Comments for the consultation on amended Royal Decree 579/2017

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Introduction

My name is Clive Bates; I am writing as a UK-based expert in tobacco policy and related science with 27 years of experience. I have run the U.K.'s main anti-smoking advocacy organisation, worked in varied policy environments as a senior civil servant, and now run a sustainability and public health consultancy. I declare no relevant conflicts of interest or issues arising under Article 5.3 of the Framework Convention on Tobacco Control.

I have read the Preliminary Draft Comprehensive Prevention and Tobacco Control Plan 2024-2027 via an online translation to English, and I apologise that I am unable to respond with confidence in Spanish.

The central challenge in Spain

Much of the proposed framework is worthwhile and makes sense for the most dangerous products, which are cigarettes and other smoking products. Spain's high rates of cigarette smoking should be the focus of urgent policy attention. Spain has around three times the smoking prevalence of the United Kingdom*.

> **Spain:** *In 2022, 69.6% of the population aged 15 to 64 years had used tobacco at some point in their lives, 39.0% in the last year, 37.2% in the last month and 33.1% on a daily basis in the last month.*[1]
>
> **United Kingdom**: *In the U.K. population in 2022, 12.9% of people aged 18 years and over, or around 6.4 million people, smoked cigarette*s.[2]

From a public health and healthcare system perspective, the most urgent challenge for Spain is to *reduce smoking as deeply and rapidly as possible*.

The main policy weakness in the proposals

However, overall, the proposed policy makes one critical strategic error. This is to ignore the potential for low-risk alternatives to smoking to reduce the use of cigarettes and to be beneficial to population health, including young people. Vaping and other low-risk nicotine products are alternatives and function as economic substitutes for cigarettes. This means that policies designed to reduce vaping are susceptible to serious unintended consequences, causing more smoking, more illicit trade, and more risky workarounds such as mixing flavours at home.

Benefits of substitution of smoking by vaping or other low-risk alternatives

There are significant positive public health effects arising from these "related products", which include e-cigarettes (ENDS), nicotine pouches, heated tobacco products and smokeless or oral tobacco. They work through several mechanisms to dramatically reduce risk and improve welfare:

* The comparison is not exact but illustrates the scale of the difference.

1. Better health and welfare for adult smokers who switch from cigarettes to vaping, including pregnant women.
2. Avoided harmful consequences for adult vapers who do not relapse to smoking.
3. Avoided harmful consequences for young people diverted from smoking initiation to vaping instead.
4. The value of the *option* for young smokers today to switch to vaping before they are 40 and thereby avoid almost all the serious risks of smoking, which generally take many decades to accumulate.
5. The use of vaping in a staged quit process, going from smoking to vaping to address the main health risks and then from vaping to abstinence to eliminate the nicotine*, if they choose to*.
6. Reaching so-called "accidental quitters" – people who had no intention to stop smoking but gradually migrated to vaping.
7. The greatly reduced toxic exposure to bystanders from "secondhand" emissions, including children at home and in vehicles.
8. Familial benefits arising from parents or caregivers who live longer are more productive and draw less on the household budget.
9. The loss of an inter-generational role-modelling effect arising from less smoking in families and denormalisation of smoking in society more generally.
10. Reduced pressure on healthcare budgets and scarce healthcare resources.

Against these ten very substantial benefits, there are possible trade-offs. For example, some young people who may not have become smokers may take up vaping. But it is essential to recognise that the many young people using vapes will be doing it for experimental or frivolous reasons. Their vaping experience is likely to be transient and short-lived. Equally, the most intensive youth users of vapes and other alternatives are likely to be those who would otherwise have smoked. For that group, the vaping is beneficial.

The impacts of policies on smoking and low-risk alternatives are linked. Being tough on vaping could easily be advantageous for the cigarette trade or cause users to find ways to sidestep regulation. Being tough on smoking could help to drive people to vaping. Being tough on both could drive nicotine users to the illicit trade and help nourish criminal networks.

An expert perspective

As the Royal College of Physicians (London) puts it:[3]

> *If [a risk-averse and 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.*

The point is that measures designed to control vapes can backfire and lead to more smoking. Any cost-benefit analysis of vaping policies will be overwhelmed by even small changes in levels of smoking.

A framework for considering low-risk alternatives to cigarettes

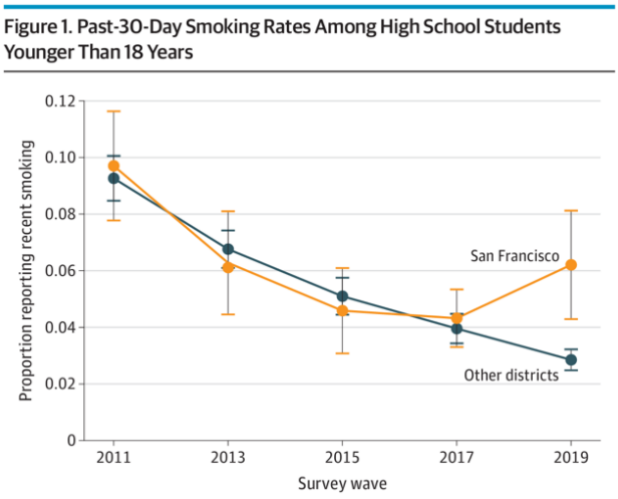
I hope the following framework helps officials and politicians consider a revised approach.

Policymaking for non-combustible tobacco and nicotine products is complicated by the following:

- These smoke-free products are, beyond reasonable doubt, *far safer* than the dominant tobacco products (cigarettes). See Appendix 1.[4]
- These products function as *substitutes* for the dominant high-risk tobacco products (cigarettes). See Appendix 2.[5] To function as substitutes, they must appeal to smokers as consumer products.
- Policies to address youth vaping and smoking can cause more harm than good to the population and *young people*. There are reasonable ways to address concerns about youth vaping without harming adult smokers and young people who would smoke in the absence of vaping. See Appendix 3.[6]
- Regulatory interventions can trigger unintended consequences that the regulator may not expect or want, such as switching back to smoking, engaging in illicit trade, or finding workarounds. The perverse unintended consequences should dominate policy analysis for low-risk alternatives to smoking.
- Full or partial prohibitions do not cause banned products to disappear; they change how they are supplied and by whom. Governments lose regulatory, fiscal, and legal control to criminal networks. Strict controls imposed on vapes may, in practice, only apply to a small share of the market, as experience in the United States and Australia has shown.

Specific policy considerations

Banning flavoured ENDS. Tobacco harm reduction works by encouraging consumers of cigarettes to switch their product choice from smoking to much safer, smoke-free products. Smoke-free products must appeal to smokers to compete with cigarettes. One example of this appeal is the wide range of flavourings of ENDS.[7] A ban on flavours makes alternatives to cigarettes less competitive with cigarettes and, in doing so, protects and aids the cigarette trade. One study showed that when vape flavours were banned in San Francisco, cigarette smoking increased *among high school students*:[8]



A recent U.S. study by independent academics showed that ENDS flavour bans had the average effect of increasing smoking:[9]

> "*We find a trade-off of 15 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions*".

A survey of French consumers found that half said they would source flavours illegally, and about one-quarter said they would return to smoking.[10] Several academic studies have identified risks with flavour bans: Posner et al. (2021)[11] found that one-third of e-cigarette users would be likely to switch to cigarettes.

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Gravely *et al.* (2021)[12] examined possible responses to flavour restrictions in the United States, Canada, and England, finding that 28.8% would access their preferred flavours via illicit means and 17.1% would stop vaping and smoke instead.

A rational approach to ENDS flavour regulation. Multiple factors drive vaping uptake, not just flavours. In studies reporting the stated motivation of teenage users, *harm reduction* is an important reason for young people to use ENDS,[13] [14] [15] as well as a wide range of psychosocial factors. A flavour ban stops the lawful supply of flavoured products, *but it does not stop the demand*. It follows that many young people will simply find ways around the prohibition or take up smoking. Control of flavours should focus on *descriptors* (packaging, branding, and trademarks that describe the flavour), a form of marketing. Not the flavour sensation itself.

Taxing ENDS. A substantial body of evidence shows that ENDS and cigarettes are economic substitutes. This means that when the price of ENDS increases, the demand for ENDS falls, and the demand for cigarettes rises, all other things being equal,[16] including for youth,[17] and young adults.[18] It is, therefore, not possible to analyse the impact of an ENDS tax without also accounting for the effect on alternatives to ENDS, including cigarettes. One U.S. estimate suggested a "*proposed national e-cigarette tax of $1.65 per millilitre of vaping liquid would raise the proportion of adults who smoke cigarettes daily by approximately 1 percentage point, translating to 2.5 million extra adult daily smokers*."[19] A tax on ENDS protects and promotes the cigarette trade and can easily do more harm than good.

Controlling nicotine strength. Proposals to limit nicotine strength are based on a misunderstanding that strength reflects nicotine exposure or 'addictiveness'. In reality, *users* control their exposure to nicotine through a widely understood process known as nicotine titration.[20] Note this also applies to alcohol – people drink smaller quantities of whiskey than beer. This titration effect has been well-documented in smokers for several decades.[21] [22] The user's puffing pattern and possibly their choice of device will change to achieve a desired nicotine intake, for example, by puffing more deeply or more often – a process known as 'compensation'. By adjusting their puffing patterns, users consume lower volumes of higher-strength liquid. But a nicotine strength limit also means that users will consume higher volumes of lower-strength liquid using more energy – potentially creating higher exposures to toxicants generated by heating liquids.[23] [24] [25] As with alcoholic spirits, the strength of nicotine in ENDS is self-limited by consumer acceptability and the excessive harshness of high-strength products. Any limits imposed on nicotine characteristics should focus on pharmacokinetics – the peak nicotine concentration in the brain (C_{max}) in the brain and how quickly it can be reached (T_{max}). As long as these characteristics show lower abuse liability (e.g. C_{max}/T_{max}) than cigarettes, there is no case for imposing controls.

Banning disposables. Disposable single-use ENDS products have risen rapidly among adults and adolescents in several jurisdictions. They are important in reaching poorer smokers because they are low-cost, have no upfront cost, are easy to use, and deliver an immediately satisfactory alternative to cigarettes. They offer the easiest exit route from smoking and work well for people experiencing various forms of disadvantage. A ban on these products would create barriers to vaping uptake and create a regulatory barrier to entry that protects the cigarette trade. These products would not disappear but become part of extensive illicit trade – informal estimates suggest illegal products account for around 50% of the vape market in the U.K. and U.S.

Banning the advertising and promotion of novel and emerging products. Advertising has multiple functions, including introducing new designs and products, gaining market share, building premium brands, and raising consumer awareness. Almost all ENDS advertising functions as "anti-smoking advertising" as it is trying to draw users towards an alternative to smoking. Banning advertising favours incumbents (the

cigarette trade) and penalises entrants and innovators (ENDS) who need to build their competitive position against cigarettes. There is some evidence that suggests that bans on advertising ENDS reduce the number of smokers who quit,[26] and increase demand for cigarettes.[27]

Outright prohibitions of novel and emerging products. Prohibitions trigger various responses, including illicit supply, switching to products not banned (cigarettes), and workarounds (making and selling DIY products).[28] Illicit trade can involve young people in criminal supply, as WHO was forced to admit as the ban on tobacco in Bhutan unravelled in 2020.[29] [30] The main argument against such proposals is not merely the harmful unintended consequences but the ethics of denying people at risk of serious disease the lawful right, the information, and the means to switch to much safer, smoke-free products while keeping the most dangerous products widely available on the market.[31] [32]

Oral nicotine pouches. Oral nicotine pouches represent perhaps the safest form of alternative low-risk nicotine product as they do not create an inhalable aerosol or involve chemical decomposition arising from heating. The risk profile for products made by reputable manufacturers is likely to be similar to nicotine replacement therapy,[33] though they may be more effective in delivering nicotine at doses satisfactory to smokers. Pouches offer the same harm reduction model as snus,[34] showing how low-risk products can drive out high-risk products in Sweden and other Scandinavian and Nordic countries.[35] [36]

The right overall approach: risk-proportionate regulation.

The aim of tobacco and nicotine policy should be to realise the vast benefits of displacing cigarettes with far less risky products. Advocates of tobacco harm reduction are not opposed to the regulation of safer alternatives to nicotine. The aim should be to take the toughest, most restrictive measures to address the risks of smoking to the user and bystander. The focus for regulation of safer nicotine products should be on consumer protection (chemical, electrical, and thermal safety and reliable information) and limiting youth uptake through measures to ensure responsible supply, retailing and marketing. The table below provides an overview of a regulatory system based on risk-proportionate regulation.

Spain could lead in adopting and introducing this regulatory philosophy.

An outline of a risk-proportionate regulatory system for tobacco and nicotine

Measure	**Cigarettes, hand-rolling tobacco, and other combustibles**	**Vaping, heated and smokeless tobacco and oral nicotine**
Overall aim	Reduce appeal and deter use	Consumer protection
Taxation	Relatively high taxes	Low or zero tax (sales tax only)
Advertising	Prohibit other than within trade	Control themes and placement
Warnings	Graphic warnings depicting disease	Messages encouraging switching
Public places	Legally mandated controls	Up to the discretion of the owner
Plain packaging	Yes	No – control imagery
Risk communication	Major risks to health	A far safer alternative to smoking
Age restrictions	No sales to under-21s	No sales to under-18s
Flavours	Ban characterising flavours	Control flavour *descriptors*
Product standards	Control risks and reduce appeal	Control safety risks to the user

Focus of regulation. The appropriate risk-based distinction in regulation is between "combustible" and "non-combustible", not between tobacco and non-tobacco or between traditional and novel products. Non-combustible tobacco products are much closer in risk characteristics to non-combustible non-tobacco products than to combustible tobacco products because smoke inhalation is the dominant problem.

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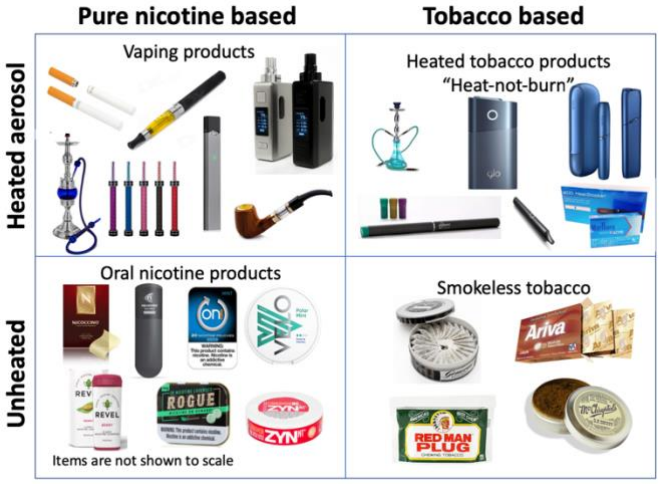
Appendix 1: vaping is far less harmful than smoking

Smoking is a uniquely harmful consumer behaviour, creating major risks for cancer, cardiovascular and respiratory disease.[1] Nearly all the risks from tobacco use arise from smoking: inhaling thousands of chemical agents, many toxic or carcinogenic, produced during the combustion of tobacco leaves in the burning tip of a cigarette.[2] *Smoking* dominates (99.4%) the global tobacco-related death toll: the Global Burden of Disease study shows 7.69 million deaths attributable to smoking annually, 1.30 million attributable to secondhand smoke, and just 55,600 attributable to smokeless tobacco.[3] This annual smoking-related death toll exceeds the annual excess mortality attributable to COVID-19 in 2020 and 2021.[4]

The imperative to stop smoking. Stopping smoking at any time reduces risks of serious disease and premature death. Nearly all excess mortality risk is eliminated by stopping before age 40.[5] It is beyond reasonable doubt that vaping (e-cigarette or ENDS use) and the use of other smoke-free nicotine products (oral nicotine pouches, smokeless and heated tobacco) are far safer than cigarette smoking. Smoke-free products do not involve combustion or produce products of combustion. Switching from smoking to smoke-free nicotine use leads to greatly reduced exposure to the main toxicants associated with serious disease.

Four main categories of smoke-free nicotine products.



Though each non-combustion product category has a different risk profile, they are clustered closely together on a continuum of risk that has cigarettes at the opposite extreme. Most of the hazardous chemical agents in cigarette smoke are either not present in vape aerosol at detectable levels or present at much lower levels. Similar findings apply to all the smoke-free alternatives to smoking.[6]

Chemical basis for reduced risk. Combustion of tobacco creates thousands of chemical reactions and new toxic chemicals not found in the tobacco. Tobacco smoke contains around 7,000 identifiable chemical agents, of which at least 158 are known to be toxic or carcinogenic.[7] The switch to non-combustible, smoke-free nicotine radically changes the chemical risks and demands a rethink of our whole approach to nicotine. According to independent American experts, these alternative products have "*the potential to disrupt the 120-year dominance of the cigarette*".[8]

Major assessments. Several high-quality, independent reviews conclude that exclusive ENDS use poses a small fraction of the risks of cigarettes and is likely to be at least 95% lower risk than smoking:

- *Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.* National Academies of Sciences, Engineering, and Medicine, United States (2018).[9]

- *Based on the reviewed evidence, we believe that the 'at least 95% less harmful estimate' (that is, smoking is at least 20 times more harmful to users than vaping) remains broadly accurate, at least over short- and medium-term periods, but it might now be more appropriate and unifying to summarise our findings using our other firm statement: that vaping poses only a small fraction of the risks of smoking.*
  Office for Health Improvement and Disparities, England (2022).[10]
- *Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.*
  Public Health England (2018).[11]
- *Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, 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.*
  Royal College of Physicians, London (2016). [12]

This suggestion that vaping is at least 95% less risky than smoking has often been misunderstood: it is intended as a clear and actionable way of communicating the scale of risk reduction to consumers and professionals.[13]

Public health advice. The National Health Service of the UK provides straightforward advice to smokers: "*Also known as vapes or e-cigs, they're far less harmful than cigarettes, and can help you quit smoking for good*"[14] , and English authorities advertise vaping on TV as a smoking cessation strategy. New Zealand, which has seen an extremely impressive decline in smoking, has similar advice to the public: "*Vaping is not harmless, but it is much less harmful than smoking*."[15]

Toxicants in the body. The most persuasive evidence comes from biomarker data.[16] These are measures of toxicants found in users' blood, saliva, or urine. Switching from cigarettes to ENDS,[17 18 19 20 21 22] heated tobacco,[23 24 25 26] snus,[27 28 29] or nicotine pouches[30 31 32] dramatically reduces the exposure to hazardous chemicals associated with smoking. Many biomarkers of exposure fall to background levels or below the limit of detection, and most others are radically reduced.[33]

Emissions toxicity. Similar findings arise from well-conducted studies of the chemical composition of aerosol emissions, including tests for cytotoxicity, mutagenicity and genotoxicity.[34] However, because no humans are involved, these studies are prone to exaggerating risk. The exaggeration of risk arises because the devices can be operated in unrealistic, overheated conditions that would be intolerable for human users. This makes the liquid prone to pyrolysis, generating excessive levels of thermal decomposition products.[35]

Health indicators. Other supportive data show improvements in health and welfare for those who switch from smoking to ENDS use completely. Studies show improvements in asthma[36], chronic obstructive pulmonary disease (COPD),[37] blood pressure,[38] lung function,[39 40] respiratory conditions, [41 42 43] cardiovascular risk factors,[44 45] and gum disease.[46] One study showed that ENDS typically has a cancer potency of just 0.4% of cigarette smoke.[47]

Snus as proof-of-concept for tobacco harm reduction. The data for snus (oral tobacco) provide a powerful proof of concept for tobacco harm reduction: epidemiological evidence "*provides scant support for any major adverse health effect of snus*"[48 49] and also that switching from cigarettes to snus reduces the risk of cancer and heart disease, and the risk in switchers being similar to that in those who quit cigarettes.[50] Through the use of snus, Sweden has the lowest smoking prevalence in the European Union (7%

compared to the EU average of 23% in 2021)[51] , and this is attributable to snus use displacing smoking,[52] with similar effects in Norway.[53] One estimate suggests among men over the age of 30, 355,000 lives per year could have been saved if the other European Union countries had matched Sweden's tobacco-related mortality rate.[54] The ban on snus in the European Union has no basis in science or ethics.[55] [56] Policy decisions about nicotine pouches must be informed by the experience gained with snus.

Common concerns. Critics of tobacco harm reduction raise a range of concerns, but these are often based on misunderstandings or poor methods.

1. **Correlation and causation**. Many studies find an association between vaping and specific health effects, yet most are deeply flawed.[57] Almost everyone who uses ENDS and is old enough to suffer serious illness has been smoking for decades. Few studies can isolate the effect of vaping from the impact of a long smoking history; some studies even counted effects associated with vaping that happened before users took up vaping.[58] [59] As noted above, studies which avoid these issues by following within-person changes when switching from smoking to ENDS show substantial reductions in harmful biomarkers and disease symptoms.

2. **"EVALI".** In 2019-2020, there was an outbreak of severe lung injuries in the United States that was misleadingly named E-cigarette or Vaping Associated Lung Injury.[60] It was not caused by ENDS, which are *electronic nicotine delivery systems*. It was caused by a thickener, Vitamin E Acetate, added to cannabis (THC) liquids.[61] Nicotine vaping was not and could not have been involved in EVALI.[62] [63] There were EVALI victims who claimed not to use THC, but there are strong incentives not to disclose cannabis due to consequences with the law, probation, employment, education, visas and parents.

3. **"No long-term data"**. It is often asserted that we just do not know the long-term effects. While technically accurate, the point is also misleading. Toxicology has advanced dramatically since the discovery of the health risks of smoking in the 1950s, and we now know a great deal from occupational and environmental health disciplines. We cannot know everything about ENDS risks, but we already know *enough* to be confident that the risks from the use of smoke-free products will be *far less* than those from smoking. Also, the much simpler chemistry will more easily allow remedial action if needed (for example, removing ingredients, changing materials, or controlling temperatures). Discouraging or restricting ENDS use while we wait for detailed evidence on long-term outcomes – given that we already know they are much lower risk than smoking – allows the harms of smoking to continue.

   We should be mindful of the wise words of the great tobacco epidemiologist Austin Bradford Hill:[64]

   > *All scientific work is incomplete – whether experimental or observational. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.*

4. **"Dual use".** Some people use both cigarettes and ENDS ("dual use") and experience lower benefits or no benefits as they continue to smoke. However, many are in a gradual transition to exclusive ENDS use or to dual use with only occasional smoking. Most dual use should be seen as progress from exclusive smoking. Dual use is not the most common form of ENDS use: in the United States, just 29% of adult ENDS users were dual users in 2021.[65] In Britain, the proportion of vapers also using cigarettes has come down from around two-thirds to around one-third over the last ten years.[66] It does not appear to reduce quitting intentions.[67] More likely, it includes people who do not want to quit smoking at all but go on to become "accidental quitters".[68] [69] Some argue that dual use makes smokers worse off, as if the exposures are additive. This arises from a misrepresentation of cross-sectional studies comparing current smokers and current dual users and, therefore, does not account for differences in dependence

and intensity of smoking. Studies that track individuals through smoking to dual use show benefits.[70]

Myth-busting. Several excellent resources have been created to tackle myths about product safety and other common concerns about ENDS use. These include:

- A consumer-orientated myth buster by the UK National Health Service[71] and myth-busting advice to health professionals from Public Health England.[72]
- A detailed myth buster by Action on Smoking and Health (UK) verified by practising scientists.[73]
- An analysis of multiple false and misleading claims made in a WHO fact sheet on ENDS.[74]
- Academic responses to flawed assessments, notably those produced in Australia[75] [76] or the position statements of medical associations.[77]
- Detailed methodological criticisms of misleading research on specific topics, such as carbonyl formation,[78] heavy metals migration,[79] or flawed epidemiology.[80] [81]

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Appendix 2: ENDS use reduces smoking

The best way to assess the evidence that ENDS use reduces smoking is to look at all the different types of evidence together. It all points towards ENDS having a powerful effect on suppressing adult smoking via five main effects:

1. The people who use e-cigarettes are more likely to quit smoking, and success rates increase over time as smokers become familiar with e-cigarettes as an alternative.
2. More people are willing to try ENDS to quit smoking because it does not require them to give up nicotine to secure significant health, welfare, and economic gains. This is easier to achieve than abstinence from nicotine.
3. People who would not otherwise try to quit are drawn into smoking cessation via ENDS uptake and gradual migration away from smoking. These are known as "accidental quitters".
4. Young adults who would otherwise have become smokers diverted into ENDS use and never started smoking.
5. Adults, including recent quitters, who may have relapsed to smoking turn to vaping instead.

Randomised controlled trials show ENDS to be more effective than nicotine replacement therapies and at least as good as pharmacotherapies at achieving smoking cessation in trial conditions.

- The January 2024 Cochrane review examined 88 studies and, based on seven studies that met its strict inclusion criteria, concluded that vaping nicotine was 59% more effective for quitting than nicotine patches and gum.[1]
- A review of 363 studies by the UK National Institute for Health Research found that vaping was the most effective single quitting aid.[2]
- A 2023 Cochrane review of all smoking cessation therapies concluded that nicotine ENDS and varenicline were the two most effective treatments for quitting smoking.[3]

Observational and population studies. Smokers switching to ENDS are replacing cigarettes with a much lower-risk way of taking nicotine – they are making a different consumer choice rather than taking a smoking cessation medication. Smoking cessation rates using vaping *increase* over time as smokers adjust to exclusive e-cigarette use.[4] In contrast, conventional quit approaches have *declining* quit rates over time as abstinence gives way to relapse back to smoking.[5] Vaping is associated with increased quitting in observational studies,[4 6 7] and population studies.[8 9 10 11] Significant use of ENDS policy is reflected in national smoking rates.[12 13 14] Japan has seen dramatic decreases in smoking, attributable to heated tobacco products.[15 16]

Economic data. There is also substantial evidence from economic data that ENDS function as cigarette substitutes. In a paper for FCTC COP-7, WHO concluded, "*ENDS/ENNDS and cigarettes are substitutes*".[17] Economic evidence supports WHO's claim. There are pronounced substitution effects between combustibles such as cigarettes and smoke-free alternatives.[18 19 20 21 22 23 24 25 26] Substitution should be expected: both meet user demands for nicotine, ENDS with much lower risk.

"Accidental quitters." Vaping is also the only quitting aid to assist smokers with no intention of quitting ('accidental quitters').[27 28 29] That is important because this group is most likely to continue smoking and,

therefore, is most at risk of serious disease and premature death.

Impact versus efficacy. Controlled trials can give insights on "efficacy" (how likely someone using the product is to quit smoking. But they can't say much about how many people will use the product. ENDS have the potential for a substantial positive public health *impact*, a function of individual effectiveness multiplied by the number of people willing to try. There is evidence that ENDS have made such an impact at the population level in terms of sharper declines in cigarette smoking than originally expected. For example, US adult smoking prevalence is now lower than anticipated from pre-ENDS era trends – with the most significant declines in smoking occurring in the age groups with higher uptake of ENDS (i.e., adults under 44 years of age).[30]

Guidance for healthcare providers. The UK National Centre for Smoking Cessation and Training produces high quality guidance in the use of vaping products to quit smoking for good.[31]

User testimony. Thousands of users provide eloquent testimony of their success in quitting smoking using ENDS. These provide compelling accounts of tobacco harm reduction at the individual level.[32] Though often dismissed as anecdotes, these first-person accounts of experience are in fact rich in detail and a compelling strand of evidence that triangulates well with trials, observational data, trends and economic analysis.

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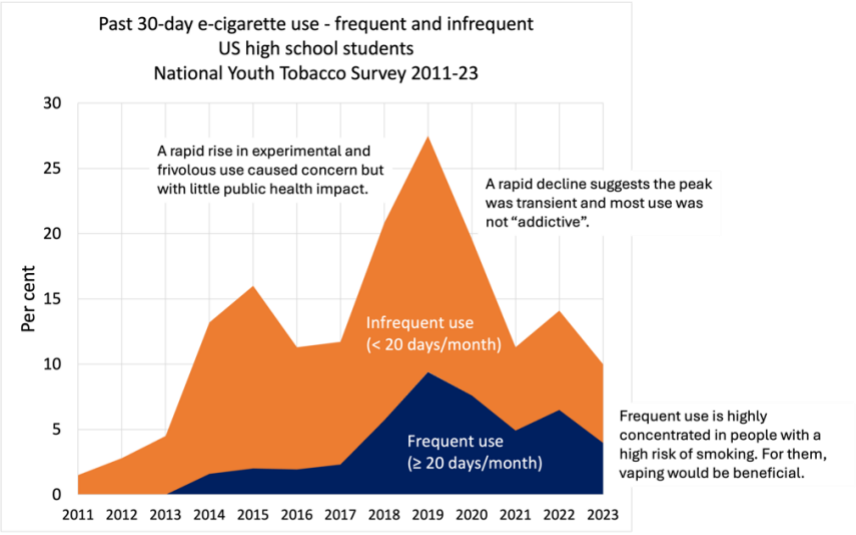
Appendix 3: ENDS use and youth

ENDS use as a youth risk behaviour. No one concerned with public health recommends or welcomes youth nicotine use. The same applies to alcohol and illicit drug use, premature or risky sexual practices, dangerous driving, and a range of other youth risk behaviours.[1] Nevertheless, such behaviours are a real part of society and require a response to reduce the harm they cause. Many are concerned about youth ENDS use, especially regarding potential "gateway" effects and signs of nicotine dependence. However, it is essential to place ENDS use in the broader context of youth risk behaviours, including smoking. For most adolescents, ENDS use would not be particularly harmful, and for some, it would be an alternative to smoking and beneficial.

Causes of youth tobacco use. Evidence suggests that a wide range of psycho-social factors drive nicotine use. For example, these are characteristics of the individual (genetic, mental health, rebellious outlook, etc.) and their circumstances (household, peer group, marketing, etc). One systematic review identified *ninety-eight* conceptually different predictors of smoking onset.[2] Studies of ENDS users suggest use arises from seeking an "alternative to cigarettes", the "wider social environment",[3] and curiosity.[4]

The danger for policymakers. It is not possible (or desirable) to make straightforward cause-and-effect claims about youth smoking or vaping, such as attribution of youth use to factors such as flavours, packaging, or marketing to vaping uptake. The danger of designing policy based on a simplistic understanding of causes will leave the underlying demand intact and cause users to find alternative ways to use nicotine, including switching to smoking.[5] [6] ENDS use is one of a range of youth risk behaviours that a subset of young people will engage in, even if adults disapprove related to substance use, violence, sexual behaviour, and risk-taking.[7] The public health challenge is to reduce the risks to these young people to the extent possible – including the risks arising from the unintended consequences of poorly designed policy.

Understanding youth vaping. The annotated chart below provides a basis for understanding youth ENDS use. It is based on US data from the National Youth Tobacco Survey as it developed over the last 12 years, peaking in 2019.[8] Many themes will be common with other countries.



Youth ENDS use has declined or plateaued in many countries. In the US, the proportion of high school-aged youth who used ENDS in the past 30 days peaked in 2019 at 27.5%[9] but has since declined by almost two-thirds to 10.0%.[10] In the UK, occasional or weekly ENDS use plateaued between 2021 and 2022,[11] as did past-30-day ENDS use in Canada.[12] There may be different types of use. Firstly, relatively frivolous use based on youthful experimentation, fads, and fashion is unlikely to persist – this is of little serious public health consequence. Secondly, more intensive and longer-term use – but this is most likely to be displacing smoking. There is reasonable evidence to support this model.

- **Most youth ENDS use is experimental and temporary.** Most youth who ever try ENDS do not persist in using them currently. In both the US and the UK, just under half of youth who had ever tried ENDS continued to use them 1+ times in the past 30 days. [12] [13] Similarly, in the UK, over 60% of youth who used ENDS had either used them only once or twice or had used them more but discontinued them. [11] These patterns of temporary experimentation align with youths' stated reasons for *ever* using ENDS, which are most often curiosity/experimentation, boredom, and social reasons.[14] [15] [16]

- **ENDS use is concentrated in youth who had (or would have) used other nicotine products.** US youth with an *established* history of other nicotine product use were over five times as likely to have used ENDS in the past 30 days.[17] 70% of UK youth who currently used ENDS had a history of cigarette smoking.[11] ENDS use that is frequent and/or is accompanied by nicotine dependence is even more strongly concentrated in those who had already used cigarettes or other nicotine products: approximately 98% of US youth who used ENDS frequently had used another nicotine product.[17] Youth who vape have risk factors that also predispose them to smoke cigarettes,[18] suggesting that they would have otherwise been cigarette smokers.[19]

- **Higher youth ENDS use is accompanied by larger declines in smoking, suggesting displacement rather than gateway.** If ENDS were a gateway to cigarette smoking, then youth smoking trends would be higher than otherwise expected as ENDS use increases. However, population-level studies show the opposite: youth and young adult smoking prevalence declined *faster* after ENDS use became common,[20] and this pattern is remarkably consistent across countries, including the US,[20] [21] [22] UK,[23] [24] Canada,[25] and New Zealand.[26] [27] These declines have been drastic and unexpected: in the US, actual youth smoking in 2020 was far lower (3.3%)[28] than what was thought possible in 2010 according to the US Healthy People target for 2020 (16%).[29] These trends are consistent with ENDS diverting youth with a predisposition for nicotine use away from more harmful combustible cigarettes.[22] [26]

Evidence for the gateway hypothesis is better explained by a "common liability" to nicotine use. Claims that ENDS are a gateway to smoking are based on a misunderstanding of the evidence (i.e. that youth who use ENDS are also more likely to smoke cigarettes). Rather than ENDS *causing* youth to also smoke cigarettes (which confuses correlation and causation), it is more likely that ENDS use and smoking are both explained by pre-existing characteristics which predispose some youth to use nicotine. There are dozens of these "common liability" factors (e.g., other substance use, poor mental health, risk-seeking personality) which are not accounted for in most studies. [18] The apparent gateway association becomes successively weaker as more common liability factors are accounted for[30] [31] – in some cases becoming not statistically significant[31] [32] – suggesting that it is better explained by pre-existing propensity to use nicotine.

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