yale Journal of International Law* 2004, 209, at 216.

substantially the prevalence of tobacco use and exposure to tobacco smoke." (emphasis added)

Thus, the FCTC sets out its overall "objective" in Article 3. In Article 4, it formulates – following the example of the UNFCCC – its "guiding principles." And, in Article 5, it outlines a number of "general obligations." The FCTC contains references to certain obligations that must be met "as a minimum."[18] In respect of such obligations, provided they are in accordance with each Party's constitution or constitutional principles, the Parties are legally bound to implement the specific obligation.

Apart from other obligations that need to be implemented, the Convention creates an institutional framework by establishing a Conference of the Parties ("COP") in Article 23. The COP is given the task to "keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation," moreover, it "may adopt protocols, annexes and amendments to the Convention […]" (Article 23(5)). The COP thus has a monitoring and advocacy function, on the one hand, and a potential legislative function through the development and adoption of protocols, annexes or amendments to the Convention, on the other hand.

In light of these provisions, Devillier summarizes the framework nature of the FCTC in the following manner:

"We are in face of a system of multiple stages. The framework convention/protocol method allows for a progressive normative approach. One starts by establishing a framework convention which establishes norms and general institutions and defines inter alia the objectives, the principles, the obligations and the basic institutions as well as the decision-making procedures, the financing rules, the rules on dispute settlement and on amendments. In other words, the function of a framework convention is to define a general system of governance. Subsequently, protocols will be adopted which are based on the mother treaty and create additional obligations and institutional arrangements […]. The FCTC establishes rules and general obligations, structures… and more specific obligations in certain areas will follow later, with the ratification of protocols."[19]

[18] See notably Article 13(4) FCTC which provides that "[a]s a minimum, and in accordance with its constitution or constitutional principles, each Party shall…."

[19] Emphasis added. Unofficial English translation of N. Devillier, "La convention-cadre pour la lutte anti-tabac de l'Organisation mondiale de la santé," 701, at 704-705: "[L]'on se trouve en presence d'un système en plusieurs étapes. La méthode convention-cadre/protocole permet une approche normative progressive. On commence par établir une convention-cadre qui établit des normes et les institutions générales et à définir entre autres les objectifs, les principes, les obligations et les institutions de base ainsi que les procédures relatives à la prise de décision, au financement, au règlement des différends et

Although the initial consensus in the negotiations in favour of a genuine framework convention shifted somewhat in the two last sessions of the Intergovernmental Negotiating Body, where especially developing countries (with the support of NGOs) insisted on precise and normative provisions on a number of issues, in particular on product labeling, counterfeiting and smuggling, publicity, promotion and sponsorship,[20] the approach of developing specific obligations through protocols remained essentially the same. Indeed, the Convention appears to anticipate the elaboration of a variety of protocols, as it repeatedly uses the expression "this Convention and its protocols."[21] For instance, regarding advertising under Article 13, the FCTC explicitly provides that Parties "shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship" (Article 13(8)).

5. Conclusion on the relevance of the 'framework' nature of the FCTC

The FCTC's principal function is to serve as an umbrella agreement that sets forth objectives and principles and that creates the institutional mechanisms and instruments to transform these goals into specific legal obligations that are to be implemented by the Parties. The "framework convention/protocol" approach that characterizes the FCTC thus relies on its subsequent implementation through protocols to impose specific legal obligations. In line with this approach, the FCTC sets forth the general objectives of tobacco control as agreed by the Parties, a governance structure (e.g. the COP, the Secretariat) and the mechanisms to convert these objectives into specific legally binding international obligations (i.e. protocols).

Part II. Meaning of the References to Domestic and International Law in the FCTC

This part of the Report highlights the deference that the FCTC accords to domestic and international law, in addition to and consistent with its 'framework' nature. The frequent references to what is permissible under domestic law qualify the nature of the FCTC and the legal scope of the obligations that the FCTC gives rise to, in particular under Articles 11 and 13 and their related Guidelines. The various references to domestic law and to international law and their meaning will be presented before drawing a conclusion on the role and relevance of such references to the limited legal obligations that

aux amendements. En d'autres termes, la fonction d'une convention-cadre est de définir un système général de gestion. On adopte par la suite des protocoles qui s'appuient sur la convention-cadre mère et font naître des engagements supplémentaires et des accords institutionnels […]. La CCLAT établit des règles et des obligations générales, des structures … et des obligations plus spécifiques dans certains domaines interviendront plus tard, avec la ratification de protocoles."

[20] G.L. Burci, "La Convention-cadre de l'OMS pour la lutte antitabac," *Journal de Droit International* 2005, para. 20.

[21] In Art. 2(1) and (2), Art. 3, Art. 4, first para., Art. 4(7), Art. 5(1), (4) and (5).

the FCTC imposes in respect of labelling and packaging, on the one hand, and advertising and promotion, on the other hand.

1. References to Domestic Law in the FCTC

The FCTC contains numerous references to the fact that the obligation of the Parties to adopt and implement tobacco control measures is subject to the limitations imposed by national law, thereby confirming the limited nature of the international "obligation" that is imposed by the FCTC. This is notably the case for, among others, the following provisions: Art. 5(3); Art. 8(2); Art. 10; and Art. 11.

Furthermore, Article 13 of the Convention regarding tobacco advertising, promotion and sponsorship makes on three occasions a reference that the relevant obligations are subject to a Party's domestic "constitution or constitutional principles." This applies to:

a) the obligation of each Party, "in accordance with its constitution or constitutional principles," to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship (Art. 13(2));

b) the obligation of a Party that is not in a position to undertake a comprehensive ban "due to its constitution or constitutional principles," to apply restrictions on all tobacco advertising, promotion and sponsorship (Art. 13(3)); and

c) the obligation to, "as a minimum, and in accordance with its constitution or constitutional principles," prohibit all forms of false, misleading or deceptive tobacco advertising, promotion and sponsorship, require health or other appropriate warnings or messages, require the disclosure of expenditures by the tobacco industry on advertising, promotion and sponsorship, etc. (Art. 13(4)). Two *litterae* under this paragraph make an additional reference to "the case of a Party that is not in a position to [undertake a comprehensive ban/to prohibit] due to its constitution or constitutional principles," to restrict tobacco advertising and tobacco sponsorship of international events (Art. 13(4)(e) and (f), respectively).

These references to national law and the constitution or constitutional principles can be said to perform various functions with regard to the limited legal effects of the FCTC:

1) They introduce an element of "subsidiarity," taking into account the great diversity of national legal systems, and thereby leaving flexibility to the Parties to determine the manner in which they intend to meet their obligations.

2) They aim at reconciling the implementation of FCTC obligations with the respect for otherwise applicable national rules and thus at limiting the "obligation" to what is permissible under domestic (constitutional) law. It is in part because of such "self-restraint" and deference to national law that so many countries were willing to become parties to the FCTC – a total of 180 countries are now parties to the FCTC.

As noted above, the object and purpose of the FCTC, as expressed in Article 3, is to provide a *framework* for tobacco control measures. It is thus a 'framework agreement' which contains a number of general minimum requirements to be applied, when effective and when in accordance with national laws. The broad wording of the FCTC cannot be interpreted as setting forth additional legal obligations but rather supports a reading that only those minimum obligations clearly stipulated in the agreement are binding.

It is interesting to note that, unlike Articles 11 and 13 of the FCTC, the relevant 'Guidelines' for the implementation of Article 11 and Article 13 do not contain explicit references to national law. This is due to the fact that, as explained below, these Guidelines are merely non-binding recommendations or suggestions for implementing the general "obligations" expressed in Articles 11 and 13 of the FCTC. The deference that is accorded to national law in Articles 11 and 13 thus applies *a fortiori* to the Guidelines.

2. References to International Law in the FCTC

Apart from multiple references to national law and to the interplay between national, regional, sub-regional and international action on public health, the FCTC also contains several references to international law, for example in its preamble.

In the corpus of the FCTC, there is an explicit reference to international law in Article 2(1). This provision, under the heading "relationship between this Convention and other agreements and legal instruments," emphasizes that "nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with [the FCTC's and its protocols'] provisions and are in accordance with international law."

Article 2(1) plays the role of an implicit "conflict clause" in that it makes the imposition of stricter requirements subject to the respect of international law obligations of the Parties. In so doing, the FCTC makes it clear that its general provisions cannot be read as requiring action that is not consistent with other international legal obligations undertaken by the Parties. In other words, in so far as the FCTC obligations are concerned, the FCTC defers to any limitations imposed by each Party's national

law or constitution and it defers to international law constraining the regulatory freedom of the Parties.

There is no *specific* provision in the FCTC dealing with the relationship of the FCTC and the WTO agreements. The most relevant obligations concerned can be found in three WTO agreements. First, the General Agreement on Tariffs and Trade 1994 (GATT 1994) lays down basic obligations governing trade in goods. Second, the Agreement on Technical Barriers to Trade (TBT Agreement) deals with technical regulations and standards. Third, the measures adopted by the FCTC signatories have to be consistent with the obligations set forth in the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). All three WTO agreements restrict the freedom (regulatory autonomy) which WTO Members have in regulating products and related intellectual property rights.

During the FCTC negotiations there was an intense debate between those countries and stakeholders supporting a position that the FCTC expresses the position that health trumps trade[22] versus those that considered that even health-related measures must comply with basic WTO obligations, as contained in the GATT 1994 and other WTO agreements. Ultimately, the negotiators could not agree on even the most modest of conflict rules and thus the FCTC remains silent on the relationship under international law between the FCTC and the WTO agreements, leaving the Vienna Convention on the Law of Treaties ("VCLT") and customary international law to resolve any problems of interpretation and possible conflict. Whether a conflict between the limited obligations contained in the FCTC and those contained in the WTO agreements actually exists can only be determined in case of the adoption of an actual measure by a State that is both a Party to the FCTC and a Member of the WTO.

Leaving aside the question about the relationship between measures required under the FCTC and the rules of the WTO, the reference to international law in Article 2(1) FCTC makes clear that any measure that goes beyond the minimum obligations imposed by the text of the FCTC must in any case be in accordance with international law.

3. The legal obligations imposed by Articles 11 and 13 FCTC and the role of the FCTC Guidelines on Articles 11 and 13

Here below, the legal scope of Articles 11 and 13 FCTC is analysed in light of the references which they contain to domestic law and given the 'framework' nature of the FCTC. The role of the FCTC Guidelines regarding these provisions will also be dealt with.

[22] See the draft language quoted by S. Lester, "Domestic Tobacco Regulation and International Law: The Interaction of Trade Agreements and the Framework Convention on Tobacco Control," 49 *Journal of World Trade* 2015, 19, at 42.

Article 11 FCTC on packaging and labelling of tobacco products imposes some specific obligations on signatories, such as prohibiting "misleading" packaging and labelling and putting a 30% textual health warning on tobacco packages, adding however that it is for each Party to "adopt and implement … effective measures" to ensure that these objectives are met "in accordance with its national law" (Article 11(1), first para.).

Likewise, **Article 13 FCTC** on tobacco advertising, promotion and sponsorship imposes specific obligations on the signatories, such as for example the prohibition on promotion of a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions. It otherwise provides that "Each Party shall [implement such obligations], *in accordance with its constitution or constitutional principles*." A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles "shall apply restrictions on all tobacco advertising, promotion and sponsorship" (Article 13(3)).

It follows from the wording of Article 13 that it is for each Party to determine, based on its domestic constitution or constitutional principles, whether it can prohibit or only restrict such advertising.

With respect to measures that are in accordance with national law but that go beyond these minimum obligations, it follows from Article 2(1) FCTC that they must be in accordance with international law. This can be seen as a confirmation of the well-known customary international norm of *pacta sunt servanda* as reflected in Article 26 VCLT, which requires a country to respect its international treaty obligations.

The **Guidelines** on Articles 11[23] and 13[24] as adopted by the COP in 2008 do not impose additional legal obligations beyond the legal obligations noted above. As has been rightly observed, they do not purport to be binding,[25] but rather are "intended to assist Parties in meeting their obligations"[26] under

[23] Conference of the Parties to the FCTC, *Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and Labelling of Tobacco Products)*, adopted during the third session of the COP on 17-22 November 2008, FCTC/COP3(10).

[24] Conference of the Parties to the FCTC, *Guidelines for Implementation of Article 13 of the WHO Framework Convention on Tobacco Control (Tobacco Advertising, Promotion and Sponsorship)*, adopted during the third session of the COP on 17-22 November 2008, FCTC/COP3(12).

[25] D.W. Layton and J.C. Lowe, "The Framework Convention on Tobacco Control and the World Trade Organization: A Conflict Analysis under International Law," 9 *Global Trade and Customs Journal* 2014, 246, at 248.

[26] FCTC Guidelines for Implementation of Article 11, para. 1; see also FCTC/COP/3/REC/3, at 50.

the Convention and "to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures."[27]

When the Guidelines were adopted, the Parties expressly stated that they "are not intended to increase Parties' obligations under this Article."[28] That is why the Guidelines are worded in a hortatory fashion, using "should" rather than "shall," and frequently suggest that the Parties "should *consider*" certain measures rather than to suggest that parties "should *adopt*" such measures.[29]

In sum, there is no debate about the status under international law of the non-binding nature of the FCTC Guidelines.[30] In accordance with the above sketched "framework convention/protocol" approach, the operative regulations that specify and elaborate on the general obligations of the FCTC are contained in "protocols" and not in the Guidelines. Any part of the Guidelines that goes beyond the minimum obligations imposed by the FCTC will raise the question whether they are permissible in the light of domestic and international law.

Part III. Relationship of the International Legal Obligations Emanating from the FCTC and those Emanating from the WTO Agreements

The FCTC and the WTO agreements co-exist as treaties under international law. The relevant question of public international law that is addressed in this section concerns the relationship between FCTC's limited obligations on packaging and labelling, discussed above, on the one hand, and the legal obligations imposed by the relevant WTO agreements, such as the TBT Agreement and the TRIPS Agreement, on the other hand.

There are two possible ways in which international norms can relate to one another: there can be a conflict of norms when two legally binding obligations from different treaties impose inconsistent obligations on the signatories of these two agreements; or there can exist an overlap between different but not otherwise inconsistent legal obligations. Furthermore, as was concluded by the Working Group of the International Law Commission on the fragmentation of international law, "it is a generally

[27] FCTC Guidelines for Implementation of Article 11, para. 1.

[28] See third recital of the preamble to the draft decision on the elaboration of guidelines for the implementation of Article 11 FCTC, FCTC/COP/3/REC/3, at 50.

[29] For example, in paragraphs 9,11,12, 13,22,24, 36, 38, 39, 46, 48, 51, 53, 57, 58, 61, 63, 65, 66, 68, 69, 71 and 74 of the Guidelines to Article 11 FCTC. The Guidelines to Article 13 FCTC are worded in a similar manner.

[30] There has been a suggestion by one author, though, to consider these guidelines as international standards for the application of the TBT Agreement: L. Gruszczynski, "The WHO Framework Convention on Tobacco Control as an International Standard under the TBT Agreement?," 9 *Transnational Dispute Management* 2012, Special on "Legal Issues in Tobacco Control" edited by A.D. Mitchel and T. Voon.

accepted principle that when several norms bear on a single issue they should, to the extent possible, be interpreted so as to give rise to a single set of compatible obligations."[31]

Measures adopted by WTO Members have to be consistent with the obligations which these Members have agreed to by virtue of being a Member of that organization. All measures must comply with basic non-discrimination obligations, such as the Most Favoured Nation treatment obligation (Article I:1 GATT 1994) and the National Treatment obligation (Article III:4 GATT 1994). In the event a measure is found to be inconsistent with any of these provisions, it might still be justified under Article XX GATT 1994. In such a situation a measure has to fall within the scope of one of the subparagraphs of that Article (e.g. subparagraph (b) on the protection of public health). Moreover, it has to be shown that the measure is "necessary" to achieve the objective pursued. Finally, the application may not result in arbitrary or unjustifiable discrimination by virtue of the 'chapeau' of Article XX GATT 1994.

However, measures that implement a Member's commitments under the FCTC may amount, under certain circumstances, to "technical regulations." Technical regulations, such as product, packaging or labelling requirements, are governed by the WTO TBT Agreement, which builds on the disciplines laid down in the GATT 1994. One of the obligations in this agreement, Article 2.2, requires Members to ensure that its technical regulations do not constitute "unnecessary obstacles" to trade. The provision further stipulates that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks which non-fulfilment would create."

It can be submitted that there is no conflict between the limited obligations of the FCTC and the obligations of the WTO agreements. For example, examining the obligations in relation to packaging, labelling and advertising, there is little debate that a non-discriminatory measure based on Article 11 FCTC, which requires that 30% of the "principal display area" contains a textual health warning, is consistent with WTO Members' obligations under the GATT 1994. Where a measure does not favour domestic products over imported goods (i.e. does not accord 'less favourable treatment' to imported goods), the measure will be consistent with the national treatment obligation contained in Article III:4 GATT 1994. Even if an inconsistency with Article III:4 GATT 1994 were to be found, the measure could arguably be justified on grounds of public health under subparagraph (b) of Article XX GATT 1994. Where the particular measure constitutes a technical regulation in the sense of the TBT Agreement, it will also be consistent with the national treatment obligation contained in Article 2.1 TBT Agreement. However, Article 2.2 TBT Agreement contains an obligation that requires Members not to adopt

[31] *Conclusions of the work of the Study Group on the Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law*, 1, available at http://legal.un.org/ilc/texts/instruments/word_files/english/draft_articles/1_9_2006.doc.

measures that "are more trade-restrictive than necessary." This provision is considered to be one of the WTO obligations that might potentially severely restrict WTO Members' regulatory autonomy.[32] However, this constraint does not solely apply to tobacco regulation. It applies to all domestic regulation. In terms of regulatory measures that are not required by any specific legal obligation under the FCTC but which are adopted in furtherance of the latter's general principles and objectives, there does not seem to be a conflict, because there is no operative "obligation" that is being imposed and no suggestion or rule in the FCTC that measures that are taken in furtherance of these general objectives are *ipso facto* consistent with international law. Article 2(1) FCTC rather stands for the proposition that measures going beyond what the FCTC requires shall be consistent with a Party's international law obligations. In sum, in a situation where the only specific legally binding obligation is that of the WTO, it is only this obligation that will discipline the regulatory freedom of Members that are also signatories of the FCTC.

In addition to a general public international law perspective on the obligations imposed on WTO Members that are also signatories to the FCTC, it is perhaps useful to consider the question from the perspective of the WTO. After all, it is most likely that any dispute will be brought before the WTO dispute settlement mechanism given the lack of a genuine dispute settlement system under the FCTC.

Under WTO law, a regulatory measure that sets forth requirements in respect of the packaging and labelling of a product is a "technical regulation" that is covered by the disciplines of the TBT Agreement. Therefore, WTO Members are under an international legal obligation to ensure that all such regulatory measures are not more trade restrictive than necessary. A WTO dispute settlement panel will apply the rules of the WTO agreements that set forth this 'necessity' test and, if it can be demonstrated that the trade-restrictive measure is not actually contributing to the legitimate objective or is not apt to materially contribute to that objective, a violation may be found to exist. WTO panels will not apply non-WTO law like the provisions of the FCTC.

The WTO dispute settlement system is intended to "preserve the rights and obligations of Members under the covered agreements" and to clarify "those agreements," not other international agreements such as the FCTC. This intention is clearly stated in Article 3.2 of the Understanding on Rules and Procedures governing the Settlement of Disputes ("DSU") and is confirmed in the terms of reference under Article 7 DSU, which refer to the covered agreements. Both Articles 3.2 and 19.2 DSU confirm

[32] S. Lester, "Domestic Tobacco Regulation and International Law: The Interaction of Trade Agreements and the Framework Convention on Tobacco Control," 49 *Journal of World Trade* 2015, 46.

that WTO panels cannot "add to or diminish the rights and obligations provided in the covered agreements."

This is, however, not to say that international law does not play any role in clarifying a Member's obligations under the WTO. International agreements, like the FCTC, and public international law in general may be referred to by a panel in the context of interpreting the obligations imposed by the WTO agreements. The WTO has repeatedly said that its agreements should not be read in clinical isolation from other developments in international law and have thus relied on international agreements as evidence of the existence of a particular situation. For example, the Convention on International Trade in Endangered Species ("CITES") played a role when examining whether certain animals were in danger of extinction.[33] Such a role for international agreements is, of course, very different from reading obligations from outside the WTO agreements into the WTO agreements as part of the context of the WTO obligation.

Moreover, Article 31.3 VCLT provides that, when interpreting a treaty, "any relevant rules of international law applicable in the relations between the parties" to the treaty "shall be taken into account" together with the context of the treaty. This rule that other relevant international obligations are to play a role in the interpretation of treaties applies also in the WTO context. However, in the case of the FCTC and its Guidelines, WTO case-law suggests that they can be of little importance as an interpretive tool to clarify WTO obligations.

First, for international rules to be applicable between the parties they have to be either "binding by virtue of being part of an international treaty" or "reflect customary international law or general principles of law."[34] As indicated above, the FCTC Guidelines are not binding on the parties as an international treaty and are clearly not part of customary international law. In addition, the FCTC itself has not been ratified by all WTO Members (including, for example, Argentina, Switzerland, and the United States). The FCTC or its Guidelines have not attained the level of customary international law and do not reflect general principles of law either.

Second, the FCTC and its Guidelines are not, technically speaking, directly "relevant" for the purposes of interpreting the WTO obligations stipulating that a measure must not constitute an unjustifiable

[33] See Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, para. 132.

[34] Appellate Body Report, *United States – Definitive Anti-Dumping and Countervailing Duties on Certain Products from China*, WT/DS379/AB/R, adopted 25 March 2011 ("*US – Anti-Dumping and Countervailing Duties (China)")*, para. 308, referring to Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, adopted 14 November 2008, DSR 2008:X, 3507 ("*US – Continued Suspension")*, para. 382.

encumbrance of trademarks under the TRIPS Agreement or not be more trade restrictive than necessary under the TBT Agreement. The "subject matter" dealt with by the FCTC and the Guidelines is different from that addressed by these WTO provisions in need of interpretation.[35]

Finally, and importantly, as an interpretive tool, the normative weight ascribed to any international obligation of the FCTC, much less its non-binding Guidelines, is merely that it should be "taken into account" in interpreting the relevant WTO obligation if it is ambiguous.[36]

Furthermore, it is worth recalling that subparagraph (d) of Article XX GATT 1994 may justify otherwise WTO-inconsistent measures when they are necessary to secure compliance with WTO consistent domestic laws, but not when they are necessary to secure compliance with international law.[37] So, from the WTO perspective, the FCTC or its Guidelines cannot constitute a defense to a violation of the GATT 1994 by arguing that a regulatory measure was "necessary" to comply with this other international obligation.

In any case, based on the principle of international law of mutual supportiveness or harmonization of different legal regimes (*supra*), conflicts must be avoided and where it is possible to comply with both a Party's obligation under the FCTC (e.g. textual warnings covering not less than 30% of the principal display areas of tobacco products) and its WTO obligations under the TRIPS and TBT Agreements, a Member is required to do so.

When confronted with a health warning of *more than* 30%, however, there can be no conflict as only legally binding obligations arise under the WTO agreements, namely to justify the potentially trade restrictive regulatory measure based on the well-known necessity test. This is so because there is no corresponding legal obligation under the FCTC that could be argued to conflict with these WTO obligations. This approach is further confirmed, in so far as necessary, by the fact that Article 2.1 FCTC provides that going beyond the requirements of the FCTC is possible if it is done in a manner that is in accordance with international law. This does not mean that the Parties cannot impose such larger warnings on tobacco products. It simply means that when they do so, they must ensure that they are

[35] Appellate Body Report, *US – Anti-Dumping and Countervailing Duties (China)*, para. 308; Appellate Body Report, *European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft*, WT/DS316/AB/R, circulated to WTO Members 18 May 2011 ("*EC and Certain member States – Large Civil Aircraft")*, paras. 849-855.

[36] This was emphasized by the Appellate Body in *EC and Certain Member States – Large Civil Aircraft*. *See* Appellate Body Report, *EC and Certain member States – Large Civil Aircraft*, para. 841.

[37] Appellate Body Report, *Mexico – Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/AB/R, adopted 24 March 2006, DSR 2006:I, 3 ("*Mexico – Taxes on Soft Drinks")*, para. 75.

not creating unnecessary obstacles to trade and that other relevant agreements of the WTO like the TRIPS Agreement on trademarks are complied with.

In addition, in Article 11 and throughout the FCTC,[38] the emphasis is always on the need for 'effective' measures in accordance with national and international law. The FCTC thus, in a way, confirms the WTO's justified focus on 'necessity' and 'effectiveness' as setting the boundaries for what is required or desirable from the FCTC perspective. For example, Article 11 FCTC requires the Parties to adopt and implement measures that are 'effective.' The Guidelines to Article 11 also state: "Parties should consider the evidence and the experience of others when determining new packaging and labelling measures and aim to implement the most effective measures they can achieve."[39] If a trade-restrictive measure is not effective, it should give way to a more effective alternative measure. That is what the WTO requires and the FCTC does not state otherwise.

It should be noted that at the Fourth Conference of the Parties to the FCTC, two decisions that relate to the obligations of the parties under the WTO agreements were adopted:

a) the "Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control" (the "Punta del Este Declaration");[40] and

b) the "Decision on Cooperation between the Convention Secretariat and the World Trade Organization" (the "Decision on Cooperation").[41]

Neither of these Decisions expresses an agreement among the Parties that international trade rules may be ignored or that actions taken under the FCTC Guidelines are necessarily consistent with WTO rules.

The Punta del Este Declaration essentially recalls the various relevant obligations under the WTO agreements and declares that the Parties may adopt measures to protect public health, including regulating the exercise of intellectual property rights in accordance with national public health policies,

[38] References to "effective" legislation and other measures is found in many of the operative articles of the FCTC including Articles 4(1), 5(2)(b), 6(1), 7, 8(2), 9, 10, 11(1), 12, and 14(1).

[39] Conference of the Parties to the FCTC, *Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and Labelling of Tobacco Products)*, adopted during the third session of the COP on 17-22 November 2008, FCTC/COP3(10), para. 4.

[40] Conference of the Parties to the FCTC, Fourth Session, Punta del Este, Uruguay, 15–20 November 2010, FCTC/COP/4/DIV/6, 6 December 2010, FCTC/COP 4 (5), Punta del Este Declaration on the Implementation of the WHO Framework Convention on Tobacco Control," at 7.

[41] Conference of the Parties to the FCTC, Fourth Session, Punta del Este, Uruguay, 15–20 November 2010, FCTC/COP/4/DIV/6, 6 December 2010, FCTC/COP 4 (18), Decision on Cooperation between the Convention Secretariat and the World Trade Organization, at 77.

"provided that such measures are consistent with the TRIPS Agreement."[42] Admittedly, the Declaration provides that "Parties have the right to define and implement national public health policies pursuant to compliance with conventions and commitments under WHO, particularly with the WHO FCTC,"[43] but this does not say anything about the relationship of such policies with WTO obligations.

Similarly, the Decision on Cooperation essentially recalls the need for "policy coherence" between trade and health, which implies the need for various ministries to "work together constructively in order to ensure that the interests of trade and health are appropriately balanced and coordinated."[44] In that context, it requests the FCTC Secretariat to "cooperate with the WTO Secretariat with the aim of information sharing on trade-related tobacco control issues."[45] However, nothing in the Declaration supports the argument that trade objectives must be ignored whenever a country claims to pursue health objectives or that measures adopted in line with the FCTC Guidelines are necessarily WTO consistent.

A similar expression of support for a balanced approach to measures addressing health concerns can be found in the WTO Doha Declaration on TRIPS and Public Health. In that Declaration, WTO Members stated that Members should be entitled to take measures to protect health, but at the same time noted that they make this statement while "reiterating our commitment to the TRIPS Agreement" and "maintaining our commitments in the TRIPS Agreement."[46]

[42] Punta del Este Declaration, recital 4.

[43] Punta del Este Declaration, recital 5.

[44] Decision on Cooperation, para. 4.

[45] Decision on Cooperation, recital 2 (1).

[46] Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/Min (01)/Dec/2, paras. 4 and 5.

Part IV. Conclusion

This Report addressed three related questions concerning the 'framework' nature of the FCTC under international law, the FCTC's references to domestic and international law and its relationship with other international agreements like the WTO agreements. Based on the analysis of these three questions, the conclusion is that the FCTC constitutes an international treaty that sets forth a number of minimum obligations, the general objectives of the Parties and the institutional mechanisms (including legal instruments, i.e. protocols) by which such aims will subsequently be negotiated, developed and implemented.

In addition, the FCTC's generally worded obligations and frequent instances of deference to national law and constitutional principles, highlight the fact that the FCTC's objectives and obligations are subject to limitations imposed by each Party's national law. The minimum requirements that the Parties to the FCTC are to implement are subject to compliance with domestic and constitutional law, thus further highlighting the limited nature of the international legal obligations that are imposed.

As a matter of public international law, it is unlikely that there can be a conflict between the FCTC and other international treaties setting forth legally binding obligations, like the WTO agreements. As stated very clearly in Article 2(1) of the FCTC, measures that go beyond the minimum requirements of the FCTC must be in accordance with international law, reflecting the principle of *pacta sunt servanda*.

From the perspective of a WTO panel which has a limited mandate to examine the consistency of measures with the WTO's covered agreements only and not with public international law more generally, the WTO agreements prevail. The FCTC may play only a limited role given that the WTO agreements are not to be read in clinical isolation from public international law.

Bibliographic References

D. Bodansky, *The Framework Convention / Protocol Approach,* in Framework Convention on Tobacco Control. Technical Briefing Series, Paper 1, World Health Organization, 1999.

G.L. Burci, "La Convention-cadre de l'OMS pour la lutte antitabac," *Journal de Droit International* 2005, 135.

J. Burda, "La convention-cadre de l'OMS pour la lutte anti-tabac dans un monde aux échanges globalises: progress pour la santé ou écran de fumée?" 19 *Revue quebecoise de droit international* 2006, 19-40.

M.E. Crow, "Smokescreens and State Responsibility: Using Human Rights Strategies to Promote Global Tobacco Control," 29 *Yale Journal of International Law* 2004, 209-250.

N. Devillier, "La convention-cadre pour la lutte anti-tabac de l'Organisation mondiale de la santé," 701-728.

J. Fall, "Designing Framework Conventions to Promote and Support Transboundary Protected Areas: Theory and Practice from the Carpathian Convention," in G. Tamburelli (ed.), *Biodiversity Conservation and Protected Areas: the Italian and Ukrainian Legislation,* Giuffrè, 2007, 101-117.

L. Gruszczynski, "The WHO Framework Convention on Tobacco Control as an International Standard under the TBT Agreement?," 9 *Transnational Dispute Management* 2012, Special on "Legal Issues in Tobacco Control" edited by A.D. Mitchel and T. Voon.

G.F. Jacob, "Without Reservation," 5 Chicago Journal of International Law 2004, 287-302.

L. Joossens, "From public health to international law: possible protocols for inclusion in the Framework Convention on Tobacco Control," *Bulletin of the World Health Organization* 2000, 930-936.

A.C. Kiss, "Les traités-cadres: une technique juridique caractéristique du droit international de l'environnement," *Annuaire français de droit international* 1993, 792-797.

D.W. Layton and J.C. Lowe, "The Framework Convention on Tobacco Control and the World Trade Organization: A Conflict Analysis under International Law," 9 *Global Trade and Customs Journal* 2014, 246-252.

S. Lester, “Domestic Tobacco Regulation and International Law: The Interaction of Trade Agreements and the Framework Convention on Tobacco Control,” 49 *Journal of World Trade* 2015, 19-48.

N. Matz-Lück, “Framework Conventions as a Regulatory Tool,” 1 *Goettingen Journal of International Law* 2009, 439-458.

N. Matz-Lück, “Framework Agreements,” in *Max Planck Encyclopedia of Public International Law*, 2011.

R. Roemer, “Origins of the WHO Framework Convention on Tobacco Control,” 95 *American Journal of Public Health* 2005, 936-938.

R. Roemer, A. Taylor and J. Larivière, “Origins of the WHO Framework Convention on Tobacco Control,” 95 *American Journal of Public Health* 2005, 936-938.

K. Shibuya Ciecierski, E. Guindon, D.W. Bettcher, D.B. Evans and C.J.L. Murray, “WHO Framework Convention on Tobacco Control: development of an evidence based global public health treaty,” 327 *BMJ* 2003, 154-157.

A. Taylor and D.W. Bettcher, “WHO Framework Convention on Tobacco Control: a global ‘good’ for public health,” *Bulletin of the World Health Organization* 2000, 920-929.

World Health Organization, *Elements of a WHO framework convention for tobacco control*, A/FCTC/WG1/6, 8 September 1999, 34.