

Counterfactual

Committee on Health
Houses of the Oireachtas
Leinster House
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Ireland

24 January 2022

Public Health (Tobacco and Nicotine Inhaling Products) Bill

Dear Health Committee members

I write as former Director of Action on Smoking and Health in the UK and currently as an advocate for harm reduction as a critical tobacco control strategy. I have no conflicts of interest concerning the tobacco, vaping or pharmaceutical industries. In this context, harm reduction means supporting smokers or would-be smokers to switch to low-risk smoke-free alternatives to cigarette smoking such as vaping, nicotine pouches or heated tobacco products.

The Committee is conducting pre-legislative scrutiny of the Public Health (Tobacco and Nicotine Inhaling Products) Bill and conducted hearings with interested organisations on 17th November. In response to concerns raised by Irish consumer organisations, I wanted to provide an alternative perspective on several points that were made to the Committee by tobacco control advocates. I have provided a short paper following this cover letter covering the following eight areas with links to relevant literature, should you wish to access the source material.

- 1 Professional support for vaping and tobacco harm reduction
- 2 Concerns that youth smoking in Ireland increased from 2015 and 2019
- 3 Evidence that vaping helps people to quit smoking
- 4 Is vaping a gateway for the tobacco industry to get adolescents smoking?
- 5 Flavoured vaping products and banning flavours
- 6 Policymaking and the dangers of perverse consequences
- 7 The optimum approach to regulating nicotine products
- 8 Conclusion

I hope this input is helpful. I would be pleased to follow up on any questions, provide further information, or appear before the Committee should the opportunity arise in the future.

Yours sincerely

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Vaping and tobacco harm reduction: a briefing for the Health Committee

1 Professional support for vaping and tobacco harm reduction

Tobacco harm reduction means recognising the significant health opportunities that arise from displacing high-risk cigarettes with much lower risk smoke-free nicotine products, such as vaping products, heated tobacco products or nicotine pouches. Though opposed by some Irish organisations, there is considerable international expert support for tobacco harm reduction, including among some of the most highly regarded independent experts in the field of tobacco control. For example, in August 2021, fifteen past presidents of the independent Society for Research on Nicotine and Tobacco (SRNT) wrote an analysis voicing their support for tobacco harm reduction and including rebuttals to many of the arguments made to the Health Committee.¹

While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind. That is not happening.

Also, one hundred experts wrote to parties to Framework Convention on Tobacco in October 2021. They made reasoned arguments supporting tobacco harm reduction, addressing both the risks and potential benefits, and drawing attention to the dangers of perverse consequences (such as increases in smoking) arising from policies designed to place excessive restrictions on vaping and other low-risk smoke-free products.²

2 Concerns that youth smoking in Ireland increased from 2015 and 2019

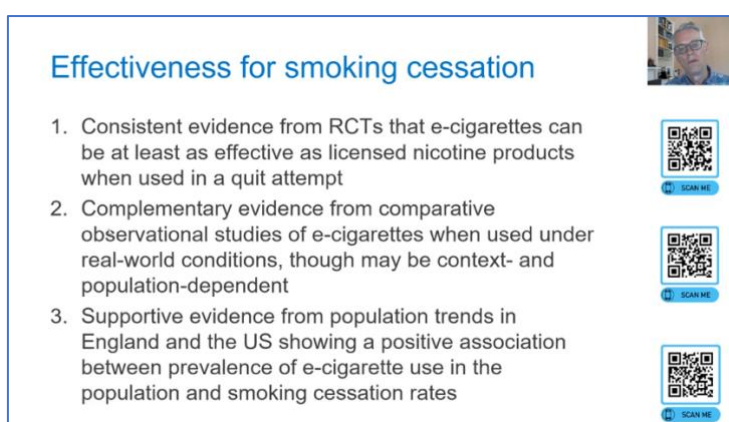
As reported in the Irish Times, some have argued that a regulatory crackdown on vaping is justified because *smoking* has increased among 15–16-year-old boys.³ But it is important not to draw the wrong lessons from the survey, the European School Survey Project on Alcohol and Other Drugs (ESPAD), on which these findings were based. The survey concluded that smoking was down while vaping had increased. The headline finding was: “*Smoking and drinking among 15–16-year-old school students are showing signs of decline*”⁴. Most of the international evidence suggests vaping *displaces* smoking in teenagers. It would, therefore, be wrong automatically to attribute adverse changes in smoking to vaping. If there is a problem with youth smoking in Ireland, it is more likely attributable to failures of tobacco control, unique factors affecting youth or randomness.

However, the situation is not as negative for Ireland as these headlines imply. The ESPAD finding of an increase in boys’ smoking in Ireland relates to any smoking, even one cigarette, in the past 30 days. This is an imprecise measure that includes a wide range of behaviours, from intense to very occasional use. A closer look at the reports suggests that the more problematic behaviour, daily smoking, fell in both Irish boys and girls between 2015 and 2019 from 6% to 5.3%, and fell more steeply in boys, from 8% to 6.5%. In the 2019 survey, of the 35 countries surveyed, Ireland had the fifth-lowest daily smoking rates, behind Iceland, Norway, Malta and Sweden. This is a cause for celebration rather than distress. The three Nordic countries with lower rates than Ireland have achieved this mainly because a low-risk alternative to smoking (oral tobacco or ‘snus’) has displaced cigarette use. That experience provides a proof of concept for tobacco harm reduction.

3 Evidence that vaping helps people to quit smoking

There is considerable converging evidence from multiple sources, including randomised controlled trials, observational studies, population trends, and market data, that people use vaping to quit smoking, cut down, transition over time, or as a diversion from smoking in the first place. Some of the evidence is summarised in the letter from fifteen past presidents of SRNT, cited above.¹

The evidence for vaping as a substitute for smoking and a driver of smoking cessation comes from multiple sources, each with its strengths and weaknesses, but taken together make a strong case – and more robust than the conventional smoking cessation treatments. British smoking cessation expert, Professor Robert West, summarised the state of evidence in a 2019 presentation.⁵ The slide from Professor West’s presentation above summarises his view of the evidence, and a link to the full presentation is provided in the endnote.



The slide is titled "Effectiveness for smoking cessation" in blue text. It features a small video thumbnail of Professor Robert West in the top right corner. The main content consists of three numbered points, each followed by a QR code and a "SCAN ME" button. The points are: 1. Consistent evidence from RCTs that e-cigarettes can be at least as effective as licensed nicotine products when used in a quit attempt; 2. Complementary evidence from comparative observational studies of e-cigarettes when used under real-world conditions, though may be context- and population-dependent; 3. Supportive evidence from population trends in England and the US showing a positive association between prevalence of e-cigarette use in the population and smoking cessation rates.

The following provides an overview of studies that support the evidence framework articulated in Professor West’s presentation.

- *Randomised controlled trials.* Several recent trials show positive results.^{6 7} The most substantial clinical trial to date showed e-cigarettes with approximately twice the smoking cessation efficacy of NRT⁸. There is an accumulating evidence base: the Cochrane Review now recognises evidence of vaping efficacy in smoking cessation.⁹
- *Observational data.* There is evidence that smokers who use e-cigarettes are more likely to quit smoking than those who do not.^{10 11}
- *Population trends.* There is evidence that smoking cessation activity also increases as the prevalence of e-cigarette use increases in a population.^{12 13 14 15}
- *Modelling studies.* Modelling studies based on the experience show substantial public health potential even when parameterised with sceptical assumptions.^{16 17}

Professor Kenneth Warner of the University of Michigan summarises the position as follows:¹⁸

Evidence from six completely different sources demonstrates that vaping is increasing smoking cessation.

1. *Randomized controlled trials. The Cochrane Review, the gold standard of scientific credibility, says there is “moderate certainty evidence” that vaping increases smoking cessation more effectively than do nicotine replacement therapy products.*

2. *Population studies find e-cigarettes increasing smoking cessation, especially when people use e-cigarettes frequently.*
3. *As e-cigarette sales rise, cigarette sales fall. Econometric studies confirm the two products are substitutes.*
4. *Other studies have found that policies intended to decrease youth vaping have increased youth smoking. Another study found that a tax on e-cigarettes in Minnesota increased adult smoking and decreased smoking cessation.*
5. *Multiple simulation analyses have concluded that the potential benefit of vaping for adult smoking cessation substantially outweighs any risk that vaping might increase youth smoking.*
6. *Swedish men's substituting snus, a smokeless tobacco product, for cigarettes demonstrates the potential for lower-risk products to dramatically reduce tobacco-produced diseases.*

Tragically, public health organizations that focus exclusively on the potential risks of vaping for young people – risks that, frankly, have been grossly exaggerated – are likely to be damaging the health of the public.

In fact, the evidence suggests that vaping encourages smoking cessation in smokers who were not otherwise interested in quitting smoking to become what is known as “accidental quitters”.¹⁹ The reason is that it does not require them to quit nicotine, the most important reason for smoking, but does allow them to eliminate the smoke inhalation that causes nearly all the harm associated with nicotine use.

4 Is vaping a gateway for the tobacco industry to get adolescents smoking?

4.1 The gateway effect

The claims about a gateway effect from vaping to smoking are based on a misunderstanding about correlation and causation. There is no dispute that young people who vape are also more likely to smoke, but that does not mean the vaping *causes* the smoking. The evidence suggests a different explanation, sometimes known as “common liabilities”. These are characteristics of the individual or their circumstances that incline the person both to vaping and to smoking.^{20 21} These common causes include genetics, mental health, delinquency, parental smoking, poverty, school environment etc.^{22 23 24} The more these risk factors are taken into account, the fainter the association between vaping and smoking becomes until it disappears in some cases.²⁵ It does not mean the vaping caused the smoking, nor does it mean that making the vaping less appealing will eliminate the subsequent smoking. The reverse is more likely: making vaping less appealing will cause the young person to smoke instead. This is because the evidence points to vaping *as a diversion* from smoking for adolescents.^{26 27} This is consistent with observed US adolescent population trends, which have seen a sharp decline in smoking as vaping has risen.^{28 29}

4.2 The spectre of the tobacco industry

Though many activists invoke the tobacco industry to support their cause, this should never be done at the expense of health. By promoting the (false) idea that vaping is a gateway to smoking and that this is a tobacco industry tactic, they risk obstructing access to products that divert users away from smoking. The primary public health goal for tobacco policy is to reduce the burden of disease and premature death overwhelmingly attributable to smoking. By shaping the incentive structure of tobacco companies with regulation, taxation, and communications. Legislators and governments can

press the companies and consumers to move the market from high-risk smoking products to low-risk smoke-free products, with a public health dividend. The argument that these companies should only make the most dangerous products or that consumers should be denied low-risk alternatives is impossible to justify on practical or principled grounds.

5 Flavoured vaping products and banning flavours

All vaping products are flavoured in some way. Tobacco flavours are just a different type of flavour and are added in the same way as any other. There are many factors to consider.

5.1 Vaping, flavours and young people

- Those arguing for banning e-liquid flavours to protect young people have several challenges to address. Do the flavours *cause* the vaping? Would removing the flavours stop the vaping or trigger workarounds like the black market or home mixing? Would users do something more harmful instead, such as smoking? Would it turn adults back to smoking and prevent adult switching? Would removing flavours increase or decrease the total burden of harm?
- For some young people, those most at risk of smoking, vaping is overall beneficial as it displaces smoking. US and UK data show that the most intensive use of vaping among young people is among those most likely to smoke.^{30 31 32} While we may wish that young people did not smoke, vape, drink, take drugs, have teenage sex etc., they do all of these things, and the responsibility of adult society is to mitigate the harms caused to the extent possible.
- There is little evidence of dependence in vapers who are never-smokers, and these users generally use vapes infrequently.³³ The US adolescent past-30-day vaping rate fell from 27.5% of high school students in 2019 to just 11.3% in 2021.³⁴ This suggests there is a core of more intense users who would otherwise be smoking (and hence benefit from vaping) and a broader group of experimental or frivolous ‘party’ users.
- The underlying psychosocial drivers of smoking and vaping are broader and deeper than the appeal of flavours. Wellman and colleagues examined the literature on causes of smoking initiation, stating: “*Ninety-eight conceptually different potential predictors were identified in 53 studies*”.³⁵ Nicksic et al. (2019)³⁶ examined the reasons given for youth vaping and:

...found two overarching factors, “alternative to cigarettes” and “larger social environment”, which combine sub-categories to explain the main motivators of e-cigarette use

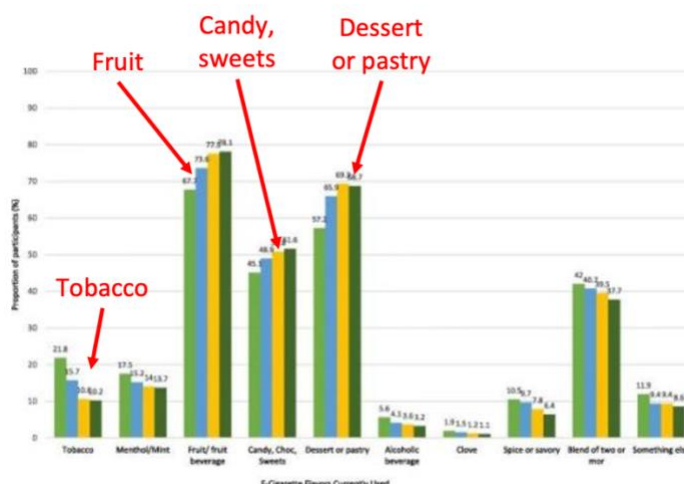
Removing flavours does not remove these drivers and, therefore, the inclination to engage in risk behaviours.

- Advocates of banning e-liquid flavours essentially *assume without evidence* that banning e-liquid flavour will cause young people to stop vaping and turn to virtuous activities instead. The more likely response is that a significant number will simply adjust their risk behaviours, for example, by smoking instead, using more cannabis, accessing black markets, or making their own ‘DIY’ flavours. This points to the central challenge in this policy field: the potentially perverse consequences of regulation.

5.2 Vaping, flavours and adults

- Further, it is clear that adults make extensive use of non-tobacco flavours, including fruit and candy, even though these may be considered childish or even “kid-appealing”. Russell and

colleagues conducted a large survey of US users:³⁷ The data show extensive and increasing use of non-tobacco flavours in the United States. See the chart below showing high preferences for flavours among adults (authors' annotations in red):



- One study found 68% of American adult e-cigarette users had used non-tobacco flavours in the past 30 days. Of these, 45% had used fruit, 44% menthol or mint, and 26 per cent candy, chocolate or other sweet flavour.³⁸
- The adult behavioural and supply-side response to a flavour ban is difficult to predict. There is evidence that the availability of non-tobacco flavours helps some adult smokers transition entirely away from smoking.³⁹ However, given that smoking is far more harmful than vaping, the impact of only a slight uptick in smoking would overwhelm any conceivable benefits from reductions in vaping. This applies to both adults and adolescents.

6 Policymaking and the dangers of perverse consequences

The Royal College of Physicians (London) set out the fundamental policy challenge for regulation of vaping products:¹

... if [a risk-averse, precautionary] 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.

Few jurisdictions have so far confronted this challenge.

It is difficult to assess in advance what would happen in response to a flavour ban, but one approach is to ask people how they would react. Posner et al. (2021)⁴⁰ asked 18–34-year-olds what they would do if non-tobacco flavours were banned (bold emphasis added):

If restricted to tobacco flavors, 39.1% of e-cigarette users Reported being likely (very/somewhat) to continue using e-cigarettes (30.5% not at all likely); **33.2% were likely to**

¹ Royal College of Physicians. Nicotine without smoke: tobacco harm reduction. London: RCP; 2016. [link](#) (Section 12.10 page 187)

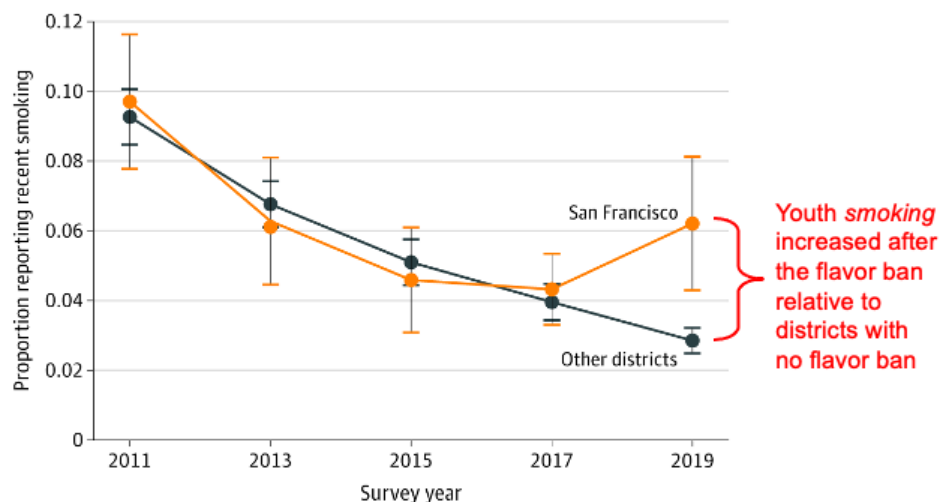
switch to cigarettes (45.5% not at all). Considering complete vape product sales restrictions, equal numbers (~39%) were likely vs. not at all likely to switch to cigarettes.

Gravelly *et al.* (2021)⁴¹ examined possible responses to flavour restrictions in the United States, Canada, and England.

Predicted behavioral responses were: 28.8% would continue vaping an available flavor, **28.3% would find a way to get their banned flavor(s)**, 17.1% would stop vaping and smoke instead, 12.9% said that they would stop vaping and not smoke, and 12.9% do not know what they would do.

The authors found a mixture of expected behavioural responses, with only one in eight saying they would cease tobacco and ENDS use altogether. A *majority* of those declaring their intent would make an *adverse* behavioural response, suggesting a high risk that such a measure would do more harm than good.

Friedman (2021)⁴² is one of the few studies that has evaluated nicotine use before and after a flavour ban. This research was supported by the National Institutes of Health and the FDA Center for Tobacco Products. Friedman found a *significant increase in adolescent smoking*. The increase observed in San Francisco was not replicated in districts that had not imposed a flavour ban. The figure from Friedman 2021 is shown below with an annotation in red.



However, smoking is not the only possible outcome: a flavour ban could have the following effects.

- Initiation or relapse to smoking, *e.g.*, San Francisco and as reported by young people when asked how they will respond - see Friedman (2021) and Posner (2021) above, respectively.
- Switching to whatever flavoured vaping products are permitted, with no change in risk to young people.
- Accessing cross-border illicit trade in products that are legally manufactured and available in other jurisdictions.

- Increasing home mixing and ‘garage’ production of e-liquids with informal distribution among family, school-friends, and neighbours.
- Formation of a black market in illicitly produced or counterfeit flavoured products.
- Increased contact between young people and criminal supply networks, with adolescents engaged as both customers and low-level vendors.
- Accelerated development of flavoured synthetic nicotine products.

7 The optimum approach to regulating nicotine products

Regulators should seek to avoid foreseeable perverse consequences, encourage pro-health behavioural transitions (such as switching from smoking to vaping), and impose burdens and restrictions on consumers and producers commensurate with the potential harms. This leads to an approach called “risk-proportionate regulation”. This means placing the strictest controls on the most dangerous products and focussing regulation of the low-risk on consumer protection. For example, this would mean high excise taxes on cigarettes and low or zero excise taxes on vaping products. It would mean a complete ban on advertising smoked products but placing controls on themes and placement of vaping advertising to allow it to function primarily as anti-smoking advertising. To protect young people who would not otherwise use nicotine, the approach to vaping should focus on:

- Impose age and access restrictions as envisaged in the Bill.
- Control on marketing to limit placement, timing and themes that will reach and appeal to youth, encourage irresponsible use, or improperly imply benefits or deny detriments.
- Control of flavours should be focussed on potentially toxic ingredients or on youth appealing flavour *descriptors*, which are an extension of branding and promotion.

8 Conclusion

Public health in Ireland would be well served by pursuing the harm-reduction opportunities arising from the emergence of consumer-acceptable low-risk alternatives to cigarettes. The priority is to reduce smoking, and smoke-free products are a rapidly evolving means to migrate smokers away from smoking products to much safer forms of nicotine use. Given vaping products and cigarettes function as substitutes, legislators and regulators should be mindful of foreseeable perverse consequences arising from excessive or poorly designed measures to control vaping.

About the author

Clive Bates has had a diverse career in the public, private and not-for-profit sectors. He started 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 civil servant and worked in senior roles in the public sector and the United Nations in Sudan. He is now Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health.

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