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Dear European Commission

Evaluation of the legislative framework for tobacco control – Open Public Consultation

European Tobacco Harm Reduction Advocates (ETHRA) is the voice of 27 million EU consumers of safer nicotine products. The safer nicotine products we use include vapes, nicotine pouches, snus, and heated tobacco products. ETHRA is a consortium of 25 grassroots consumer associations in 17 European countries, supported by experts in tobacco control and nicotine research. We are a voluntary operation with no industry funding or conflicts of interest. Our transparency registration number is 354946837243-73.

Please find attached our response to the Evaluation of the legislative framework for tobacco control's Open Public Consultation. We have focused on *how* the European Commission and other bodies evaluate the evidence, drawing on what we see as the failures in the SCHEER report. Our main points are that the value of evidence should depend on:

- How the evidence is evaluated. For example, are the risks associated with vaping compared to those from smoking or to abstinence?
- What questions are asked and not asked? For example, will the questionnaire ascertain how many Europeans no longer smoke because they are using safer nicotine products instead?
- What counterfactuals are considered? For example, if policies are introduced which make safer nicotine products less accessible or appealing, will people smoke instead?

We found that the questionnaire was constructed with inherent bias against harm reduction, to force answers in favour of measures making safer nicotine products less accessible or appealing for people to switch to. A question such as "Considering the TPD, please rate each of the below product categories according to the level of threat they pose to the public health, particularly among young people" excludes the option of considering these products as providing opportunities which can benefit public health. The questionnaire also does not capture the effects of anti-vaping policies on youth and adult smoking or likely countermeasures by consumers and suppliers. Therefore, the questionnaire is not an adequate framework for evaluating the evidence.

EU TRANSPARENCY REGISTER: 354946837243-73

We highlight the importance of rigorous application of the EU's core principles relating to the internal market, proportionality, and non-discrimination in policymaking. We believe rigorous application of these foundational ideas would change the current approach to safer nicotine products. These principles justify a risk-proportionate regulatory philosophy with a critical distinction drawn between combustible and non-combustible nicotine products, not between tobacco and non-tobacco or between novel and established products.

We provide a summary of evidence to support some basic insights that should inform tobacco control policy as it applies to safer nicotine products and tobacco harm reduction.

- Smoke inhalation, not nicotine, is the primary cause of ill-health, and there are, beyond any reasonable doubt, significantly lower risks in using non-combustible forms of nicotine products. European Union policy should focus on reducing *smoking*, not nicotine use.
- Cigarettes and safer alternatives function as economic substitutes; therefore, tax, regulation or other interventions designed to address vaping will affect smoking behaviour. These substitution effects are the source of perverse consequences arising from poorly designed policies for safer nicotine products, and cause increased smoking.
- Multiple lines of evidence triangulate to show that vaping products support adult smoking cessation at minimal risk – these products should be primarily treated as an opportunity rather than a threat.
- A more sophisticated approach to youth uptake of safer nicotine products is necessary. There is no evidence for gateway effects, but there is accumulating evidence that safer nicotine products divert some young people from smoking and may be beneficial to young people who would be more likely to take up smoking.

We hope the views in the attached submission are helpful. We look forward to further engagement with the Commission during the targeted stakeholder phase on these important issues.

Yours sincerely

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On behalf of ETHRA and partners

A framework for evaluating nicotine policy in the European Union

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A framework for evaluating nicotine policy in the European Union

1 Introduction

1.1 About ETHRA

European Tobacco Harm Reduction Advocates (ETHRA) is the voice of 27 million¹ EU consumers of safer nicotine products. ETHRA is a consortium of 25 grassroots consumer associations in 17 European countries, supported by experts in tobacco control and nicotine research. We are a voluntary operation with no industry funding or conflicts of interest. Our transparency registration number is 354946837243-73.

1.2 The Open Public Consultation

We write to respond to the European Commission's Evaluation of the legislative framework for tobacco control's Open Public Consultation.² The Commission sets out its purpose as follows:

Due to factors such as the rapid rise in emerging products and recent technical developments, the Commission will evaluate the legal framework for tobacco control.

The evaluation will cover product regulation, advertising, promotion, and sponsorship, in the broader context of related tobacco control policies.

It will evaluate to what extent the framework has fulfilled its goals and whether it is able to support a 'tobacco-free generation' by 2040, as announced in Europe's Beating Cancer Plan.

We believe the most critical imperative in developing the legal framework for tobacco control is *the use of a more sophisticated real-world framework for assessing the public health impact of different tobacco and nicotine products*. Our submission concentrates on evidence that underpins a robust framework for evaluating policy and evidence. Without this, individual elements of evidence will be misinterpreted or make little sense – at a cost both to public health and the efficient functioning of the internal market of the European Union.

1.3 The framework for assessing tobacco harm reduction and policy options

Tobacco harm reduction aims to address the harms associated with nicotine use by encouraging the uptake of smoke-free nicotine products as an alternative to smoking and reducing the harms arising from tobacco control policies (regressive taxation, stigma, isolation etc.). We believe tobacco harm reduction is a major public health strategy that will ultimately render cigarettes mostly obsolete. It will ultimately end the epidemic of smoking-related diseases that still kills 700,000 European Union citizens each year and leaves millions more living in misery.

This should be achieved within a framework of risk-proportionate regulation, mindful of unintended consequences, and open to innovative entrants that will drive out the harmful incumbent products, cigarettes. As far as possible, such a framework should harness the power of consumer choice and the internal market dynamics rather than rely on punitive and coercive measures that will provoke resistance and stimulate workarounds and illicit trade. Developing a legal framework that draws on the consent of citizens rather than bullying them into compliance with punitive or coercive regulation is a more promising direction for the European Union at this time.

2 The need for a robust framework for assessing evidence

Our main point is that the value of evidence usually depends on how it is evaluated. For example, is vaping risk compared to smoking or abstinence, and which is more relevant? The use of evidence depends on what questions are asked and not asked. For example, the question “*how many Europeans no longer smoke because of vaping, snus, heated tobacco or pouches?*” provides a valuable framework for assessing evidence of tobacco harm reduction, but not if it is never asked. A further issue is what counterfactuals are assumed and investigated: for example, will people prevented from vaping be assumed abstinent, or might they smoke instead? Questions like “*how do we prevent youth vaping?*” do not provide an adequate framework for evaluating evidence because they do not capture effects on youth and adult smoking or likely countermeasures by consumers and suppliers. The evidence evaluation should start from a broader objective: *how do we reduce harm?*

2.1 The poor evaluation framework of the SCHEER opinion

The SCHEER opinion on e-cigarettes³ was intended to provide advice to EU policymakers. However, its approach shows that the framework for assessing evidence matters at least as much as the evidence itself. Critics highlighted multiple flaws in the framing of the preliminary assessment:⁴

For the delivery of a robust and comprehensive final report, the members of the Working Group of the Scientific Committee on Health, Environmental and Emerging Risks will need to consider

- (1) the potential health benefits of ENDS substitution for cigarette smoking,*
- (2) alternative hypotheses and contradictory studies on the gateway effect,*
- (3) its assessment of cardiovascular risk,*
- (4) the measurements of frequency of use,*
- (5) non-nicotine use,*
- (6) the role of flavours, and*
- (7) a fulsome discussion of cessation.*

The overwhelming problem with this assessment was its failure to evaluate e-cigarette use in the context of widespread cigarette use. The Special Committee on Beating Cancer report attempted to rectify this by recommending: “the assessment of the risks of using these products compared to consuming other tobacco”. Numerous comments made about the preliminary report highlighted problems with framing.⁵

- 1. Inadequate comparison with cigarettes*
- 2. Inadequate comparisons with other benchmarks*
- 3. Inadequate quantification of risk*
- 4. Poor differentiation between observable effects and markers for risk*
- 5. Overstating evidence on secondhand vapour*
- 6. Misunderstanding the public health mechanism of vaping*
- 7. Overplaying uncertainty over the long term*
- 8. Misunderstanding basic epidemiological concepts regarding the gateway effect*
- 9. Ignoring and selectively interpreting evidence*
- 10. Shifting and raising evidential hurdles*
- 11. The complete absence of policy impact research*

For this reason, ETHRA is concentrating its response on the appropriate way to assess the evidence that is available.

3 Tobacco harm reduction and the internal market

We are surprised that the Commission has not more enthusiastically recognised tobacco harm reduction as a success for the functioning of the internal market, promoting a high level of health and consumer protection. Europe has a flourishing vaping industry challenging the dominance of the cigarette trade, and European citizens are benefiting from the diffusion of innovative new technologies displacing smoking and improving health. Yet, safer nicotine products are treated mainly as a threat rather than an opportunity. The internal market is distorted as a result.

3.1 Foundational principles

We believe that three foundational principles of the European Union and the internal market provide a reasonable basis for regulation in this area. The application of these principles will assist with the evaluation of evidence and policy options.

- **The internal market.** The objectives of the internal market are specified in Article 26 and give primacy to the free movement of goods:⁶

The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.

This general commitment to economic freedoms is qualified by broader objectives of EU policy in Article 114 of the Treaty on the Functioning of the European Union to require a high level of health and consumer protection:⁷

The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

- **Proportionality.** This principle directs regulators to keep the burdens as low as necessary to achieve the objectives. The relevant text is Article 5.4 of the Treaty on the European Union:⁸

Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

- **Non-discrimination or ‘equal treatment’.** The principle of non-discrimination, as elaborated by the Court of Justice, should apply in EU policymaking. It has been articulated as follows:⁹

the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.

These principles establish the foundation for a “risk-proportionate” regulatory framework for all consumer nicotine products in the European Union.

3.2 Implications of foundational principles for tobacco policy

The rigorous application of these three concepts would form a sound basis for the legal framework. However, it would also require a redesign of current regulations to reflect the following:

- The dynamics of consumer preferences and the internal market will address the harms of smoking.** The treaties require that free movement of goods and services is a default unless a health or consumer protection objective justifies intervention. The European Union should see the rise of non-combustible nicotine products [vapes, heated tobacco products, snus and smokeless tobacco, and novel oral nicotine products like pouches] as a process of technology innovation and ‘creative destruction’ that will ultimately displace cigarettes and render them obsolete. The regulatory framework should allow competition and consumer preferences to expedite this process. The Commission should not be concerned only with limiting risks, especially trivial or transient risks, but also *exploiting opportunities* to secure a high level of health protection. A lost opportunity or lost benefit is a form of harm, but regulators are too often indifferent to such harms. Snus is a case in point: the EU banned oral tobacco in the early 1990s because it was considered a *novel and unacceptable risk* at the time. However, experience in Sweden and Norway suggests snus is better understood as an *opportunity* to radically reduce smoking. That opportunity to use the internal market to reduce smoking to the low levels seen in Sweden has been denied to most of Europe’s citizens against all evidence, logic and ethics.¹⁰ One analysis suggests that among men over 30, 355,000 lives per year could have been saved if the other EU countries had matched Sweden’s tobacco-related mortality rate.¹¹ The true number of unnecessary deaths arising from the snus ban cannot be known, but it is unlikely to be zero.
- Encourage pro-health innovation.** The European Union should show that its regulators can adapt to and embrace innovation rather than line up with enemies of innovation among the interest groups surrounding the Brussels’ institutions. Equally, the promise of nicotine pouches to displace smoking should not be smothered in new regulations designed to deter the use of these low-risk products. The focus of regulation should be on protecting consumer interests – ensuring the pouch products are accurately described and appropriately labelled, that hazardous ingredients are limited, and that danger of poisoning is minimised. For heated products, there should be an additional focus on electrical and thermal safety.
- Remove barriers to smoke-free products competing with cigarettes.** Tobacco harm reduction – reducing the health burdens arising from smoking – contributes to a high level of health protection and should be *promoted* in the internal market. Regulation should not function in a way that protects the incumbent and hazardous products, cigarettes, from competition from low-risk alternatives. An example is the limit on the strength of nicotine e-liquids to 20mg/ml, which functions as a barrier to entry to safer and more compact vaping products that can better compete with cigarettes and help consumers make an initial switch. There is no reason to protect the cigarette trade in this way. Recital 38 to the Tobacco Products Directive suggest the intention was to equalise nicotine delivery between cigarettes and e-cigarettes. Unfortunately, the metric chosen to do that (the nicotine concentration) does not create a “level playing field” between smoking and vaping but distorts the market in favour of cigarettes and against a high level of health protection.^{12 13 14 15 16 17}
- Regulate according to risk.** Drawing on fundamental principles of the EU (see above), products with very different risks to health should not be treated the same way in European law – this will mean that a distinction should be made between different categories of tobacco products with significantly different risks. For example, the Tobacco Advertising Directive makes no distinction between heated tobacco products (low risk) and cigarettes (high risk).¹⁸ All tobacco products are treated equally, with a ban on all transboundary advertising, sponsorship, and promotion, and

this is extended to vaping products in Article 20 of the Tobacco Products Directive. Given that the initial advertising ban was justified on health grounds (the severe health impacts of smoking), there is no basis for indiscriminately applying the same measure to products with much lower absolute risks and that have health *benefits* if they substitute for higher-risk products. Limits on advertising should be proportionate and non-discriminatory. Neither principle is applied to safer nicotine products in the European Union.

- **Avoid unjustified discrimination.** We have highlighted inappropriate discrimination between cigarettes and e-cigarettes. Another example is the discrimination between oral tobacco (tobacco that is sucked) and chewing tobacco. A complete ban is applied to the former, and virtually no regulation is applied to the latter. Wildly divergent approaches apply primarily based on whether the product is sucked or chewed once placed in the mouth. Making policy based on this distinction is absurd. A unified system based on appropriate toxicity and ingredient standards should be used instead.
- **Justifying harms.** There are suggestions that the EU should limit or ban the use of flavoured e-liquid products because, it is alleged, that they appeal to young people. But there are multiple questions to address before such a policy can be justified:
 1. *The counterfactual* - in the absence of flavours, what would these young people be doing?
 2. *The behavioural response* - what would young people do in response to a flavour ban?
 3. *Impact on youth at risk* - are there young people for whom vaping is beneficial? If so, do flavours contribute to securing the benefit?
 4. *Impact on adults at risk* - what is the effect of constraining flavoured products on adults - both their free choice and health?
 5. *Risk to tobacco-naive users* - where does vaping fit in the spectrum of risks to youth, and how much does this justify greater harm to adults?
 6. *Underlying causes* - what are the more fundamental reasons for the uptake of tobacco or nicotine? And if these remain when flavours go - what happens?

We urge the Commission to base tobacco and nicotine policy on the rigorous application of these foundational principles, not least because that is a requirement of the Treaties.

4 An improved framework for assessing evidence

An improved legal framework would be based on the following elements:

4.1 Nicotine regulation must reflect substantial differences in risk between products

The consumer nicotine products in the European Union market have highly divergent risks – probably spanning two to three orders of magnitude, but with a major discontinuity between combustible and non-combustible products. Any regulatory regime must take account of these huge differences in risk. To meet the Treaty objectives of a high level of health and consumer protection, EU regulation should support the uptake and use of low-risk products at the expense of high-risk products. It should not create barriers to entry that protect high-risk products from competition from low-risk products.

The most crucial insight is that *smoking* is the problem. Smoking accounts for 98 per cent of the global burden of tobacco-related mortality.^{19 20} Inhalation of products of combustion – the toxic tar and gases created in the burning tip of a cigarette – is the primary cause of harm, not nicotine itself. As Professor Michael Russell famously explained in 1976:²¹

People smoke for nicotine, but they die from the tar. Their risk of lung cancer and bronchitis might be more quickly and effectively reduced if attention were focused on how to reduce their tar intake, irrespective of nicotine intake.

In this statement, Russell lays the ground for *tobacco harm reduction*: reducing exposure to the toxic tar from cigarette smoke without quitting nicotine as well.

There is no real doubt that smoke-free products are much less risky than cigarettes. Many of the toxicants in tobacco smoke are either not present at detectable levels or present at much lower levels than in cigarette smoke. The most convincing evidence comes from biomarker data (measurements of toxicants in the blood, saliva or urine of users and non-users). In 2018, independent experts for Public Health England reviewed the biomarker data for e-cigarettes and concluded:²²

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.

The United States National Academies of Science, Engineering and Medicine concluded:²³

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.

A more detailed discussion of the health impacts of e-cigarettes compared to cigarettes forms part of a recent paper by fifteen past presidents of the independent Society of Research on Nicotine and Tobacco (SRNT).²⁴ These authors, some of the world's leading authorities, summarise the safety case as follows:

Many scientists have concluded that vaping is likely substantially less dangerous than smoking because of the following:

- *The number of chemicals in cigarette smoke, greater than 7000, exceeds that of e-cigarette aerosol by 2 orders of magnitude.*
- *Among potentially toxic substances common to both products, cigarette smoke generally contains substantially larger quantities than e-cigarette aerosol. However, e-cigarette aerosol contains some substances not found in cigarette smoke.*
- *Biomarkers reflecting exposure to toxic substances are present at much higher levels in exclusive cigarette smokers than in exclusive vapers, and studies of smokers who switch to e-cigarettes find decreases in toxicant exposures.*

- *Tests of lung and vascular function indicate improvement in cigarette smokers who switch to e-cigarettes. Exclusive users of e-cigarettes (most being former smokers) report fewer respiratory symptoms than do cigarette smokers and dual users.*

The SRNT past presidents' paper was published in the American Journal of Public Health and is appended as [Appendix 1](#). Citations for the statements above can be accessed via the paper.

Extensive biomarker data also contributed to the designation of a heated tobacco product as “appropriate for the protection of public health” by the US FDA because the greatly reduced exposures meant “*a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely...*”²⁵

For nicotine pouches, *in vitro* testing suggests cytotoxicity “orders of magnitude” lower than cigarettes.²⁶ Toxicological assessment has shown nicotine pouches appear ²⁷

“likely to expose users to lower levels of toxic compounds than Swedish snus, which is recognized to offer reduced levels of harm than associated with tobacco smoking. We conclude that NPs should be placed close to NRTs on the tobacco/nicotine product toxicant delivery continuum.

4.2 Targets and overall policy should focus on reducing smoking

There must be a recognition that the essential difference between the different tobacco and nicotine products categories is the level of risk – with at least a two orders of magnitude range.

If the aim really is “to beat cancer”, then the targets should focus on reducing *smoking*, including reducing smoking by switching to smoke-free tobacco use. Europe’s Beating Cancer Plan calls for the creation of a ‘Tobacco-Free Generation’, where less than 5% of the population will use tobacco by 2040, compared to around 25% today. The most important change to the legal framework for tobacco control in the European Union would be to change this target to refer to a “*Smoke-Free Generation*” where less than 5% of the population *smokes* by 2040. The target, as it stands, does not align with the internal market and treaty objectives and implicitly dismisses the public health benefits of tobacco harm reduction, even though these benefits may be life-saving for millions of Europeans. This distorts policy and detracts from the EU aim of having free movement of goods with a high level of health and consumer protection.

4.3 Different nicotine products function as substitutes and policy aimed at one product category will interact with others

It is not uncommon for two goods to function as economic substitutes if they represent different forms of similar consumption in competition: tea and coffee, beef and lamb, or rice and pasta. This means that the price of one product will affect the demand for the other through a positive ‘cross-elasticity’. It also means that regulation that suppresses demand for one product will increase demand for the substitute product.

The implications for public health depend on whether the non-combustible smoke-free products are substitutes for the combustible products. There is considerable evidence that they are. There is impressive proof-of-concept in Sweden, where snus has displaced smoking and led to the lowest levels of smoking and smoking-related disease in the European Union by far. Economic substitution means higher taxes on smoke-free products will increase demand for smoked products. It also

means that differentiated regulation is likely to be effective. It means that advertising for non-combustible products functions as anti-smoking advertising without burdening the public finances. It also means that a ban on advertising smoke-free products would serve as a regulatory protection of the smoked products and tend to increase consumption above what it would otherwise be.

The most direct and relevant evidence comes from studies of the demand response to vaping taxes that have been imposed. The World Health Organisation argues that vaping products, sometimes described as 'ENDS' or Electronic Nicotine Delivery Systems, do substitute for smoking:²⁸

ENDS/ENNDS and cigarettes are substitutes – higher cigarette prices are associated with increased ENDS/ENNDS sales.

A significant body of literature broadly supports WHO's assertion that vaping and smoking are economic substitutes.^{29 30 31 32 33 34 35 36 37 38 39}

Further evidence for substitution comes from analyses of the effects of measures to control vaping use. Evidence suggests e-liquid flavour bans,⁴⁰ e-cigarette advertising bans,⁴¹ and access restrictions⁴² may increase cigarette smoking.

Because of these substitution effects, policies for one nicotine product cannot be assessed in isolation without considering the impact on demand for others. *Substitution effects make a significant difference to the overall public health consequences of regulation.* The fact that smoked and smoke-free products are economic substitutes should be a central consideration in regulatory policy for nicotine. This is the mechanism by which prohibition or excessive regulation of smoke-free products are likely to do more harm than good.


4.4 Smoke-free products support adult smoking cessation

There is considerable converging evidence from multiple sources, including randomised controlled trials, observational studies, population trends, and market data, that people use vaping products to quit smoking, cut down, transition to smoke-free status over time, or as a diversion from smoking in the first place. According to the 2021 Special Eurobarometer, 31% of ever-smokers say that e-cigarettes or similar products helped them quit smoking completely, up from 17% in 2017. 27% reduced their use of combustible tobacco.⁴³




The evidence for vaping as a substitute for cigarettes 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. The British smoking cessation expert, Professor Robert West, summarised the state of evidence in a 2019 presentation.⁴⁴ The slide from Professor West's presentation below summarises his view of the evidence, and a link to the whole presentation is provided in the endnote.

We should also note that adult smokers entering middle age form the population at most significant risk, not adolescents or young adults that may take up vaping. The greatest and most immediate health gains through avoiding serious diseases will come from smoking cessation in this group. Smoking cessation should be a priority, and middle-aged adult smokers should be the priority population.

Effectiveness for smoking cessation



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.^{45 46} The most substantial clinical trial to date showed e-cigarettes with approximately twice the smoking cessation efficacy of NRT⁴⁷. There is an accumulating evidence base: the Cochrane Review, which provides a world-renowned synthesis of clinical trial evidence, concluded in September 2021.⁴⁸

Nicotine e-cigarettes probably do help people to stop smoking for at least six months. They probably work better than nicotine replacement therapy and nicotine-free e-cigarettes. They may work better than no support, or behavioural support alone, and they may not be associated with serious unwanted effects

The Cochrane Review restricts its evidence reviews to clinical trial evidence. But a range of evidence from other sources strengthens the support for vaping for smoking cessation.

- *Observational data.* There is evidence that smokers who use e-cigarettes are more likely to quit smoking than those who do not.^{49 50} Eurobarometer found smokers who have tried vapes were more likely (20-27%) to have made a quit attempt compared to those that have never tried vapes (11%).⁵¹
- *Population trends.* There is evidence that smoking cessation activity also increases as the prevalence of e-cigarette use increases in a population.^{52 53 54 55}
- *Modelling studies.* Modelling studies based on the experience show substantial public health potential even when parameterised with sceptical assumptions.^{56 57}
- *Testimonials.* Thousands of users provide compelling reports of quitting smoking by vaping.⁵⁸

4.5 Dual use is part of a positive transition – not necessarily an end state

Some claim that the “dual use” of smoke-free products and cigarettes is problematic. However, it is better understood as a part of a transition pathway from exclusive smoking to exclusive vaping – not everyone switches immediately.^{59 60 61} In Britain, the proportion of e-cigarette users who are dual users has fallen steadily from two-thirds in 2014 to less than one-third in 2021, suggesting a steady migration from dual use to exclusive vaping.⁶² The evidence also suggests that vaping encourages smoking cessation in smokers who were not otherwise interested in quitting smoking. These smokers become what is known as “accidental quitters”.⁶³ The Special Committee on Beating Cancer report acknowledged that progression from smoking to vaping was part of a quitting process,

even if not complete. The Committee “considers that electronic cigarettes could allow some smokers to **progressively quit smoking**”.⁶⁴

4.6 A more sophisticated understanding of youth risk behaviours is necessary

The public health debate about tobacco and nicotine can be charged by concerns about youth uptake and use, sometimes cynically and opportunistically. There is little dispute that it would be better if young people did not use these products – but the equivalent is true for all youth risk behaviours (drugs, alcohol, drunk or distracted driving, violence, cults etc.). The question is what young people will do regardless of adult disapproval and how can harm arising be minimised. In evaluating evidence, the Commission should consider the following:

- **The underlying reasons why young people use tobacco or nicotine products or other substances.** The evidence points to complex psychosocial causes beyond simplistic explanations related to product characteristics (e-liquid flavours) or marketing-related explanations. For example, Wellman et al. (2016)⁶⁵ published a systematic review of risk factors for smoking onset, finding “*ninety-eight conceptually different potential predictors were identified in 53 studies*”. These are mostly related to the characteristics of the individual and their circumstances. Nicksic *et al.* (2019) examined the reasons given for youth vaping.⁶⁶ They listed thirteen factors influencing e-cigarette adoption, including a weak effect of flavour appeal but also several harm reduction motivations. This study found two overarching factors, “alternative to cigarettes” and “larger social environment”, which combine sub-categories to explain the primary motivators of e-cigarette use. Suppose policy tackles irrelevant or peripheral causes (e.g., banning flavoured e-liquids) but leaves the underlying causes unaddressed. In that case, users will find other ways to use nicotine or other substances, which may be more problematic.
- **The availability of low-risk products may reduce the risks to young people.** The evidence points to interactions between e-cigarette use and cigarettes among adolescents, with e-cigarettes functioning *as a diversion* from smoking for adolescents.^{67 68 69} This is consistent with US adolescent population trends, which have seen a sharp decline in smoking as e-cigarette use has risen.^{70 71} US and UK data show that the most intensive adolescent use of e-cigarettes is among those most likely to smoke.^{72 73 74} There is little evidence of dependence in adolescent vapers who are never-smokers, and these users generally use e-cigarettes infrequently.⁷⁵ The US high school past-30-day vaping rate fell from 27.5% in 2019⁷⁶ to just 11.3% in 2021,⁷⁷ implying that much of what has been described as a youth vaping epidemic was a transient fad rather than entrenched substance use. This rapid change suggests there is a core of more intense users who would otherwise be smoking (and who likely benefit from vaping) and a broader group of experimental or frivolous ‘party’ users that justify less public health concern.
- **The impact on adults of measures to protect adolescents.** There is a danger that measures to prevent youth use will avoid a small, distant and likely transient risk (harms arising from youth uptake of low-risk vaping) but increase serious immediate risks to adults (lost opportunities for smoking cessation). Any assessment of the costs and benefits of measures to protect youth from the uptake of smoke-free products will be highly sensitive to unintended effects on adults.

4.7 There is no support for a gateway effect – there are better explanations

There is so far no compelling evidence of a gateway effect.⁷⁸ Detailed examination of the studies claiming to have found a gateway effect showed that all had fundamental weaknesses, primarily

uncorrected confounding.^{79 80} Confounding is probably an insurmountable challenge for any standard observational study.

The alternative explanation for the observed associations between vaping and smoking relates to the individual's characteristics and circumstances that incline them to both vaping and smoking. Given the similarities between the two habits (albeit with radically different health risks), it is not surprising that whatever reasons people have to smoke are also reasons to vape. These common characteristics – genetics, mental health, family, community, etc.) are sometimes known as common liabilities, common risk factors or confounders. These provide a more credible explanation for at least part of the observed associations between smoking and vaping.^{81 82}

There has been a sharp rise in adolescent vaping in the United States since 2014, but it has not generated a surge in smoking. There has also been an *accelerated* decline in youth smoking coinciding with the rise in youth vaping.⁸³ Regular smoking (≥ 20 days/month) among US high school students had fallen below 0.4% in 2021.⁸⁴ One analysis summarised the US youth vaping data as follows:⁸⁵

There was a substantial increase in youth vaping prevalence beginning in about 2014. Time trend analyses showed that the decline in past 30-day smoking prevalence accelerated by two to four times after 2014. [...] the inverse relationship between vaping and smoking was robust across different data sets for both youth and young adults and for current and more established smoking.

4.8 Behavioural responses to regulation determine impact (not the regulators' intent)

There is a tendency among regulators to believe that a ban on a product or service somehow makes it disappear. This is not the case. A ban or regulatory intervention is a market perturbation that triggers a range of behavioural responses over time.

For example, the EU ban on menthol cigarettes implemented in May 2020 did not mean that all Europeans previously smoking menthol cigarettes quit smoking. A range of behavioural responses was triggered: hoarding, buying on the black market, using mentholation products such as card inserts, switching to non-menthol cigarettes, switching to heated menthol tobacco products, switching to e-cigarettes (menthol or other flavoured), and quitting smoking. Initial assessments suggest that quitting smoking was among the least favoured behavioural responses to the EU ban.⁸⁶

Banning a product by law does not make it disappear, especially if the underlying behavioural drivers remain. A ban cannot stop current or future users from replacing the banned substance with some other risky behaviour. For example, there are many possible behavioural responses to a ban on vaping flavours, including some that significantly increase risks:

- The intended outcome - abstinence from nicotine and not adopting any other risk behaviour
- Using tobacco flavoured vape products instead of other flavoured products
- Accessing flavoured vapes via an illicit supply chain (a black market)
- Buying from foreign suppliers in person or via the internet and importing for personal use
- Buying from foreign suppliers to resell to others through informal networks
- Making and mixing their own flavours at home or buying or selling home-mixed flavours
- Using vapes that are made to look tobacco flavoured but have other flavours
- Using flavour agents for food, drink or aromatherapy for adding to unflavoured nicotine liquids

- Using flavours made for vaping but ostensibly marketed for another purpose
- Switching to cannabinoid (THC or CBD) vapes
- Relapsing back from vaping to smoking – both teenagers and adults
- Not switching from smoking to vaping and continuing to smoke
- Initiating smoking instead of initiating vaping
- Start smoking as an adolescent because parents or adult role models smoke instead of vaping
- Using other tobacco or nicotine products – hand-rolling tobacco, smokeless tobacco, heated tobacco, or new nicotine pouches
- Adopting another risk behaviour that may be worse

The critical challenge for policy evaluation is to decide if there are likely to be enough positive behavioural responses to offset the negative behavioural responses once these are weighted by risk.

4.9 The main challenge is to avoid perverse unintended consequences

Because cigarettes are much more harmful than vaping and other non-combustion products, it will only take a slight rise in smoking to offset any public health benefit from reduced vaping arising from prohibition or excessive regulation of vaping products. The critical issue is the interaction of demand for vaping products with demand for much more harmful cigarettes, as discussed above. This is not a new idea: the Royal College of Physicians (London) expressed this clearly in its 2016 report:⁸⁷

... 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.

The EU approach will need to “get this balance right” or at least recognise that a balance is necessary. Prohibition or excessive regulation of vaping or other safer nicotine products without considering the effects on smoking could easily lead to a net increase in harm to public health by “perpetuating smoking” or stimulating black market activity.

4.10 Looking at all the evidence

Taken as a whole, the evidence makes a compelling case that smoke-free alternatives to cigarettes displace smoking. The Tobacco Treatment Network of the SRNT recently argued:⁸⁸

Strategies used for combustible product cessation may be adapted for novel products, and treatment recommendations for tobacco use disorder should be made within the context of a harm reduction framework wherein alternative product use may be the desired outcome.

A further discussion of the smoking cessation evidence is summarised in the letter from fifteen past presidents of SRNT,²⁴ which is also appended at [Appendix 1](#). The authors conclude:

Although not the final word, the totality of the evidence indicates that frequent vaping increases adult smoking cessation. Smokers unable to quit smoking with evidence-based cessation methods should be well informed about the relative risks of vaping and smoking and vaping’s potential to help them quit smoking.

5 Adopt risk proportionate regulation

The most effective framework is “risk-proportionate” regulation. This is not a novel idea but reflects the standard regulatory practice of imposing burdens and restrictions that reflect the voluntary and involuntary risks to those most directly affected.

In a risk-proportionate approach, the main regulatory levers are applied differentially. The most stringent and restrictive regulation would be applied to the most harmful products, cigarettes. Regulation of the smoke-free alternatives would focus on consumer protection (i.e. benefits to the consumer) and control of adolescent uptake where this does not cause significant harm to adult smokers. The table below illustrates the concept of risk-proportionate regulation,⁸⁹ though it does not necessarily reflect ETHRA’s support for any specific policy listed.

Measure	Smoking products	Smokefree products
Taxation	Relatively high taxes	Low or zero tax (VAT or 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
Ingredients	Control reward-enhancing additives	Blacklist material health hazards
Flavours	Prohibit	Allow but restrict ingredients that could be hazardous for inhalation
Flavour descriptors	Not applicable if flavours banned	Control appeal to youth/trademarks
Age restrictions	No sales to under-21s	No sales to under-18s
Internet sales	Banned	Permitted with age controls
Product standards	Control risks and reduce the appeal	Control risks

6 Conclusion

The primary goal of European Union tobacco policy should be to reduce excess mortality and morbidity. In practice, this means reducing *smoking* as deeply and rapidly as possible. Tobacco harm reduction provides a fast-acting, market-based strategy for reducing smoking and eliminating most smoking-related risks. This is compatible with the goals of the internal market and proportionate, non-discriminatory regulation.

The regulation of vaping and other safer nicotine products should always be considered as part of a regulatory system that covers all the nicotine products, both smoked and smoke-free. The aim should be to encourage the migration from high-risk to low-risk products and support positive behaviour change. Regulators should take great care to avoid the perverse consequences of prohibitions and use regulation instead. Risk-proportionate regulation provides a robust basis for controlling the consumer nicotine market and creates strong incentives that support public health.

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Appendix 1: Evidence summary

Communication to the American Journal of Public Health by fifteen past presidents of the Society for Research on Nicotine and Tobacco (SRNT) August 2021

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Balfour, D. J. K. et al. (2021). Balancing Consideration of the Risks and Benefits of E-Cigarettes. *American Journal of Public Health*, 111(9), 1661–1672. [10.2105/AJPH.2021.306416](https://doi.org/10.2105/AJPH.2021.306416)

Balancing Consideration of the Risks and Benefits of E-Cigarettes

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The topic of e-cigarettes is controversial. Opponents focus on e-cigarettes' risks for young people, while supporters emphasize the potential for e-cigarettes to assist smokers in quitting smoking. Most US health organizations, media coverage, and policymakers have focused primarily on risks to youths. Because of their messaging, much of the public—including most smokers—now consider e-cigarette use as dangerous as or more dangerous than smoking. By contrast, the National Academies of Science, Engineering, and Medicine concluded that e-cigarette use is likely far less hazardous than smoking. Policies intended to reduce adolescent vaping may also reduce adult smokers' use of e-cigarettes in quit attempts.

Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality.

We review the health risks of e-cigarette use, the likelihood that vaping increases smoking cessation, concerns about youth vaping, and the need to balance valid concerns about risks to youths with the potential benefits of increasing adult smoking cessation. (*Am J Public Health*. Published online ahead of print August 19, 2021:e1–e12. <https://doi.org/10.2105/AJPH.2021.306416>)

The use of nicotine-containing electronic- or e-cigarettes has divided the tobacco control community along a spectrum from fervent opponents to enthusiastic supporters. Opponents emphasize that vaping can cause nicotine addiction among young people and could lead some to become dependent cigarette smokers, possibly “renormalizing” smoking. They cite research indicating that nicotine may harm adolescents' developing brains. Some consider vaping's health risks substantial, and some question whether vaping decreases smoking cessation.¹ By contrast, proponents present evidence that vaping assists smokers in quitting smoking and believe that vaping poses far less risk to users' health than does smoking. Smoking among youths,

they observe, has declined rapidly during vaping's ascendancy.²

Many US governmental health agencies^{3–6} and nongovernmental medical^{7,8} and health organizations^{9–12} focus primarily on vaping's risks for young people. These organizations' pronouncements and their influence on policymakers and the media have had a profound impact on the public's understanding of vaping. A study of US news articles on e-cigarettes found that, from 2015 to 2018, 70% of articles mentioned vaping's risks for youths, while only 37.3% noted potential benefits for adult smokers.¹³ Of respondents to a 2019 national survey, nearly half considered vaping nicotine just as harmful as or more harmful than cigarette smoking. Only 1 in 8 considered vaping less harmful. (The rest

responded “I don't know.”¹⁴) By contrast, the US National Academies of Sciences, Engineering, and Medicine¹⁵ and the British Royal College of Physicians¹⁶ have concluded that vaping is likely far less hazardous than smoking cigarettes.

The public's inaccurate perception worsened following a 2019 vaping-associated acute pulmonary disease outbreak (named “e-cigarette or vaping use-associated lung injury” [EVALI]) that caused 68 fatalities.¹⁷ Media coverage was extensive. Several states and cities promptly banned retail and online sale of flavored e-cigarettes.¹⁸ In early 2020, however, research attributed the illness to vitamin E acetate, an adulterant in illicit tetrahydrocannabinol (THC) vaping devices shown to produce pulmonary injury in animals.^{19–21} A small percentage

of patients with EVALI reported vaping only nicotine, but they were primarily in states where THC was illegal, and most had no toxicology testing.²² Once the potential harm of vitamin E acetate was publicized and adulterated THC removed from the market, the incidence of new cases fell precipitously.¹⁹ Yet, after the outbreak, two thirds of respondents to a poll related the lung disease deaths to use of “e-cigarettes such as JUUL.” Only 28% related the deaths to use of “marijuana or THC e-cigarettes.”²³

Scientists differ in their views of the relative risks and benefits of vaping nicotine, and of their implications.^{1,2,24,25} Many, including this article’s authors, believe that vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking’s toll. Our objective is to encourage more balanced consideration of vaping within public health and in the media and policy circles.

In the following pages we address:

- the health risks of vaping,
- the likelihood that vaping increases smoking cessation,
- the principal concerns about youth vaping, and
- balancing concerns about risks to youths with potential benefits for adult smokers.

THE HEALTH RISKS OF VAPING

According to the National Academies of Sciences, Engineering, and Medicine, “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.”^{15(p1)} The British Royal College of

Physicians similarly concluded that “vaping isn’t completely risk-free but is far less harmful than smoking tobacco.”¹⁶

High-quality clinical and epidemiological data on vaping’s health effects are relatively sparse. There are no data on long-term health effects, reflecting the relative novelty of vaping and the rapid evolution of vaping products. Determining even short-term health effects in adults is difficult because most adult vapers are former or current smokers.

Some studies find that vaping may worsen asthma, bronchitis, and cough, including among nonsmoking young people.^{26,27} By contrast, a few studies found that smokers with asthma or chronic obstructive lung disease see symptoms improve after switching to e-cigarettes.^{28,29} Randomized switching trials (cigarettes to e-cigarettes) document improvements in respiratory symptoms.^{30,31}

Laboratory studies have reported potentially adverse effects of e-cigarette aerosol in cells and animals.^{26,32} It is difficult, however, to extrapolate from exposure conditions in cells and animals to humans.²⁶ Human experimental studies have focused on acute effects,³³ which may not predict future disease. For example, e-cigarettes acutely impair tests of endothelial function, a common feature of cardiovascular disease, but when smokers switch from cigarettes to e-cigarettes, endothelial function normalizes.^{34,35} A recent study detected no difference in biomarkers of inflammatory and oxidative stress in exclusive e-cigarette users and nonusers of either cigarettes or e-cigarettes.³⁶

There is little evidence that e-cigarettes pose significant cancer risk.¹⁵ However, some studies raise

concerns that warrant long-term follow-up of vapers.^{37,38}

Many scientists have concluded that vaping is likely substantially less dangerous than smoking because of the following^{15,16}:

- The number of chemicals in cigarette smoke, greater than 7000,³⁹ exceeds that of e-cigarette aerosol by 2 orders of magnitude.^{40,41}
- Among potentially toxic substances common to both products, cigarette smoke generally contains substantially larger quantities than e-cigarette aerosol.^{42–44} However, e-cigarette aerosol contains some substances not found in cigarette smoke.⁴⁵
- Biomarkers reflecting exposure to toxic substances are present at much higher levels in exclusive cigarette smokers than in exclusive vapers, and studies of smokers who switch to e-cigarettes find decreases in toxicant exposures.^{31,46–50}
- Tests of lung and vascular function indicate improvement in cigarette smokers who switch to e-cigarettes.^{28,29,34} Exclusive users of e-cigarettes (most being former smokers) report fewer respiratory symptoms than do cigarette smokers and dual users.⁵¹

However, questions remain.⁵² Ongoing research will lend further insight into the products’ absolute and relative dangers.

THE LIKELIHOOD THAT VAPING INCREASES SMOKING CESSATION

A growing body of evidence indicates that vaping can foster smoking cessation, although the evidence is not definitive.^{53,54}

Randomized Trials

In an English smoking cessation randomized controlled trial,⁵⁵ smokers assigned to e-cigarettes achieved nearly twice the rate of biochemically confirmed smoking cessation at 1 year (18%) than smokers assigned to nicotine replacement therapy (9.9%); all received identical behavioral counseling. While 80% of those who quit with e-cigarettes were still vaping, they were no longer exposed to smoking's substantially higher risk.

A New Zealand trial found that at 6 months, nicotine patch with nicotine e-cigarettes outperformed patch with nicotine-free e-cigarettes and patch alone. Thus, in addition to aiding quitting when used alone, nicotine e-cigarettes may increase the effectiveness of existing cessation aids.⁵⁶

Examining 26 randomized controlled trials, a recent Cochrane Review concluded that "There is moderate-certainty evidence that ECs [electronic cigarettes] with nicotine increase quit rates compared to ECs without nicotine and compared to nicotine replacement therapy."⁵³ Another meta-analysis drew similar conclusions, albeit with less certainty.⁵⁷ However, the US Preventive Services Task Force's smoking cessation practice guideline did not find the evidence convincing.⁵⁸ As such, and for reasons the Cochrane Review describes, more well-designed clinical trials are needed.

Noteworthy is the lack of trials by e-cigarette manufacturers in pursuit of regulatory agency approval to use e-cigarettes for smoking cessation, likely reflecting the profitability of selling e-cigarettes as consumer products, rather than medicinal devices.

Population Studies

Collectively, population studies' findings are consistent with a near doubling of quit attempt success, found in the randomized controlled trials, and the fact that e-cigarettes are smokers' most used aid in quit attempts.⁵⁹ Four studies^{60–63} found significant increases in smoking cessation (10%–15%) that the authors associated with vaping. A Centers for Disease Control and Prevention study reported that, in 2018, 15.1% of smokers had quit smoking for 6 months or longer using e-cigarettes, compared with 3.3% using other noncigarette tobacco products and 6.6% using no tobacco products.⁶⁴ Another study identified a near doubling of self-reported cessation among users of e-cigarettes or varenicline compared with smokers not using these products.⁶⁵ Consistent with these population studies, simulation analyses have generally found that vaping increases smoking cessation, avoiding large numbers of premature deaths.^{66–69}

Other researchers have found regular and frequent e-cigarette use to be associated with increased smoking cessation, while infrequent use was not.^{70–75} This could reflect self-selection, with frequent vapers possibly liking vaping more and being more motivated to quit smoking. Infrequent vapers might use vaping as a temporary nicotine source where smoking is prohibited.^{73,76}

Other researchers have reported reduced cessation rates among smokers who vape.^{77,78} However, many failed to distinguish frequency of vaping, introducing the risk of the selection biases just noted. Other studies included only current vapers who also smoke, systematically excluding vapers who had successfully quit smoking.^{53,78}

An often-cited meta-analysis found vapers' odds of quitting smoking 28% lower than for nonvaping smokers.⁷⁷ This analysis combined clinical trials, cohort studies, and cross-sectional analyses, an inappropriate practice for meta-analyses.⁷⁹ Furthermore, the individual studies' sources of bias could be compounded in a meta-analysis, possibly producing an incorrect result.⁷⁶

Cigarette Sales

For years, US cigarette sales declined 2% to 3% annually. More recently, as vaping product sales increased, cigarette sales decreased much more rapidly. Conversely, following the EVALI outbreak and e-cigarette sales restrictions, sales of e-cigarettes fell and sales of cigarettes resumed their prevaping pattern.⁸⁰ Studies finding a positive cross-price elasticity of demand between cigarettes and e-cigarettes support the conclusion that the products are substitutes.^{81,82}

Support for the plausibility of an inverse causal relationship between vaping and smoking comes from countries in which startling decreases in cigarette sales have accompanied rising sales of another novel nicotine product, heated tobacco products (HTPs). Like e-cigarettes, HTPs expose users to lower levels of toxicants than do cigarettes.⁸³ In Japan, HTP adoption from 2015 to 2019 was accompanied by cigarette sales declining by a third.⁸⁴ In both cases—HTPs in Japan and e-cigarettes in the United States—as sales of reduced-risk products rose, cigarette sales fell.

Unintended Consequences of Policies Restricting Vaping

Studies have found that policies intended to restrict e-cigarette use may

have unintentionally increased cigarette smoking. One study associated a Minnesota e-cigarette tax with increased adult smoking and reduced cessation, estimating that taxing e-cigarettes at the same rate as cigarettes nationwide could deter 2.75 million smokers from quitting smoking over a decade.⁸⁵ Two other studies found state restrictions on minors' access to e-cigarettes associ-

ated with higher adolescent cigarette smoking.^{86,87}

Implications

Although not the final word, the totality of the evidence indicates that frequent vaping increases adult smoking cessation. Smokers unable to quit smoking with evidence-based cessation methods⁸⁸ should be well informed about the relative risks of vaping and smoking and vaping's potential to help them quit smoking. They should understand that, while the long-term health consequences are unknown, completely substituting vaping for smoking likely reduces health risks, possibly substantially.¹⁵ Dual use of cigarettes and e-cigarettes will not have a comparable beneficial effect.⁸⁸ However, a period of dual use may be necessary for some smokers to transition from smoking. Because vaping itself poses some risk, the best advice is to eventually stop vaping as well.

THE PRINCIPAL CONCERNS ABOUT YOUTH VAPING

The principal objections to vaping regard 3 potential effects on youths:

- Vaping can cause nicotine addiction among young people who never would have tried smoking.

- Vaping by never-smoking youths may cause some to try smoking, risking "renormalizing" smoking among young people.
- Nicotine can harm developing brains, and vaping nicotine may have other adverse health effects.

Vaping as a Cause of Nicotine Addiction

Vaping likely addicts some young people to nicotine. However, the evidence does not suggest it is addicting very large numbers.⁸⁹ Jarvis et al. concluded that "Data . . . do not provide support for claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes."⁹⁰ Jackson et al. recently reported that the e-cigarette–driven increase in nicotine product use among high-school students is not associated with an increase in population-level dependence.⁸⁹ Among tobacco-naïve youths, in addition to low vaping prevalence (9.1% in the past 30 days in 2020) and frequency (2.3% vaping \$ 20 days in the past 30 days),⁹¹ small percentages exhibited signs of nicotine dependence.⁹⁰

Frequent use is much more common among current or former smoking youths than among never-smokers.⁹⁰ Many former smokers were already addicted to nicotine before initiating vaping. With high-school students' smoking declining at an increasing rate since youths began using e-cigarettes,^{92,93} some may vape to reduce or quit smoking.

Nonetheless, to the extent that vaping creates nicotine addiction among otherwise tobacco-naïve youths, concerted efforts are needed to reduce youth vaping. The new minimum age of 21 years for purchasing tobacco products

should help.⁹⁴ Governmental agencies^{3,95} and voluntary organizations^{12,96} disseminate vaping's risks to youths through Web sites, social media, and television campaigns. Voluntary organizations lobby Congress and state governments to adopt policies restricting youth access to e-cigarettes.

Recent policy attention has focused on restricting the availability of e-cigarettes

with flavors,⁹⁷ a principal attraction for youths.^{98–101} While flavor bans could reduce youth interest in e-cigarettes, they could also reduce adult smokers' vaping to quit smoking.^{102–104} Like youths, adults prefer nontobacco flavors,¹⁰⁵ both groups favoring fruit and sweet flavors.^{106,107}

Policies regarding flavors reflect the more general issue considered in this article: the need to create a balance between the sometimes-conflicting goals of preventing youth vaping and supporting adults' smoking cessation attempts, particularly for smokers unable or unwilling to quit otherwise.¹⁰⁸

Vaping Causing Smoking Initiation

Prospective studies have found that young people who had vaped but never smoked cigarettes were more likely to have tried cigarettes several months to 2 years later than contemporaries who had neither smoked nor vaped.^{15,109–113} Some commentators thus consider vaping a "gateway" into smoking.^{114,115}

Other observers believe the relationship reflects a "common liability"¹¹⁶: young people who vape are generally more prone to risky behavior¹¹⁷; hence, they might be more likely to try smoking even without vaping.^{118–121} Three recent studies have concluded that vaping likely diverts more young people from smoking than encourages them to

smoke.^{122–124} Conversely, some prospective studies have found the vaping–smoking relationship strongest in youths at low risk of smoking.^{125–127}

Obvious plausible correlates are often not considered, however.¹²⁸ Importantly, few studies include youths' use of other psychoactive substances, including marijuana and alcohol. In 1 study, inclusion of marijuana and 3 other variables eliminated the otherwise statistically significant link between vaping and subsequent smoking.^{126,127} Most studies do not even consider previous use of tobacco products other than cigarettes. Adjustment for confounders substantially reduces the relationship between vaping and subsequently trying cigarettes.¹²⁹

Numbers of cigarettes smoked at follow-up are frequently very low, only 1 or 2 in the past 12 months in one study.¹³⁰ Furthermore, the prospective studies generally have not examined progression to regular dependent smoking, with 1 recent exception.¹³¹ Only a small proportion of youths who experiment with smoking become regular smokers. Kim and Selya found that while e-cigarette use was associated with ever trying smoking, it was not associated with current continued smoking.¹¹⁹ Pierce et al. recently concluded the opposite.¹³¹ Shahab et al. reported that less than 1% of US students who initiated nicotine or tobacco use with e-cigarettes were established cigarette smokers.¹³²

If vaping causes some young people to try cigarettes, the aggregate impact must be small. A recent study⁶⁸ estimated that if vaping increases non-smoking youths' odds of trying cigarettes by 3.5 (as reported by Soneji et al.¹⁰⁹), smoking initiation among young adults would increase less than 1 percentage point. Furthermore, US survey data

demonstrate that smoking among young people has declined at its fastest rate ever during vaping's ascendancy.^{92,93,133} If vaping increases smoking initiation, other unknown factors more than compensate.

Nicotine Harming Developing Brains

Animal model studies have found that nicotine can affect maturation of brain parts associated with executive function and decision-making, potentially leading to more impulsive behavior, cognitive deficits, and greater likelihood to self-administer other drugs.^{134,135} In addition, there is evidence in humans of neurological changes attributed to nicotine in the brains of adolescent smokers, interpreted by some as reflecting similar harmful effects to those in the animal models.^{136,137}

These studies lead some researchers to suspect that adolescent nicotine use in any form may lead to long-term structural and functional brain changes with associated negative implications for cognition or impulse control.¹³⁸ However, given species differences and questions about the relevance of experimental animal nicotine dosing paradigms to human use patterns, the validity of extrapolation to humans is speculative. Whether impaired brain development with behavioral consequences occurs in young nicotine consumers is difficult to determine because of potential confounding of genetic and socioeconomic factors, the influence of other substance abuse, and the role of preexisting neuropsychiatric problems associated with youth smoking. Research has yet to isolate nicotine use in the adolescent years and then examine later sequelae. Still, concerns about brain function effects of nicotine

exposure through vaping deserve serious examination.⁹⁸

Concerns About Youth Vaping in Context

Several considerations raise the question of whether, for youth as a whole, vaping creates dangerous levels of nicotine exposure that would not have occurred in the absence of vaping.

- The large majority of nontobacco product–using young people do not vape and, thus, have no nicotine exposure.⁹⁰
- Among those who vape, most do so infrequently; many are short-term experimenters.⁹⁰
- Frequent vaping is most common among current or former smokers, individuals already exposed to nicotine.⁹¹
- The most dangerous form of youth exposure to nicotine, cigarette smoking, has declined at an unprecedented rate during the era of youth vaping.^{92,93,133} Use of other tobacco products has declined as well.¹³⁹

Still, concerns emanating from substantial increases in youth vaping in 2018 and 2019 are readily understandable and important to address. A sizable decline in 2020 is encouraging.¹³⁹ We must continue monitoring youth vaping, learning more about potential harms and identifying effective prevention strategies. However, as public health groups, the media, policymakers, and the general public focus on youth vaping, vaping's potential to help adults quit smoking too often gets lost. That may come at a significant public health cost. Fourteen percent of US adults smoke; smoking annually causes nearly half a

million deaths. Anything that can reduce that toll deserves serious attention.

With the focus on youths creating an environment in which smokers believe that vaping is as dangerous as or more dangerous than smoking,¹⁴ many smokers struggling to quit may be unwilling to try vaping as an alternative. This likely translates into less smoking cessation than if smokers correctly understood the relative risks of vaping and smoking.

BALANCING CONCERNS ABOUT RISKS AND POTENTIAL BENEFITS

Research comparing vaping's risks for youths with potential benefits for adult smokers has found the latter to dominate,⁶⁶ potentially avoiding the smoking-produced loss of tens of millions of life-years.^{67,68} Vaping cannot end cigarette smoking. But vaping can complement tried-and-true methods of reducing smoking, including taxes on combustible tobacco products, smoke-free workplace laws, marketing restrictions, plain packaging with graphic warning labels, antismoking media campaigns, tobacco-21 laws,⁹⁴ and evidence-based smoking cessation treatment.⁸⁸

We believe the potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks to youths.¹⁴⁰ Millions of middle-aged and older smokers are at high risk of near-future disease and death. Quitting reduces risk.⁸⁸ Young people will not experience smoking-related (and conceivably vaping-related) chronic diseases for 3 decades, and likely not at all if they quit within a decade or 2. Social pressures to quit smoking will probably remain strong, and quitting aids may improve. Furthermore, as noted

previously, the rate of smoking among young people has declined while vaping has increased.^{92,93,133} Vaping may addict some youths to nicotine, but many fewer than popularly believed.^{89,90}

Seeking a Sensible Mix of Policies

To date, the singular focus of US policies on decreasing youth vaping may well have reduced vaping's potential contribution to reducing adult smoking. Those policies include taxing e-cigarettes at rates comparable to cigarette taxes,¹⁴¹ decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation,¹⁰³ and convincing the public—including smokers—that vaping is as dangerous as smoking.¹⁴

The public health objective should be to develop policies and interventions that both reduce youth vaping and increase adult smoking cessation.^{97,120,140,142} While an in-depth discussion of an optimal policy mix exceeds the scope of this article, we here present illustrative policies that would serve this objective. These are all in addition to conventional evidence-based prevention and cessation measures.

- Tax cigarettes and other combustible tobacco products heavily; impose a more modest tax on e-cigarettes. Taxes should be proportionate to risk. A much higher tax on combustibles will encourage adult smokers to quit smoking or to switch to less expensive e-cigarettes. By raising the price of e-cigarettes, a modest tax will discourage their use by price-sensitive youths.¹⁴¹

- Because both youth and adult smokers find e-cigarette flavors attractive,^{98–107} banning all (or most) flavors risks reducing smokers' use of e-cigarettes to quit smoking^{102–104} at the same time that it reduces youth vaping.^{99,101} An alternative would be to limit the retail sale of flavored e-cigarettes to adult-only outlets such as vape shops. An imperfect policy for either goal, this approach could benefit both.
- Government agencies and health organizations should develop nuanced, targeted communications that emphasize the realistic concerns about youth vaping and, separately, the potential benefits of e-cigarettes as less-risky (but not risk-free) alternatives for adult smokers otherwise unable or unwilling to quit smoking.
- The US Food and Drug Administration (FDA) should strictly regulate e-cigarette advertising and marketing, prohibiting all marketing directed at, or attractive to, youths and young adults, including all "lifestyle" advertising. They should limit advertising to a "switch" theme directed clearly, and exclusively, to adult smokers otherwise unable to quit smoking.
- FDA should implement its thoughtful comprehensive 2017 plan,¹⁴³ mandating reduction of nicotine in cigarettes to levels incapable of sustaining addiction, while ensuring the availability of consumer-acceptable reduced-risk nicotine products. To achieve the latter, the agency should develop product standards for products like e-cigarettes, ensuring minimization of risk associated with the product class while maintaining consumer acceptability.

The Role of Nicotine in Tobacco-Produced Disease

FDA predicated its comprehensive plan on recognition of the continuum of risk in nicotine products.¹⁴³ Nicotine is the chemical in tobacco that fosters addiction. However, toxic constituents other than nicotine, predominantly in smoked tobacco, produce the disease resulting from chronic tobacco use.^{143,144} Nicotine-yielding products vary in risk from FDA-approved nicotine replacement therapy products at the lowest end of the risk continuum to combustible cigarettes at the highest.

Unfortunately, the public has a distorted view of the dangers associated with nicotine per se. In a recent survey, 57% of respondents incorrectly agreed that “nicotine in cigarettes is the substance that causes most of the cancer caused by smoking.” Only 18.9% disagreed. (The rest answered “Don’t know.”)¹⁴ In a recent survey of physicians, 80% strongly, but incorrectly, agreed that nicotine causes cancer, cardiovascular disease, and chronic obstructive pulmonary disease.¹⁴⁵

CONCLUSIONS

We share the very legitimate concerns about youth vaping with the entire field of public health. Our goal is to put those concerns in perspective. We agree with former Surgeon General C. Everett Koop who, in 1998, urged that “[A]s we take every action to save our children from the ravages of tobacco, we should demonstrate that our commitment to those who are already addicted . . . will never expire.”¹⁴⁶ The latter appears at risk today.

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.

The need to pay attention to adult smokers is particularly important from a social justice perspective. African Americans suffer disproportionately from smoking-related deaths, a disparity that, a new clinical trial shows, vaping could reduce.³¹ Today’s smokers come disproportionately from lower education and income groups, the LGBTQ (lesbian, gay, bisexual, transgender, and queer or questioning) community,¹⁴⁷ and populations suffering from mental health conditions¹⁴⁸ and from other drug addictions.¹⁴⁹ Smoking accounts for a significant proportion of the large life expectancy difference between affluent and poorer Americans.^{150,151} For smokers with serious psychological distress, two thirds of their 15-year loss of life expectancy compared with nonsmokers without serious psychological distress may be attributable to their smoking.¹⁵² Vaping might assist more of these smokers to quit.^{148,153}

To the more privileged members of society, today’s smokers may be nearly invisible. Indeed, many affluent, educated US persons may believe the problem of smoking has been largely “solved.” They do not smoke. Their friends and colleagues do not smoke. There is no smoking in their workplaces, nor in the restaurants and bars they frequent. Yet 1 of every 7 US adults remains a smoker today.

Smoking will claim the lives of 480 000 of our fellow citizens this year alone. *AJPH*

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K. E. Warner wrote much of the original draft of the article and supervised revisions. N. L. Benowitz, S. M. Colby, D. K. Hatsukami, R. Niaura, N. A. Rigotti, and R. West drafted specific sections of the article or played lead roles in reviewing and revising article drafts. All authors reviewed all drafts critically,

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Note. The opinions expressed in this article are solely those of the authors. They do not represent those of SRNT, which has taken no organizational position on the issues discussed in this article and had no involvement in the preparation of this article.

CONFLICTS OF INTEREST

N. L. Benowitz is a consultant to Pfizer and Achieve Life Sciences, companies that market or are developing smoking cessation medications, and has been an expert witness in litigation against tobacco companies. S. J. Leischow is conducting a clinical trial supported by Achieve Life Sciences, which is developing a nonnicotine medication for smoking cessation, and has consulted with them. He also consulted more than 1 year ago for GSK, which is working to bring a new nicotine-replacement product to market, and he receives medication for a National Institutes of Health-funded smoking-cessation study from Pfizer. N. A. Rigotti receives royalties from UpToDate Inc for writing about smoking cessation and e-cigarettes and is a consultant for Achieve Life Sciences for an investigational smoking-cessation medication. R. West has undertaken research and consultancy for Pfizer and GSK, companies that manufacture smoking-cessation medications.

HUMAN PARTICIPANT PROTECTION

There were no human participants involved.

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