

**From:** "Viscusi, Kip" [REDACTED]  
**To:** "panel\_hs@legco.gov.hk" <panel\_hs@legco.gov.hk>  
**Cc:** "Bos, Michael" [REDACTED], "Pfeffer, Philip"  
[REDACTED]

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**Date:** Tuesday, January 10, 2017 09:07PM  
**Subject:** British American Tobacco - Expert Report in Respect of Proposal to increase Graphic Health Warnings in Hong Kong to 85%

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Dear Honourable Members :

I am writing in connection with the Government's proposal to change the graphic health warnings ("GHWs") on tobacco products in Hong Kong from 50% to 85%. I previously prepared a report in respect of the proposal dated 17 June 2015, in which I concluded that 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. A copy of that report is attached to this e-mail for your consideration.

Yours Sincerely

W. Kip Viscusi

University Distinguished Professor of Law, Economics, and Management

Vanderbilt University

**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**

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# **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**

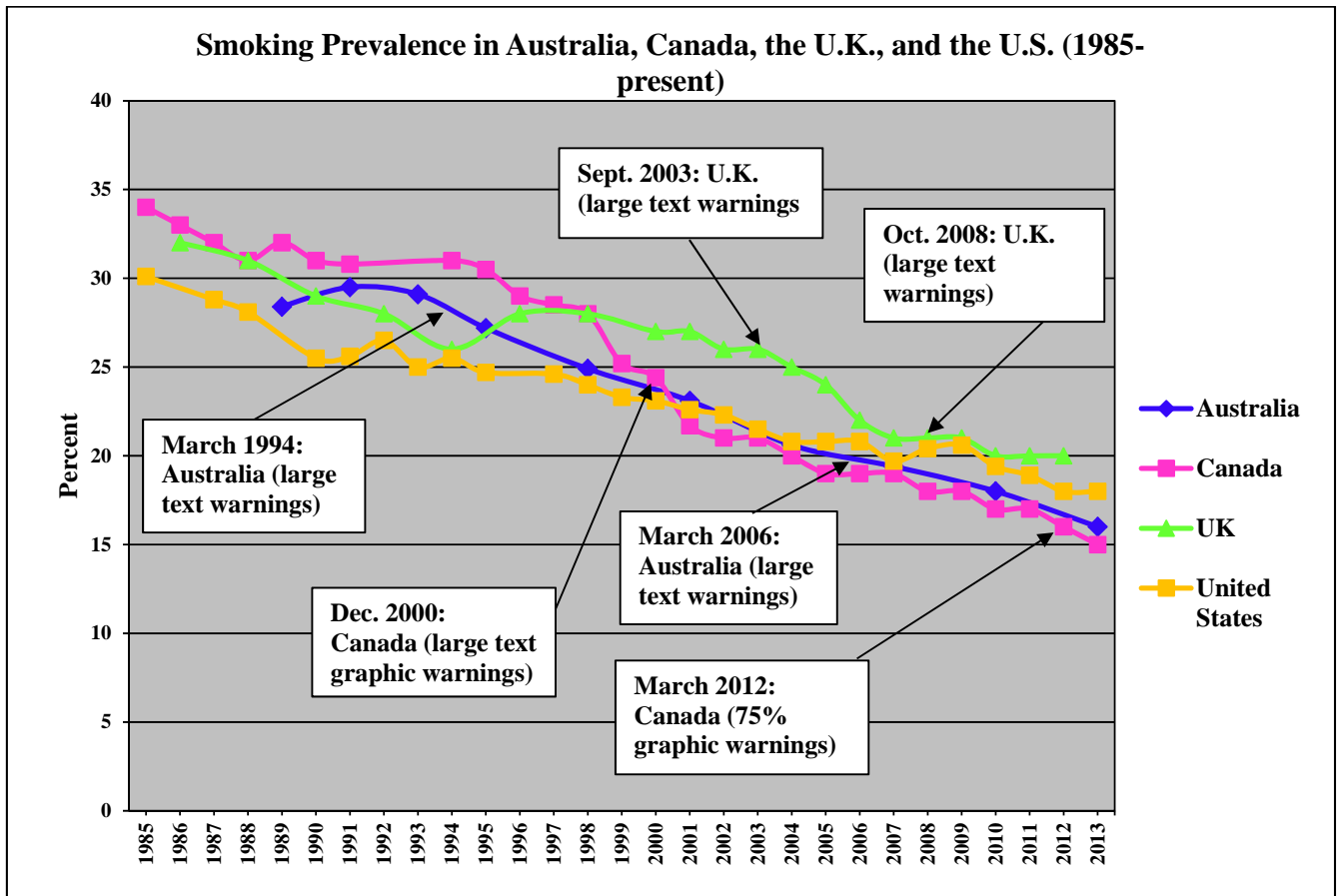
8. The most meaningful test of whether graphic warnings will have an effect on smoking behavior is to analyze the effect of these warnings on smoking prevalence in countries that have implemented these warnings. Before considering smoking prevalence trends in Hong Kong, I first present a graphical analysis 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

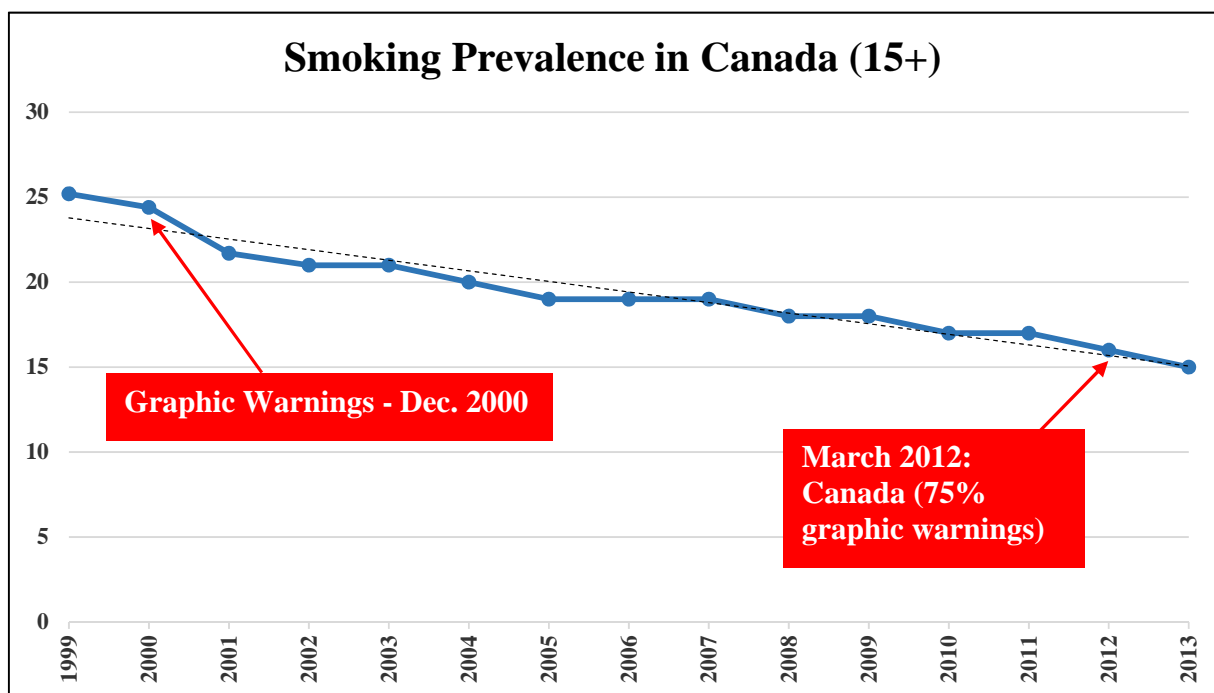


The smoking prevalence data for these countries were obtained from government sources. As indicated on the chart, these data include youth and adults.

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.

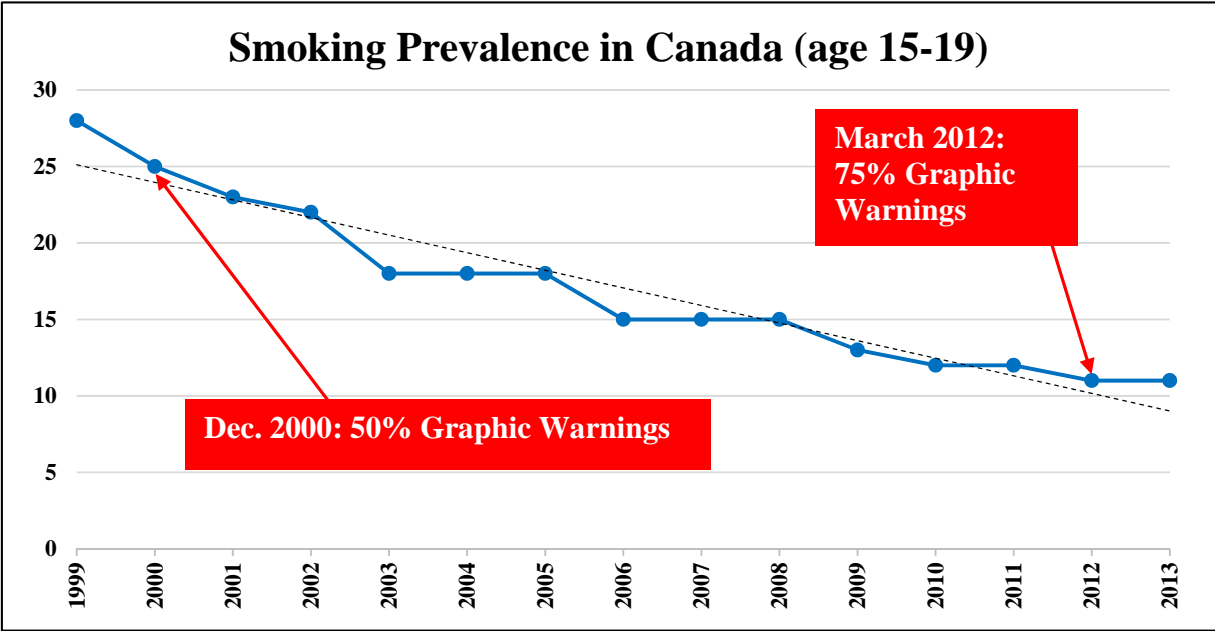
Figure 2. Smoking Prevalence in Canada (Ages 15+) by Year



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.

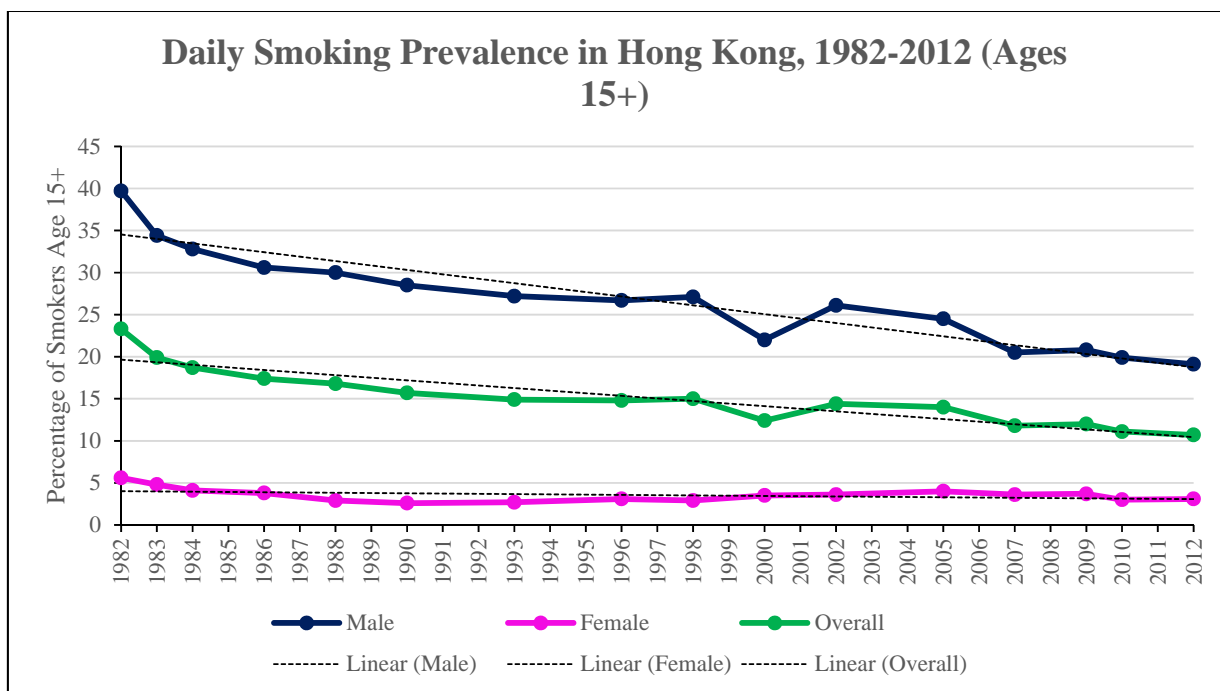
20. The data from the U.K. and Australia shown in Figure 1 are consistent and again reflect that when large warnings were adopted there was no acceleration of the pre-existing downward trend in smoking prevalence. In fact, the U.K. data demonstrates a flattening out of the decline in smoking prevalence 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

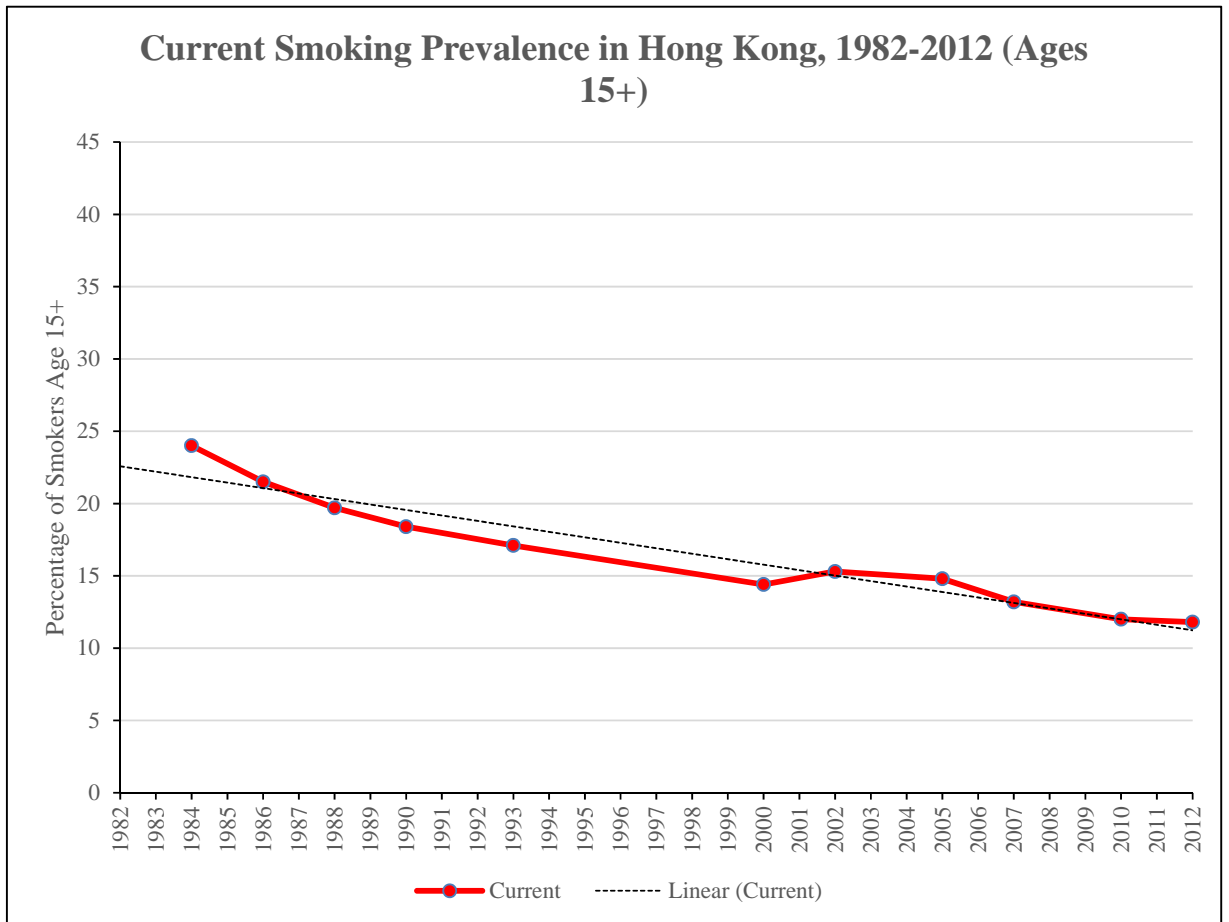


period fails to show any statistically significant drop in daily smoking prevalence rates starting in 2008. Indeed, while the effect is not statistically significant, the results indicate a positive rather than a negative effect on daily smoking prevalence rates.

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:



Non-ANSI



ANSI-1



ANSI-2

And the two laboratory warning signs shown to participants were:



Less ANSI



More ANSI

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**

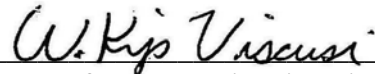
54. The available evidence on the efficacy of graphic warnings is substantial and provides a consistent basis for assessing the impact of graphic warnings. Overall, there is a



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.

  
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Professor W. Kip Viscusi