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Briefing for Legislative Council – Panel on Health Services – 19 June 2018 meeting (agenda item IV)

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#### About the author

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company, IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003 he joined Prime Minister Blair's Strategy Unit as a senior civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan.

The author has no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.

## 1 Key points for the Panel on Health Services

- Professor Gerry Stimson and I were pleased to submit views to the Panel when it considered the issue of e-cigarettes in 2015<sup>2</sup>. The arguments are fundamentally unchanged but there is more evidence now to support confidence in the findings we presented in 2015. *E-cigarettes are much less harmful than cigarettes* and there have been no signs of material adverse population effects (gateways, renormalisation of smoking, reduced quitting, increased initiation). In fact, in the countries where e-cigarettes have been made easily available smoking has been falling rapidly in both adult and youth populations.
- Tobacco smoke is the dominant cause of tobacco-related diseases it is the products of combustion of tobacco that cause the harm to smokers, not nicotine (the mild drug). The public health concern about tobacco arises from the impacts of prolonged smoke exposure on cancer, cardiovascular disease and respiratory conditions.
- E-cigarettes, heated tobacco products, smokeless tobacco and any nicotine product that does
  not involve combustion do not create smoke and the are *inevitably* much less harmful it is a
  matter of basic chemistry and physics. The chemical agents that cause harm in smoke are either
  not present in vapour aerosols at detectable levels or are detectable at levels one to three
  orders of magnitude lower than in cigarette smoke.
- We have been concerned by poor advice provided by WHO, and we caution the Panel against relying on WHO's advice in this area. Some of the world's top tobacco control scientists have consistently urged the WHO and FCTC Secretariat to embrace this aspect of tobacco control strategy<sup>3</sup>. Despite this, WHO has had a tendency to emphasis *threats* over *opportunities*, with an implicit suggestion that the best policy is to prohibit these much-safer products even though cigarettes would remain widely available<sup>4</sup>. WHO has been criticised for its poor science and an instinctive hostility to private sector innovation<sup>5</sup>.
- This is mirrored by poor and outdated advice provided by Hong Kong's own Office of Tobacco Control<sup>6</sup>. These statements pick at particular studies or effects but do not put them into context with respect to smoking-related risks or absolute risk benchmarks such as occupational exposure limits. Without insights into relative risk and the magnitude of any risk compared to other risks we bear in society, the information is providing little of value to policy-makers or legislators.
- I hope the rest of this briefing is informative and assists the Panel in establishing an appropriate 'risk-proportionate' regime for much safer alternatives to smoking.

<sup>&</sup>lt;sup>2</sup> Clive Bates, Professor Gerry Stimson, Panel on Health Services hearing 6 July 2015 – written submission, 3 July 2015 [English] [Mandarin][blog: Hong Kong health department moves decisively to protect the cigarette trade 3 July 2015]

Letter to Dr Margaret Chan, Director General WHO from 53 scientists, Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control 26 May 2014 [context][letter]

WHO. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), FCTC/COP/7/11 August 2016. [Link] – see especially WHO's policy proposals (para 29-32) which start by assuming prohibition is the norm.

UK Centre for Alcohol and Tobacco Studies (UKCTAS), Commentary on WHO report on ENDS and ENNDS, October 2016 [link][PDF]

Government of Hong Kong, Department of Health, Tobacco Control Office. Info-stations briefing - E-cigarettes [link] Heat not Burn (HnB) tobacco products [link]

### 2 Introduction – tobacco harm reduction

Tobacco harm reduction starts from the insight that the vast majority of harm done by tobacco use is done by *smoke* – the products of combustion arising from burning tobacco leaf. The nicotine is not the main or even an important harmful agent in tobacco use, but it is the reason why people use tobacco, mostly as smokers. This has been known since at least the 1970s<sup>7</sup>: *People smoke for the nicotine, but they die from the tar.* 

So the opportunity for a rapid win for health is to eliminate the tar (the smoke residues) for people who continue to use nicotine by choice or because they are dependent. Tobacco harm reduction involves the use of non-combustible products such as vaping products like e-cigarettes, heated tobacco products, or smokeless tobacco made to high purity standards. These products have risen to prominence rapidly since 2010, and their rise has coincided with rapid declines in smoking in the UK and US among both adults and adolescents.

The science and policy issues are discussed in more depth in Section 3 below which draws on five statements from the UK Royal College of Physicians' major 2016 report: *Nicotine without the smoke:* tobacco harm reduction<sup>8</sup>. The Royal College endorses the use of e-cigarette to reduce smoking:

The Royal College of Physicians' new report, 'Nicotine without smoke: tobacco harm reduction', has concluded that e-cigarettes are likely to be beneficial to UK public health. Smokers can therefore be reassured and encouraged to use them, and the public can be reassured that e-cigarettes are much safer than smoking.

This is a conclusion supported by the largest UK public health agency, Public Health England<sup>9</sup>, which has recently shown its support by advertising switching to e-cigarettes on national prime-time television. Independent American experts have reviewed the evidence in detail and have called for a fundamental change in the public health approach to nicotine, giving primary to reducing NCDs and stressing the value of harm minimisation approaches:<sup>10</sup>

A reframing of societal nicotine use through the lens of harm minimization is an extraordinary opportunity to enhance the impact of tobacco control efforts.

## 3 The impact of tobacco harm reduction

There follows some brief comments on experience with reduced-risk products.

**E-cigarettes.** In the UK, smoking rates fell considerably in the last few years: adult smoking prevalence in England declined from 19.9% in 2010 to 15.5% in 2016<sup>11</sup>. According to a 2018 Public

Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. BMJ 1976;1:1430–3. [link]

<sup>8</sup> Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [link] [press]

McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

Abrams DB, Glasser AM, Pearson JL, Villanti AC, Collins LK, Niaura RS. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives. *Annu Rev Public Health*; 2018. [link]

 $<sup>^{11}</sup>$  UK Office for National Statistics (ONS), Adult smoking habits in the UK: 2016 [link]

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Health England Review, in 2017 quit success rates were at the highest rates ever, and e-cigarettes may have contributed to as many as 57,000 additional quits in 2016<sup>12</sup>.

**Smokeless tobacco**. The country with the lowest smoking prevalence in the developed world is Sweden. A European Union survey showing adult smoking prevalence at 7% (5% daily smoking) compared to 26% (24% daily) for the European Union as a whole<sup>13</sup>. But the reason for this low smoking prevalence<sup>14</sup> and resulting low rates of NCDs in Sweden<sup>15</sup>, especially among men, is a form of smokeless tobacco known as snus. From a point of view of NCDs, Sweden has benefited from the rise of snus and decline in smoking.

**Heated tobacco products**. Similarly, there has been a remarkable decline in cigarette consumption in Japan following the introduction of heated tobacco products – again a form of nicotine product that does not involve combustion and greatly reduces exposure to hazardous chemicals compared to smoking. Cigarette volumes in Japan have fallen by an *incredible 27% in two years*, from 43.6 billion sticks in Jan-March 2016 to 31.8 billion sticks in Jan-March 2018<sup>16</sup>. Analysts at Citi Group attribute the disruption of the cigarette market to heated tobacco products<sup>17</sup>:

Heated tobacco, led by iQOS, is completely disrupting the cigarette industry in Japan and Korea: we expect that heated tobacco to cut the volume of cigarettes sold in Japan by more than 30% by the end of 2018.

These remarkable data should be a wake-up call to everyone involved in tackling NCDs – there are technology changes that can reduce smoking at rates that are unprecedented in the history of tobacco control. However, the current targets and indicators cannot reflect the very high benefit of switching from high-risk to low-risk product.

## 4 Five insights inspired by the Royal College of Physicians

To provide background on tobacco harm reduction, we draw on five key findings of the April 2016 Royal College of Physicians (London) report<sup>18</sup>: *Nicotine without smoke: tobacco harm reduction*. The Royal College first put the dangers of smoking on the public agenda with its ground-breaking 1962 report, *Smoking and Health*<sup>19</sup>.

McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link]

European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [link]

Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [link]

Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis.* 2014 Jan;12(1):14. [link]

Japan Tobacco, Japanese Domestic Cigarette Sales Results for March 2015 2016 2017 2018 – note JT provides its own volumes and market share, so the total market volume can be calculated.

 $<sup>^{\</sup>rm 17}$   $\,$  Spielman A, The new world of tobacco , Citi Group, page 20. 18 April 2018

Royal College of Physicians (London) *Nicotine without smoke: tobacco harm reduction, 28 April 2016* [report] and [press release]

<sup>&</sup>lt;sup>19</sup> Royal College of Physicians (London) *Smoking and Health*, 1962 [link]

#### 4.1 On the relative risks of vaping and smoking

Although it is not possible to precisely quantify the long-term health risks associated with ecigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure. (RCP Section 5.5 page 87)

People who smoke need to know that they have the option to switch to vaping and that doing this will radically reduce their incremental risks. Likewise, professionals involved in health care and policy need a good feel for the relative risks. The RCP aimed provide some clarity and has provided its own best estimate of relative risk based on what is known about these products — and this estimate is independent of other studies. Vaping involves completely different chemical and physical processes, and the main harmful or potentially harmful agents in cigarette smoke are either not present or present at levels well below 5% of those found in cigarettes. Even if new harmful agents are discovered, it is much easier to remove them from e-liquids than it is to remove target chemicals from cigarette smoke. Note how carefully worded this statement is — it is steering the reader to the right ball-park, acknowledging uncertainty, and pointing out it is a cautious estimate.

#### 4.2 On the idea that allowing e-cigarettes will somehow cause people to smoke

There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely. (RCP Key recommendations)

The finding is what a rational observer would expect – that people will use much safer products to reduce the risks to their health and as a way of quitting smoking, rather than to smoke more. The rise of vaping in the UK and US has been accompanied by rapid falls in adult smoking. There are strong *associations* between smoking and vaping because the same personal characteristics or circumstances that cause people to smoke also cause them to use ENDS, there is no compelling evidence that vaping causes smoking<sup>20</sup>.

The American experience is of *rapidly declining teenage smoking* coinciding with the rise in vaping, much of which is occasional and without nicotine. The National Academies of Science, Engineering and Medicine states "for youth and young adults, there is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes". However this has not translated to increases in smoking. In fact, the opposite effect, an anomalously rapid *decline* in adolescent smoking, has occurred, as the National Academies point out:<sup>21</sup>

<sup>&</sup>lt;sup>20</sup> Kozlowski LT, Warner KE. Adolescents and e-cigarettes: Objects of concern may appear larger than they are. *Drug Alcohol Depend*. 2017 May;174(1 May 2017):209–14. [link][PDF]

National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [link]

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Overall, the population-based data broadly show opposing trends in e-cigarette and cigarette use prevalence across time among U.S. youth in recent years and thus do not provide confirmatory evidence of the epidemiologic person-level positive associations of vaping and smoking.

#### Likewise, a 2017 analysis of UK survey data concluded<sup>22</sup>:

In summary, surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low.

A comprehensive American independent review of the studies and methodologies purporting to reveal 'gateway effects' found multiple flaws in methodology and interpretation, concluding<sup>23</sup>:

Only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction meet a set of proposed quality standards. Those that do are consistent with randomized controlled trial evidence in suggesting that e-cigarettes can help with smoking cessation or reduction.

#### 4.3 On the potential for bad policies to cause additional harm

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.

However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult. (RCP Section 12.10 page 187)

The Royal College draws our attention to the challenge of unintended consequences and the idea that supposedly cautious policies are not necessarily cost-free if the risk "perpetuating smoking". Policy-makers can believe they are being 'precautionary' and risk-averse, while actually being 'reckless' by protecting the cigarette trade and discouraging smokers from quitting.

The list of potential mechanisms for harmful unintended consequences arising from poorly designed regulation is long<sup>24</sup>. There is already evidence that superficially attractive regulation of ENDS can

Bauld L, MacKintosh A, Eastwood B, Ford A, Moore G, Dockrell M, et al. Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute; 2017 Aug 29;14(9):973. [link]

Villanti AC, Feirman SP, Niaura RS, Pearson JL, Glasser AM, Collins LK, et al. How do we determine the impact of ecigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor. *Addiction*. 2017 Oct 3; [link]

New Nicotine Alliance (UK consumer organization) Assessing and mitigating unintended consequences of policies for vapour technologies and other low risk alternatives to smoking, 29 April 2016 [link] See especially Appendix 1.

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have the effect of perpetuating smoking<sup>25</sup> <sup>26</sup> <sup>27</sup>, and therefore doing more harm than good. Recommendations for regulatory policy:

- The application of standard consumer protection legislation should be the starting point. Further regulation, should be carefully justified and assessed for unintended consequences.
- The optimum regulatory regime would set transparent standards for chemical, electrical, thermal and mechanical safety when these are of material benefit to consumers, together with standard testing procedures. The French AFNOR standards are good model<sup>28</sup>. Arbitrary standards, for example for maximum nicotine strength for e-liquids or maximum size of containers or tanks<sup>29</sup>, serve no purpose and may inhibit uptake or promote smoking relapse.
- Warnings and labelling should inform consumers rather than scare them and not convey the
  impression that vaping is especially harmful. The most important information would convey
  relative risk: that ENDS are much less harmful than cigarettes.
- There is no case to ban ENDS advertising and promotion. Firstly, because advertising for ENDS is effectively privately funded anti-smoking campaign spending. Secondly, because the justification for banning tobacco advertising is because of the great risk to health that it causes. Some safeguards to prevent targeting of youth may be justified: the UK Codes of Advertising Practice provide a reasonable model<sup>30</sup>.
- Any taxation on ENDS should create a price incentive to switch from the high risk cigarette to the low risk ENDS and as far as possible reflect relative risk<sup>31</sup>. In most cases, the cost of tax administration would outweigh the value of the appropriate tax, so ENDS should generally have no additional tax applies, other than standard sales taxes.
- Policy on indoor use of ENDS should be a matter for owners and managers of building. The
  application of law can be justified where there is evidence that exposure to emissions
  creates material harm to bystanders, but no such evidence exists for ENDS. The role of the
  state is to provide guidance on making these decisions<sup>32</sup> but not to impose them.

<sup>&</sup>lt;sup>25</sup> Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [link]

Cooper MT, Pesko MF. "The effect of e-cigarette indoor vaping restrictions on adult prenatal smoking and birth outcomes." Journal of Health Economics, Volume 56, 2017, Pages 178-190. [link]

Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. Prev Med (Baltim), February 2016 [link]

AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [link] Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 March 2015 [link] and Part 3: Requirements and emission-related test methods XP D90-300-3 July 2016 [link]

<sup>&</sup>lt;sup>29</sup> Bates CD: What is wrong with the Tobacco Products Directive for vapour products? Counterfactual May 2015 [link]

Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [link]

Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. New England Journal of Medicine 2015;373:594–7. [link]

Public Health England, Use of e-cigarettes in public places and workplaces, 6 July 2016 [link]

#### 4.4 On quitting smoking as a consumer behaviour

E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.

E-cigarettes appear to be effective when used by smokers as **an aid to quitting smoking**. (RCP Key recommendations, original emphasis)

Vaping products are *consumer products* marketed as an alternative to smoking. They are not smoking cessation medications any more than diet soda is an anti-obesity drug. The overall public health impact of any given approach is a function of both uptake and impact on the person's health. Vaping works well on both of these – by being attractive as an alternative to smoking and by mirroring many of the things that people want from smoking it is an effective low-risk substitute. We now have 1.5 million ex-smoker vapers in the UK. The number of UK smokers fell by 1.5 million between 2014 and 2016 (from 9.7 to 8.2 million) – a dramatic decline. Another 1.1 million people both smoke and vape – and many may be on a journey to quitting or substantially cutting down. There is an abundance of evidence that ENDS are promoting reductions in smoking<sup>33</sup>, including this substantial 2017 study from the United States<sup>34</sup>:

The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.

### 4.5 On the public health interest in vaping as a harm reduction strategy

However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK. (RCP Key recommendations, original emphasis).

Professor John Britton, chair of the RCP's Tobacco Advisory Group, said<sup>35</sup>:

The growing use of electronic cigarettes as a substitute for tobacco smoking has been a topic of great controversy, with much speculation over their potential risks and benefits. This report lays to rest almost all of the concerns over these products, and concludes that, with sensible regulation, electronic cigarettes have the potential to make a major contribution towards preventing the premature death, disease and social inequalities in health that smoking currently causes in the UK.

This is a strong recommendation from the Royal College of Physicians to embrace the concept of tobacco harm reduction as a public health policy. *That is not an alternative to other tobacco policies* – in fact it makes the traditional tobacco control policies more effective and less ethically challenging by giving smokers a viable way to respond to incentives or pressures.

Bates CD, Mendelsohn C, Submission 336 - Evidence to Standing Committee on Health, Aged Care and Sport (Australia) Inquiry The Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia Do vapour products reduce or increase smoking? A summary of published studies. 19 October 2017 [link]

<sup>&</sup>lt;sup>34</sup> Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. Bmj. 2017;358:j3262. [link]

Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction. 26 April 2016 (Press release)