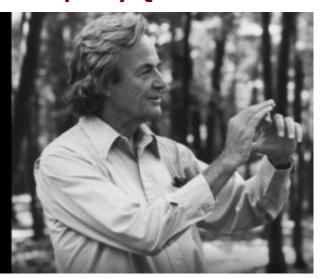
#### **February 17th, 2020**

## Nicotine science and policy Q & A

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I would rather have questions that can't be answered than answers that can't be questioned.

Richard Feynman, Theoretical Physicist



Welcome, this is my substantially upgraded 2020 Q & A on nicotine science and policy.

It mostly focusses on nicotine *vaping* as an alternative to smoking, but most of the argument also applies to heated tobacco products, modern smokeless tobacco and new oral nicotine products. It consists of about 60 questions and builds on a brief Q & A that I submitted to a consultation, a critique of an absurd anti-vaping Q & A by the WHO and my critique of numerous false and misleading claims made by Professor Stanton Glantz.

Please propose new questions and new themes, or suggest better answers or additional recommendations for further reading in the comment section. Help make this better!

## **Contents - the questions**

#### 1. Strategy - what is the purpose of tobacco and nicotine policy?

1.1 What are the goals of tobacco and nicotine policy?

1.2 What is 'tobacco harm reduction'?

1.3 What products are involved?

1.4 Shouldn't we aim for a nicotine-free society?

1.5 What is the 'endgame' for tobacco?

#### 2. Safety and relative risk - what are the risks?

2.1 Are e-cigarettes less harmful than cigarettes?

2.2 Do the recent US cases of severe lung injury prove that e-cigarettes are very harmful?

2.3 What about long term effects - shouldn't we take a precautionary approach?

2.4 It took decades for the harmful effects of smoking to emerge, won't it be the same with vaping?

2.5 How much less harmful are e-cigarettes than cigarettes?

2.6 Is it fair to say e-cigarettes are likely to be at least 95% lower risk than smoking?

2.7 Do people understand the risks of vaping?

2.8 Isn't this just the 'light cigarette' tobacco industry scam all over again?

#### Quitting smoking – do vaping products displace smoking?

3.1 Do e-cigarettes help people quit smoking?

3.2 Isn't most vaping 'dual-use' of e-cigs and cigarettes?

3.3 What is the difference between NRTs, smoking cessation pharmaceuticals and vape products?
3.4 Should the healthcare system cover e-cigarettes as smoking cessation aids?

3.5 What about people who are disadvantaged and cannot afford to vape? Should they get support? 3.6 Should the healthcare system help vapers to go nicotine-free and quit vaping?

#### 4. Youth - how should we address the uptake of adult products by young people

4.1 Why do e-cigarettes appeal to adolescents?

4.2 Is there a 'youth vaping epidemic' in the United States?

4.3 Is vaping a gateway to smoking?

4.4 Should flavours be banned to stop youth vaping?

- 4.5 Should e-cigarette sales be restricted to people aged 18 and over? 4.6 Does nicotine damage the developing adolescent brain?
  - 4.7 What can be done to protect young people?

#### 5. Regulation – how should governments handle reduced risk products?

5.1 Should e-cigarettes be banned?

5.2 Should e-cigarettes be regulated like cigarettes?

- 5.3 Should e-cigarettes be regulated as smoking cessation medicines with pharmaceutical regulation? 5.4 What is the right approach to regulating e-cigarettes?
  - 5.5 What are the potential unintended consequences of vaping regulation?
- 5.6 Should different categories of vapour products like THC or nicotine salts be regulated in different ways?
  - 5.7 Should regulators impose limits on the strength of nicotine in e-liquids? 5.8 Why does Juul use a high strength nicotine liquid in the US? 5.9 Should there be a special tax on e-cigarettes? 5.10 Does tobacco harm reduction undermine tobacco control?

#### 6. Vaping in public places - should it be permitted and who should decide?

6.1 Do e-cigarette vapours pose the same risks to bystanders as second-hand smoke from cigarettes? 6.2 Should vaping be banned by law in public places and workplaces?

#### 7. Marketing – what marketing freedoms or constraints are appropriate?

7.1 Are vaping products aggressively marketed to teens?

7.2 Should advertising for reduced-risk products be banned?

7.3 How to maximise the benefit to smokers and would-be smokers, while minimising recruitment of non-users?

#### 8. Retailing – who should sell and under what conditions?

8.1 Where should e-cigarettes and other reduced-risk products be sold and not sold?

8.2 Should e-cigarettes be available only through pharmacies or on prescription or over-the-counter everywhere?

8.3 Should vaping products be available on-line?

#### 9. Tobacco industry – pariahs, predators or player?

9.1 Are e-cigarettes a tobacco industry ploy to keep people smoking?

- 9.2 Should tobacco control authorities collaborate with tobacco-related industries in pursuit of public health objectives?
  - 9.3 If tobacco companies want to reduce the harm caused by cigarettes, why don't they just stop selling cigarettes?

#### 10. Rapid responses to the biggest myths about vaping [14 additional rapid-fire questions]

Postscript. Vaping – what people are getting wrong. The Economist

## 1. Strategy – what is the purpose of tobacco and nicotine policy?

## 1.1 What are the goals of tobacco and nicotine policy?

The primary public health policy goal should be the reduction of disease: trying to stop people dying in agony of cancer, collapsing with heart attacks and living in misery with COPD. In practice, this means concentrating on the goal of smoking cessation, especially among middle-aged adults – the population most at risk. There are many possible goals for tobacco/nicotine policy: to improve wellbeing, reduce harm, reduce disease, get rid of smoking, stop all tobacco use, stop nicotine use, protect non-smokers, protect adolescents, destroy the tobacco industry – to name a few. It used to be easy to say "all of the above" and that basically works if cigarettes are dominant and most people want to guit smoking. But with the rise of reduced-risk tobacco and nicotine products, it is no longer so easy because there are important opportunities that are lost if the objectives are indiscriminate. This is because the new products create trade-offs – for example, we can achieve deeper

reductions in disease by promoting switching to lower-risk nicotine products, but that might

mean more nicotine use. When policymaking demands a priority, the policy should in my view focus primarily on the greatest harms, and these are the major non-communicable diseases.

#### **Further reading**

- Abrams et al. Submission to the consultation to WHO High-Level Commission on Non-Communicable Diseases (NCDs), 2018. [link]
  - Clive Bates, Who or what is the WHO at war with? [link]

### 1.2 What is 'tobacco harm reduction'?

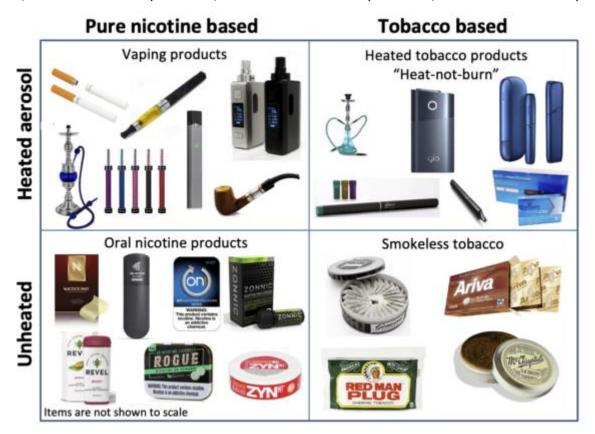
Tobacco harm reduction is a public health strategy that makes use of regulation, fiscal measures, communications and support services to reduce the harms associated with tobacco or nicotine use, including the secondary harms induced by tobacco or nicotine policy. In practice, this primarily means encouraging smokers or would-be smokers to adopt non-combustible nicotine products such as e-cigarettes rather than combustible, smoking products such as cigarettes. Harm reduction is widely practised in public health, for example in illicit drugs and sexual health, because 'abstinence-only' approaches are ineffective. Harm reduction is acknowledged as within the definition of tobacco control in the Framework Convention on Tobacco Control.

#### **Further reading**

- Letter to Director-General World Health Organisation, Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction, 2018 [link][blog]
- Beaglehole R et al. Nicotine without smoke: fighting the tobacco epidemic with harm reduction, *The Lancet* 2019 [link][PDF]

#### 1.3 What products are involved?

There are four broad categories of non-combustible consumer nicotine products. Vaping products, heated tobacco products, smokeless tobacco products, and oral nicotine products.



Most of this briefing will concentrate on vaping products, but we have already seen proof-of-concept in Scandinavia with snus (a form of smokeless tobacco) driving smoking down to the world's lowest level, with clear public health benefits as a result.

### 1.4 Shouldn't we aim for a nicotine-free society?

No, no more than we are aiming for an alcohol-free or caffeine-free society (which most of us are not), and definitely not by coercion or prohibition. Almost all societies at present and in history have made quite widespread recreational, ceremonial or spiritual use of psychoactive substances of some sort. Nicotine is not benign but as a recreational drug, it relatively innocuous. It does not cause intoxication, accidents and injuries, violence, physical or sexual vulnerability, hallucinations, incapacitation, incoherence, blackouts, overdoses or social problems like family breakdown or loss of employment. Unlike alcohol, which is linked to serious health risks, nicotine is not a cause of serious disease in its own right.

Societies should take a mature approach to substance use, and acknowledge that nicotine is a legal recreational drug, and that drug prohibitions have severe costs. Once we have recognised that, the challenge is to try to ensure that nicotine is available to adults who want it in its least damaging forms (i.e. not smoking). It is possible that people will eventually choose not to use nicotine and it will wither away by choice and consumer preference. However, an attempt to bring this about by force of law risks the creation of unregulated and irresponsible black markets forming to meet demand.

If there is to be an overarching public health goal, it should be focussed on a 'smoke-free society' not a 'nicotine-free society'. However, in pursuit of any overarching goal, the *means* are as important as the *ends* and we should never pursue public health goals by imposing a tyranny against a particular group. Policymakers should resist excessively coercive and punitive measures, reject prohibitionist approaches and take a more liberal approach to nicotine. The idea of a nicotine-free society owes its roots to a War-On-Drugs mindset and *that war is not going well*. Its origins are in a puritanism that is ineffective and counterproductive for public health in the modern world.

#### **Further reading**

 Abrams D et al. Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives, Annual Review of Public Health, 2018 [link]

### 1.5 What is the 'endgame' for tobacco?

A range of strategies has been proposed for bringing about the end of tobacco – the so-called 'tobacco endgame'. These include (I paraphrase):

- 1. Outright prohibition
- 2. A cap and trade system: 'the sinking lid" that steadily reduces the total quantity of tobacco products that can be placed on the market
- 3. A system of raising the age for legal of sale of tobacco by one year every year, thus creating a "the smokefree generation"
  - 4. Removing almost all the nicotine from cigarettes and other combustibles
    - 5. Nationalising tobacco companies and making them reduce sales
    - 6. Regulating tobacco companies to require them to reduce sales by law

A detailed critique of these ideas is included in further reading below. But in summary, these are unlikely to work, mainly because of the degree of coercion and appropriation involved.

A much more plausible endgame would be built on 'creative destruction' through market forces. This means the contraction of smoking to very low levels through its technological obsolescence by superior products (vaping etc). This would be achieved by:

- 1. Focussing the endgame on *smoking*, not on nicotine or tobacco
- 2. Accurately communicating risk and the comparative risk of smoking, vaping and the full range of low-risk products
- 3. Ensuring regulation is proportional to risk and encourages switching from smoking to vaping
  - 4. Use of the tax system to incentivise switching
  - 5. An approach to regulation that encourages innovation and experimentation with consumer preferences given the pace of innovation in this field, we have to imagine how the vaping products of 2030 will compete with smoking.

If the alternatives are good enough, there will be no need to prohibit cigarettes. But if they are not good enough it will be very difficult to ban cigarettes. Whatever approach is taken to the endgame, we need really good alternative products.

#### **Further reading**

- Clive Bates. The tobacco endgame: a critical review of the policy ideas, 2015 [link]
- Clive Bates & Carrie Wade. FDA wants to reduce nicotine in cigarettes what could possibly go wrong (and right)? 2017 [link]
- Attorney General Miller (Iowa) and 17 others, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, July 2018 [link]

### 2. Safety and relative risk - what are the risks?

#### 2.1 Are e-cigarettes less harmful than cigarettes?

Yes. Beyond any reasonable doubt, e-cigarettes are *much less* harmful: one to two orders of magnitude less risky. Almost all the harm done by cigarettes arises from the *smoke*, inhaling the products of high-temperature combustion of dried and cured tobacco leaf. The smoke is the sticky smoke particles and hot toxic gases that are drawn into the lung. E-cigarettes do not produce smoke because there is no combustion and no burning organic material, just heated tiny droplets of nicotine-carrying liquid. Combustion is the key difference and this creates completely different physical, chemical and biological effects.

### 2.2 Don't the recent US cases of severe lung injury prove that ecigarettes are very harmful

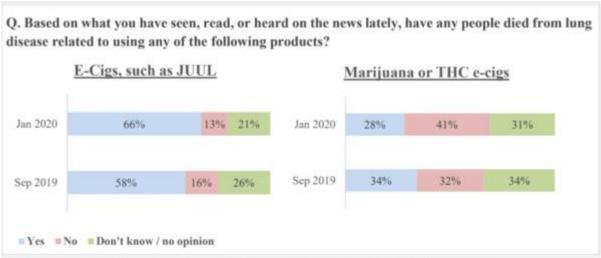
As of February 2020, there have been nearly three thousand hospitalisations and over sixty deaths from a severe lung injury condition. Are these a serious new risk from nicotine vaping?

No, definitely not. These cases have gained worldwide publicity, but they are completely unrelated to normal nicotine e-liquids and e-cigarettes. The cases occurred in users of cannabis vaping products and were caused by the use of a particular additive used for thickening cannabis (THC) oils – Vitamin E Acetate. It is possible other additives were also involved. This cannot be used in nicotine-based e-liquid and would serve no purpose. The additive is used to 'cut' (i.e. dilute) expensive THC oils for economic gain, but without losing the viscosity (thickness of the liquid) that consumers use to gauge quality.

There is no credible evidence that links nicotine vaping to these injuries. The only source is the inherently unreliable testimony of users, who have incentives not to candidly disclose THC use because of possible legal, employment, education or parental consequences. This is why analysis should focus on the <u>suspect supply chain</u>. Once a cause has been identified in one supply chain (Vitamin E acetate added to illicit THC vapes), there is a vanishingly small chance that a separate independent cause would emerge at the same time and same place with the same symptoms in commercially available e-cigarettes.

The lung injury cases are a tragedy, but they are primarily caused by the illegal supply of cannabis vapes and provide no basis for changing policy on e-cigarettes. They do, however, provide a warning about creating black markets by banning products – and that would be an additional risk of bans on e-cigarettes or flavours: a black market will develop.

Though these cases have nothing to do with regular nicotine liquids or e-cigarettes. The way key US agencies like CDC and FDA handled the controversy has meant that public opinion falsely attributes the cause to the nicotine products, with over 60% blaming regular nicotine vapes. No less dangerously, only 28% attribute the cause to adulterated THC vapes.



Source: Morning Consult, polls conducted among U.S. adults, 12-14 Sep 2019 and 28-30 Jan 2020

These misperceptions are potentially deadly: vapers or dual users may revert to smoking or be put off switching. THC users may continue to use THC vaping products from a compromised supply chain that poses lethal risks. Policymakers may take excessive regulatory action against nicotine products to address risks that do not, in reality, exist. This is a major public health failure, but no-one is accountable.

#### **Further reading**

- David Downs, Vape pen lung injury: Here's what you need to know, *Leafly* January 2020 [link]
- Gartner et al. Miscommunication about the causes of the US outbreak of lung diseases in vapers by public health authorities and the media, *Drug and Alcohol Review*, January 2020 [link]
- Mike Siegel, Newest CDC Data Confirm that Respiratory Disease Outbreak was Caused by Vitamin E Acetate Oil in THC Vaping Cartridges, The rest of the story, December 2019 [link]
- Guy Bentley, The CDC Is to Blame For More Americans Than Ever Being Misinformed About Vaping and E-Cigarettes, Reason Foundation, January 2020 [link]
  - CDC. Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products [link]. CDC's advice has belatedly focused on THC vapes.

## 2.3 What about long term effects – shouldn't we take a precautionary approach?

It is true (and a truism) that we cannot have 50-year studies of a product that has only been in use for about 10 years, but that does not mean we have no data. We have extensive data on the toxicants in the vapour and measurements of 'exposure biomarkers' in the blood, urine and saliva of users – all suggest very much lower risks than smoking.

One argument is that we should impose very tough regulation by applying the 'precautionary principle' until we have certainty about long term risks (by which those supporting the

precautionary principle usually mean 'never'). This is based on a basic misunderstanding of the precautionary principle. This idea, which is difficult to operationalise in practice, requires an assessment of both the costs of doing nothing but also the possible harms from intervening with excessive regulation, having estimated both the what is known and what risks are less certain. We have no doubt that cigarettes are very harmful, so intervening to discourage switching to vaping on the basis of hypothetical, unknown or trivial risks is likely to be more reckless than it is precautionary.

#### **Further reading**

• The 'no long term evidence' gambit [link] and Abusing the Precautionary Principle [link] discussed in the Ten perverse intellectual contortions: a guide to the sophistry of antivaping activists [link]

## 2.4 It took decades for the harmful effects of smoking to emerge, won't it be the same with vaping?

No. We would know immediately today that smoking is highly harmful. We would not have to wait five decades for epidemiology to show that smoking was causing cancer, heart disease etc. This is because the discipline of systems toxicology has hugely advanced since the midtwentieth century. We also know a lot more about the risks of particular exposures, for example to heavy metals, without needing data from e-cigarette studies. Instead, we can draw on findings from other disciplines such as occupational health and the limits that are imposed on exposure in the workplace. These limits provide benchmarks for the tolerability of risk that we can use to benchmark vapour emissions and exposures.

### 2.5 How much less harmful are e-cigarettes than cigarettes?

The US National Academies of Science Engineering and Mathematics said that compared to cigarettes e-cigarettes are:

"likely to be far less harmful"

The premier British medical organisation, the Royal College of Physicians, said e-cigarettes are

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

The main English government public health agency, Public Health England, said that

"...stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk.

None of these bodies, or the experts advising them, has any connection to the e-cigarette or tobacco industries. In each case, the experts based their view on a comprehensive published review of the evidence.

#### **Further reading**

- National Academies of Science, Engineering and Medicine NASEM (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [link] Launch presentation summary (slide 44) [link][link]
- Tobacco Advisory Group of the Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016 [link]
- McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

## 2.6 Is it fair to say e-cigarettes are likely to be at least 95% lower risk than smoking?

Yes, the statements above are reasonable expert estimates of the relative long-term risks based on what we know of the respective toxicology of cigarette smoke and vape aerosol and also what we know of the exposure to toxicants in the body as measured in blood, saliva and urine. Based on the available evidence on relative toxicity and human exposures to toxicants, independent experts making assessments for PHE in 2015 and the RCP in 2016 concluded that it is reasonable to work on the basis that e-cigarettes are likely to be at least 95% lower risk than cigarette smoking and potentially substantially lower than that. In the short to medium term, there does not appear to be any significant risks given the experience of tens of millions of users over 10 or more years.

At present, there is no new evidence that would challenge that assessment and much that would reinforce it. While it is possible that some risks will emerge it is also quite possible that long term effects will be negligible or that technology improvements or regulation will allow us to tackle any risks that do emerge. In practice, we will not be able to directly determine the actual health effect of vaping for many decades, if ever (given that most vapers have also been smokers). But knowledge of systems toxicology is far advanced from the early days of smoking and health research and we do not need to wait many decades to understand risk.

It is important to be clear what these communications are.

- These communications are designed to address a widespread problem the misperception of relative risk among the public (see below) whereby many people believe the products are as harmful or more harmful, and if there is a difference, the risk is only a little less.
- Perceptions inform behaviours, and in this case, we expect false perceptions to be causing more cigarette smoking and dual-use than would otherwise be the case – therefore causing material physical harm.
- It is what is known as a heuristic (a rule of thumb), that aims to guide people in making good, well-informed decisions, that are less vulnerable to biases induced by the way that messages are communicated.
- Figures of this nature are widely used in health and risk communication to help the
  public understand what otherwise confusing and complex data really mean for them
  using the best judgement of experts.
- The alternative is to leave those at risk to form their views from the media based on many misleading communications from academics, activists and billionaire funders and their proxies.
  - The format "likely to be at least 95% lower" is not a point estimate based on deterministic calculations, but expressed as a rough guide to where the risks are likely to come out based on expert judgement
- It is based on what is currently known, but by definition, it cannot assess 'unknown-unknowns' however, after 10 years of widespread use there are no signs of surprises and it is important to assess the likelihood of something novel emerging.

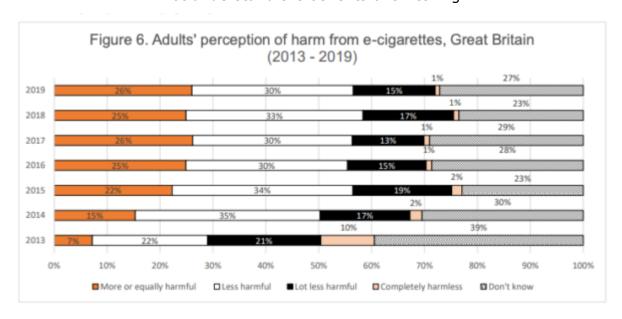
Why the hostility to these claims? These basic risk communications have been the subject of sustained attacks from tobacco control activists. I do not believe this is because those involved are concerned about misleading smokers or vapers (few complain when academics mislead smokers by falsely claiming that smoking and vaping are of equivalent risk). It is more because they just do not like this approach, which is based on empowered consumers interacting with innovative businesses in a lightly regulated market. This is antithetical to the tobacco control playbook, which tends to favour punitive, coercive and stigmatising measures.

#### **Further reading**

- Clive Bates. Vaping is still at least 95% lower risk than smoking debunking a feeble and empty critique, January 2020 [link]
- Clive Bates. Public Health England says truthful realistic things about e-cigarettes, August 2015 [link]
- Clive Bates. Smears or science? The BMJ attack on Public Health England and its ecigarettes evidence review, November 2015 [link]

### 2.7 Do people understand the risks of vaping?

No, most people greatly over-estimate the risks compared to smoking. The chart below from ASH (UK) is the position in Britain – only 15% accurately identify e-cigarettes as a lot less harmful than smoking. But 26% think they are more or equally harmful. Because behaviour is informed by perceptions, it means that many people may be still smoking because they do not understand the benefits of switching.



This is not confined to the UK, in fact, it is worse in the United States – only 3.6% correctly recognise e-cigarettes are much less harmful than smoking, 45% wrongly believe e-cigarettes are very harmful, 56.5% incorrectly believe that nicotine is the substance that causes most of the cancer caused by smoking, and only less one in seven (13.4%) correctly understand that smokeless tobacco is less risky than cigarettes (and 'much less risky' – the real answer is not an option in this survey).

#### **Further reading**

- National Cancer Institute, Health Information National Trends Survey (HINTS) 2018. E-cigarettes compared to cigarettes [link]; E-cigarettes harm to health [link]; Smokeless tobacco compared to cigarettes [link]; Nicotine as a cause of cancer [link]
  - Huang J, et al. Changing Perceptions of Harm of e-Cigarette vs Cigarette Use Among Adults in 2 US National Surveys From 2012 to 2017. JAMA Netw Open. March 2019[link]

## 2.8 Isn't this just the 'light cigarette' tobacco industry scam all over again?

No. Light cigarettes work by diluting the smoke with air drawn in through holes in the filter. This fools machines into measuring less tar and nicotine or a given puffing regime But humans compensate for this dilution by consuming more smoke or by instinctively blocking

the ventilation holes and/or taking more and deeper puffs. They aim to 'compensate' to absorb the same nicotine they want, but that means they also get all the tar that comes with it. The non-combustible products do not produce the toxicants in the first place, so for a given dose of nicotine, the toxic exposure is much lower. The fact that people were fooled by light cigarettes does not mean a false analogy (used by some unscrupulous tobacco control activists) should be used to fool them and harm them again by exaggerating the risks of ecigarettes.

# 3. Quitting smoking – do vaping products displace smoking?3.1 Do e-cigarettes help people quit smoking?

Yes. There are now four strands of evidence that suggest e-cigarettes are effective in helping people to quit smoking:

- 1. Evidence from randomised controlled trials, notably, Hajek et al 2019, which showed vaping to be about twice as effective as NRT; "E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support."
  - 2. Observational studies (watching what happens when people use e-cigarettes) for example, Jackson et al 2019; "Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England."
- 3. Population data (unusually rapid reductions in smoking prevalence or cigarette sales visible in market data), for example, Zhu S-H et al, 2018. "The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions."
- 4. The thousands of testimonials of users who have struggled to quit smoking using other methods. See, for example, CASAA (12,500 testimonials) and, before dismissing 'anecdotes' see Carl V Phillips on why Anecdotes ARE scientific data

None of these is decisive in its own right, but all four strands point towards e-cigarettes displacing smoking.

There are also several pathways by which vaping can displace smoking, not simply as a quit aid. The following mechanisms are possible:

- 1. As an aid for someone who already wants to quit smoking a kind of souped-up NRT.
- 2. By encouraging people who would not otherwise try to quit to give it a try, because it continues pleasurable aspects of a habit they like. In this way, it increases the number of quit attempts.
- 3. It may form part of a (reluctant) response to a tobacco control measure for example, the economic pressure created by cigarette taxation
- 4. It may never be a conscious effort to quit smoking, but become a change of behaviour by default.
- 5. It may prevent relapse to smoking among people who have already quit smoking, but miss it or are vulnerable to relapse to smoking (e.g. due to stressful life events).
  - 6. It may displace smoking uptake in young people or be a diversion from smoking experimentation that would otherwise consolidate into a more entrenched smoking habit

We need to avoid simplistic analogies with smoking cessation treatments and see the emergence of reduced-risk products as a pervasive technology diffusion and disruption in a market dominated until now by a very dangerous product.

#### Further reading and viewing

- Clive Bates, Colin Mendelsohn. Do vapour products reduce or increase smoking? 19
   October 2017 [link]
- Villanti AC et al. How do we determine the impact of e-cigarettes on cigarette smoking cessation or reduction? Review and recommendations for answering the research question with scientific rigor. Addiction. 2017 [link]
  - Carl V Phillips, Science lesson: how vaping leads to smoking cessation, 2017 [link]
    - For more on this, see Robert West's presentation:

Should health professionals recommend smokers to switch to e-cigarettes? from Robert West on Vimeo.

### 3.2 Isn't most vaping 'dual-use' of e-cigs and cigarettes?

Many vapers do use both e-cigarettes and cigarettes. But this is not the bad thing that it is often made out to be. The proportion of dual users has been falling in the UK and the United States, and in the UK is now well below half. This is probably due to several factors: many dual users are in transition from smoking to vaping over a period of months or years. Also, as the technologies improve over time, it is likely that more of the users will find exclusive vaping a satisfactory alternative to smoking. Dual-use should be properly understood as part of a behavioural pathway that evolves over time, not something this is static and fixed. Vaping may start with no intention to quit smoking, but as the user becomes more familiar and finds the product they like they gradually make more use of the product in more situations.

We should remember that just about every attempt to quit smoking using established methods involves continuing to smoke, usually by serial quitting and relapse. Unless cold-turkey, smoking cessation therapies or behavioural counselling are 100% and immediately effective, people who are trying to quit will continue to smoke over the course of quitting.

It's also worth remembering the effect that anti-vaping messages have on smokers and dualusers. If they are being told there is no benefit and that it is harmful or anti-social, why should they feel motivated to make a complete switch? Many of the same activists who are raising dual-use as a problem (it isn't) are also doing what they can to slow down or reverse the migration from dual-use to exclusive vaping (which is a major problem).

#### **Further reading**

- Clive Bates. Claim 10: Dual-use undermines the value of vaping, August 2019 [link] in Vaping risk compared to smoking: challenging a false and dangerous claim by Professor Stanton Glantz [link]
- Simonivicius et al. What factors are associated with current smokers using or stopping e-cigarette use? *Drug and alcohol dependence*, 2019 [link]
- Persoskie A et al. Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users, *Addiction*, 2019 [link]

## 3.3 What is the difference between NRTs, smoking cessation pharmaceuticals and vape products?

From a public health perspective, we should support the use of whatever options we can to reduce *smoking*, which is the primary driver of disease. The impact of any approach to quitting smoking is a product of two things – (1) how effective it is and (2) how willing people

are to use it. At least in the UK and the US, e-cigs are now the most used product by smokers trying to quit smoking, more than any of the officially-approved smoking cessation medications.

The great strength of the vaping approach is that it is effective at replacing cigarettes because it replicates many aspects of smoking but without the harm (for example, nicotine effects, sensory experience, hand-to-mouth movement, and a behavioural ritual). But it also does this in a way that appeals to smokers – it is fun and interesting and there is a subculture to go with it. The secret of vaping is the *combination* of effectiveness and appeal. There may be occasions when it makes sense for a vaper to use NRT – for example, while learning to vape, on long flights, perhaps even overnight. The consumer market is developing diverse nicotine products – for example, oral nicotine pouches – which may also help.

#### **Further reading**

• Notley et al. The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention, 2018. [link] found that: *E-cigarettes meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related aspects of tobacco addiction* 

## 3.4 Should the healthcare system cover e-cigarettes as smoking cessation aids?

Generally, no. These are consumer choices and alternatives to smoking and not medications. People who can afford to smoke can afford to vape. The healthcare system should, however, offer encouragement, advice and expertise to potential switchers and possibly partner with vape shops or chains for delivery. One of the strengths of the 'tobacco harm reduction' approach is that the health gains are made on the initiative of the users and at the users' own expense.

## 3.5 What about people who are disadvantaged and cannot afford to vape? Should they get support?

There may be a case for support. If people can afford to smoke, they can generally afford to vape – and the tax system should aim to keep it that way. So healthcare providers should not be funding vaping long term. However, for the economically disadvantaged (very poor, homeless, etc) there are issues at the point of transition:

- 1. There are upfront costs for a device the user may save money in the medium term, but if they don't have the upfront cash the savings can't be made
- 2. The user may worry about ending up paying for both cigarettes and vaping equipment if the latter doesn't work for them and this is a barrier to experimentation
- 3. Some sort of inducement to try might be necessary and be highly cost-effective for the provider

## 3.6 Should the healthcare system help vapers to go nicotine-free and quit vaping?

It might be a surprise, but I would say no. In the nicotine field, public resources should be focussed exclusively on reducing *smoking*. This is because the risks of vaping are very low and therefore the benefits of quitting vaping are also very low. So it follows that it is unlikely ever to be cost-effective to spend public resources on providing services for quitting vaping, especially if the alternative is to spend more on quitting smoking. Also, some caution is needed: continued vaping may protect against relapse to smoking. Many users find they enjoy vaping and that it adds to their wellbeing without a substantial increase in risk – much as many can enjoy alcohol, even though it is extremely damaging for some. If people want

to quit nicotine altogether that is fine and they should go ahead, but there is no reason for a healthcare system to cover it. In my view, when someone has quit smoking, public health has done its job.

## 4. Youth – how should we address the uptake of adult products by young people?

### 4.1 Do e-cigarettes appeal to adolescents?

Yes, but it's complicated. The first thing we need to do is actually understand what is going on. Most adult or illicit products or behaviours will appeal to some adolescents – this applies to alcohol, drugs, gambling, pornography etc. Adolescence is a transition from childhood to adulthood. There has been a recent rapid increase in e-cigarette use by American adolescents. But the definition used includes anyone taking one puff in the past 30 days before the survey. Drilling down into this data shows most US teen vaping is infrequent. Among frequent users, the vast majority had already smoked and for them, e-cigarettes may be beneficial. Amongst users with no prior tobacco use, there is little sign of adolescent vaping causing addiction.

The most common reason given by US adolescents for taking up vaping is 'curiosity' (not flavours) – see CDC.

Reason given (top 5 only)	E-cig only users	E-cig and other tobacco users
I was curious about them	56.1%	38.4%
Friend or family used them	23.9%	22.2%
They are available in flavors, such as mint, candy, fruit, or chocolate	22.3%	26.6%
I can use them to do tricks	22.0%	29.0%
They are less harmful than other forms of tobacco, such as cigarettes	17.0%	19.1%

It is quite possible that the publicity surrounding youth vaping in the United States has stimulated curiosity and so contributed to its cause. An own goal.

#### **Further reading**

 Clive Bates, Research suggests broader causes for youth vaping uptake than flavours, 2019 [link]

## 4.2 Is there a 'youth vaping epidemic' in the United States?

No. This has been hyped up into a national and international moral panic. There has been a rise in the use of vaping products by adolescents, and in the United States, this has risen rapidly to from 2017 (11.8%) to 2019 (27.5%). This is a concern, but it is necessary to drill down to understand what is really going under the headline numbers.

- 1. The definition of teen vaping is very broad and includes anyone who took a single puff in the past 30 days.
  - 2. Most teen vapers are vaping infrequently mostly experimental or just 'party use'
- 3. Nearly all of the daily or frequent users were already using tobacco, mainly smoking for them vaping may be a beneficial diversion either now or in the future

4. Among young people who have not previously used tobacco, there is little sign of dependence among those who vape

#### **Further reading**

- Clive Bates: The great American youth vaping epidemic. Really? 29 January 2019 [link]
- West et al. QEIOS, Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (2019 Preprint) [link]
- Abrams et al. Most Young People Do Not Vape, and Even Fewer Vape Regularly, 2019 [link]

#### 4.3 Is vaping a gateway to smoking?

No, there is no compelling evidence for this theory. However, we do see a quite strong association between young people who vape and then subsequently smoke. They are about four times as likely to smoke if they have vaped. This has allowed some academics or activists to claim a gateway effect. But this approach is flawed – you would need to know what the person would have done in the absence of vaping, and many would have progressed straight to smoking. It is most likely that 'common liability' explains the associations. This means that the same factors that incline young people to smoke also incline them to vape. The factors might include genetics, family smoking history, home circumstances, mental health and personal efficacy, delinquency, educational attainment, social group etc. Statisticians can try to eliminate these 'confounding' factors from the association to show that what is left of the association can be attributed to trying vaping. The trouble is that they can never do this completely – they will never have enough data or accurate models for confounding, and therefore never be able to eliminate these factors completely.

#### **Further reading**

- Carl V Phillips, Science Lesson: How Understanding 'Confounding' Can Combat Anti-Vaping Junk Science, 20 November 2017 [link]
- Lee PN et al. Considerations related to vaping as a possible gateway into cigarette smoking: an analytical review, 2019 [link]

## 4.4 Should flavours be banned to stop youth vaping?

No. E-cigarettes and e-liquids are *inherently* flavoured products – all products, including the tobacco flavoured products – have flavouring agents added to give them flavour. Banning all or most flavours would be like banning all or most toppings on pizzas – it would effectively prohibit all or most of the products, leaving only the unattractive base or tobacco-flavoured liquids. This would make e-cigarettes nearly useless as alternatives to smoking for adults, promote a black market and may even increase risks to young people if it encourages them to smoke or to access black markets. It may make sense to ban certain flavour descriptors (the names given to flavours), if these are designed to appeal to youth.

#### **Further reading**

• Clive Bates. The US vape flavour ban: twenty things you should know. 4 November 2019 [link]

## 4.5 Should e-cigarette sales be restricted to people aged 18 and over?

Yes, probably. It is widely held that under-18s should not be using any tobacco or nicotine products and therefore it should be against the law to sell such products to them. Though this is necessary to reassure parents and to give legitimacy to products and an industry aimed at

adults, it may have possible unintended consequences. There is some evidence that when ecigarette age restrictions were introduced in the United States, there was a relative *increase* in teenage cigarette smoking. It is possible that under-18s benefit from e-cigarettes by displacing or not initiating smoking and therefore that making them more difficult to access could be a source of unintended harm. So although there is near-universal support for age restrictions at 18 or 21 for sales of e-cigarettes, even this idea has potential harmful unintended consequences.

#### **Further reading**

- Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ*: October 2015. [link]
- Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. Prev Med (Baltim), February 2016 [link]

### 4.6 Does nicotine damage the developing adolescent brain?

No, this is a scare story and the claims do not bear scrutiny. Some public figures, including the US Surgeon General, have suggested that nicotine damages the adolescent brain. The evidence for this hypothesis comes only from a few rodent studies. These are an unreliable guide to human risk because the rodent brain does not offer a reliable proxy for the human brain and it is difficult to design experiments that are controlled to give a mouse equivalent exposure to a human.

But this is not the main reason for doubt. Over the last 60 years, millions of adolescent nicotine users have grown up as smokers and either continue to use nicotine or have quit. The problem for the Surgeon General and others is that there is <u>no sign</u> of any cognitive impairment in the population of former teenage smokers and many of today's finest adult minds were once young smokers. If a detrimental cognitive effect of nicotine existed in the human population, it is inconceivable that we would not already have seen extensive evidence of it from the study of smokers, non-smokers and ex-smokers over several decades.

#### **Further reading**

• Arnold Foundation, Why Journalists Should Stop Publishing Studies Conducted With Mice, 2018 [link]

## 4.7 What can be done to protect young people?

Regulations to protect youth should always be targeted at youth and not indiscriminately affect adults (for example through flavour bans, nicotine limits, blanket advertising bans, or taxes). There are three main legitimate policy approaches to protect young people:

- 1. control access by setting age limits and restricting where and how products can be purchased;
  - 2. control marketing, packaging and branding to prevent marketing targeted at adolescents;
- 3. provide credible reality-based campaigns, information and warnings targeted at young people.

Pretty well everything else is either ineffective or counterproductive.

## 5. Regulation – how should governments handle reduced risk products?

5.1 Should e-cigarettes be banned?

No, absolutely not. This would prevent smokers (of any age) accessing much less risky alternatives to cigarettes, protect the cigarette trade from disruptive competition, and cause more disease and death. It would also put legitimate suppliers out of business, create a large black market and stimulate international internet trade. If nicotine is a legal drug, like alcohol or caffeine, then policymakers should be encouraging the least risky options to use it – not banning the safer alternatives to create a monopoly for the most dangerous nicotine products, cigarettes. Bans on e-cigarettes can be explicit prohibitions (as in India), implemented through poisons regulation (as in Australia), through classification as a medicine (Japan) or can be *de facto* prohibitions of essential elements of the product like bans on flavours (United States) or insurmountable evidential hurdles required for authorisation (United States).

There are multiple likely negative consequences arising from prohibition or *de facto* prohibition. These include:

- current vapers reverting to smoking
- current smokers not switching to vaping
- new users (adolescents) taking up smoking instead of vaping
- a boost for the cigarette trade as it benefits from reduced competition
  - the development of widespread home DIY mixing
- the development of a black market in vaping products with issues of quality and consumer rights and loss of regulatory supervision
  - the enrichment of criminals and increase in crime
- the exposure of more people to criminal suppliers who also supply illicit drugs and other illegal commodities
- ...and above all... the basic infringement of the liberty and autonomy or people to control their own risks, make their own pro-health decisions and to take their own initiatives to protect their own health at their own expense. On what basis does a government or public health activist intervene to stop that?

Policymakers and activists proposing prohibitions need to show that they have assessed the consequences listed above and concluded that the benefits outweigh these costs. Not a single state that has prohibited vaping has done this.

## 5.2 Should e-cigarettes be regulated like cigarettes?

No. Cigarettes are far more harmful than e-cigarettes and e-cigarettes can help people quit smoking. For these two reasons alone, the policy needs to take account of difference in risk and the potentially large benefits of e-cigarettes. The aim should be to use 'risk proportionate' regulation to encourage switching from cigarettes to e-cigarettes while controlling safety risks and preventing youth uptake of all tobacco and nicotine products. See 5.4 below.

## 5.3 Should e-cigarettes be regulated as smoking cessation medicines with pharmaceutical regulation?

No, do not do that. These products are not medicines. They work as *consumer* products – effective competitors to cigarettes rather than medicinal therapies for tobacco dependence. They are not medicines, the people using them do not see themselves as sick and many do not want to enter a healthcare setting. They are using these products as a lifestyle consumer choice and as a better alternative to cigarettes. The fundamental problem with medicine regulation is that 'appeal', which is the key to the success of vaping as a consumer rival to smoking, becomes 'abuse liability' in the regulatory framework for medicines.

### 5.4 What is the right approach to regulating e-cigarettes?

Regulation of tobacco and nicotine products should be "risk-proportionate" – with more stringent controls placed on the highest risk products. This means (in brief) a regulatory agenda as follows:

- 1. relatively high taxes on cigarettes, but low or no taxes on much safer products including e-cigarettes;
- 2. bans on cigarette advertising, but controls on content and placement of e-cigarette advertising to prevent marketing to teens;
- 3. bans on smoking in public places, but indoor vaping policy should be a decision for the owners or managers of buildings;
- 4. large graphic health warnings on cigarettes, but messages encouraging switching on ecigarettes;
  - 5. plain-packaging for cigarettes, but not e-cigarettes;
  - 6. regulation of product formulation that makes switching to vaping relatively more attractive than continuing to smoke;
  - 7. regulation that addresses electrical, chemical, thermal and mechanical product risks where these benefit consumers;
    - 8. regulation of containers to make them child-resistant;
- 9. differential age restrictions, for example, age 21 for cigarettes, but 18 for e-cigarettes;
  - 10.bans on internet sales of cigarettes, but not on e-cigarettes;
    - 11.vaping-friendly stop-smoking services
  - 12.campaigns to discourage smoking, but to encourage switching

#### **Further reading**

- ASH New Zealand, A surge strategy for New Zealand. 2019 [link] (discussion of `risk proportionate regulation')
- Fairchild A. et al. Evidence, alarm, and the debate over e-cigarettes: Prohibitionist measures threaten public health, Science, December 2019. [link]

## 5.5 What are the potential unintended consequences of vaping regulation?

The danger is that excessive regulation will make vaping (or heated, smokeless or oral nicotine products) relatively less attractive to nicotine users compared to cigarettes. Poorly designed regulation has the potential to shift the calculations of users in favour of more harmful products. As the Royal College of Physicians said in its 2016 report, *Nicotine without smoke: tobacco harm reduction:* 

However, if [a risk-averse, precautionary approach to e-cigarette regulation] 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. (Section 12.10 page 187)

But there is an important fact to consider when striking this balance, the possible unintended consequences (more smoking) are much more serious than almost all of the conceivable harms that the regulation of low-risk products is designed to prevent. This means that regulators and policymakers should be paying particularly vigilant attention to unintended consequences that would cause more smoking. The uncritical endorsement of outright

prohibitions by WHO, suggests that at the highest levels this simple idea has not been grasped.

#### **Further reading**

• Clive Bates, Plausible unintended consequences of excessive regulation of low-risk nicotine products. 2019 [link]

## 5.6 Should different categories of vapour products like THC or nicotine salts be regulated in different ways?

Yes, if they present different types of risks. The underlying principle should be risk-proportionate regulation (see 10). One obvious candidate for better regulation is cannabinoid vapes, for example, THC oil vapes. The current model of THC regulation is 'prohibition', but this has just created a black market and that has created extremely serious supply chain risks (see 3 above). But more regulation is not always good. There are dangers that regulators become the enemies of innovation and protect incumbents (including cigarettes) and from innovative entrants. For example, the Juul product has been extremely successful with adults in providing a good nicotine delivery to rival a cigarette but in a compact and easy to use form. This has been achieved by the use of nicotine salts and relative strong e-liquids. It would be wrong to use regulation to stop this. Measures to protect youth should be focussed on youth, not on undermining the strong selling points of innovations aimed at adults.

### 5.7 Should regulators impose limits on the strength of nicotine in eliquids?

No, definitely not. The danger of limiting nicotine is that it leaves cigarettes in place as the most rapid and effective way of delivering nicotine. Such limits will make e-cigarettes ineffective alternatives for heavier smokers or those struggling to convert from smoking to vaping. It also may be a block on current and future innovation (e.g. to make products safer, smaller, easier to use) and make them more dangerous by forcing users to consume more liquid for a given dose of nicotine. Limits should only be set for poison-safety reasons (for example 7.2% or approximately 72mg/ml is a poison threshold in the UK) and not to limit nicotine uptake as this would provide an advantage to cigarettes

#### **Further reading**

- Clive Bates. Who cares about a few thousand dead? Defending EU limits on the strength of nicotine e-liquids. 2016 [link]
- N. Voos, et al., What is the Nicotine Delivery Profile of Electronic Cigarettes?, Expert Opinion on Drug Delivery (2019) [link]

## 5.8 Why does Juul use a high strength nicotine liquid in the US?

In the United States, Juul uses a 5% nicotine liquid (59mg/ml) in its pods. The maximum concentration allowed in the European Union is 20mg/ml (under 2% strength).

Some commentators have misunderstood the purpose of Juul's higher strength e-liquid. It is not primarily there to deliver more nicotine to the body but to deliver whatever the user is seeking in a smaller volume of liquid. Juul is a compact and convenient device and therefore has a small battery and a small container for the liquid (0.7ml compared to a maximum EU tank size of 2ml – already low compared to products on the market elsewhere). The small battery means it has lower power and can only heat a smaller volume of liquid in response to user puffing. Also, partly for energy efficiency reasons, the Juul device also operates at a relatively low temperature, meaning that it is less likely that the product will overheat liquid and start to generate products of thermal decomposition, such as aldehydes.

Juul also uses nicotine salts form by adding benzoic acid. This means that more of the nicotine from a Juul and similar devices is in 'protonated' or salt form (the nicotine molecule

is bound to a hydrogen ion, which is a proton). This means less of the nicotine is in 'freebase' form and so it is less easily absorbed on its journey through the mouth and throat and more of it is eventually absorbed in the lungs, from where it is transported more rapidly to the brain. This improves the 'pharmacokinetics' (the speed and peak of the blood nicotine level in the brain, sometimes known as the 'PK') of nicotine delivery. This is essential for this product to compete with nicotine delivery – the PK profile – of cigarettes and it explains why Juul has been a very successful product with a very high rate of conversion from smoking to vaping. The success of teh Juul is based on its nicotine delivery, a range of pleasant flavours, combined in a small form factor with the ease of use of a cartridge-based system.

The strength of the nicotine in the liquid is not a reliable guide to how much the device delivers to the user. The only point at which regulators should become concerned is if the nicotine delivery and PK profile exceed that of cigarettes in actual users, and we should remember that the <u>user controls nicotine exposure</u>, not the device or liquid.

#### **Further reading**

- Hajek P. et al. Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products, Addiction, January 2020 [link]
- Russell C et al. Factors associated with past 30-day abstinence from cigarette smoking in a non-probabilistic sample of 15,456 adult established current smokers in the United States who used JUUL vapor products for three months, Harm Reduction Journal, 2019 [link]

### 5.9 Should there be a special tax on e-cigarettes?

No. In any country with high rates of smoking, most vapers will be using e-cigarettes to cut down or quit smoking – they are doing this on their own initiative and at their own expense to improve their own health. Policymakers should be trying to make this as economically attractive as possible by using taxes to maintain a difference in the cost of vaping and smoking. At this stage, the priority is to reduce smoking as deeply and as rapidly as possible and a tax on e-cigarettes would slow down that progress, protect the cigarette trade, and increase the burdens of disease and premature death.

#### **Further reading**

- New Nicotine Alliance: To tax or not to tax? Response to EU on taxing vaping and other reduced-risk products, 2016 [link]
  - Pesko M, et al. The Effects of Traditional Cigarette and E-Cigarette Taxes on Adult Tobacco Product Use. Cambridge, MA; 2019 Jun. [link]
  - Cotti CD, The Effects of E-Cigarette Taxes on E-Cigarette Prices and Tobacco Product Sales: Evidence from Retail Panel Data; NBER, January 2020 [link]
  - Chaloupka FJ, et al. Differential Taxes for Differential Risks-Toward Reduced Harm from Nicotine-Yielding Products. New England Journal of Medicine 2015. [link]

#### 5.10 Does tobacco harm reduction undermine tobacco control?

No, this is an empty myth. In fact, tobacco harm reduction is supportive, not undermining, of conventional tobacco control. For example, if taxes are raised on cigarettes, smokers can respond by quitting, cutting down, paying more (regressive) tax, trading down to a cheaper brand or by accessing the black market. But if there are also low-risk products available to switch to, then this increases the options available to respond to a tax-induced price change. Because switching from smoking to vaping involves giving up less than going from smoking to abstinence, it is likely that this pathway will be relatively attractive to many users. The vaping route may also reduce the numbers making the pro-smoking responses to a cigarette tax increase (carry on smoking and pay the tax, cut down, trade down or go to the black market). The effect of adding switching as an option is to improve positive

behavioural responsiveness to tobacco control measures and avoid some of the harms induced by such measures (e.g. regressive effects of tax). Similar arguments can be made for other pressures on users created by tobacco control policies.

## 6. Vaping in public places – should it be permitted and who should decide?

## **6.1** Do e-cigarette vapours pose the same risks to bystanders and family members as second-hand smoke from cigarettes?

No, far from it. Overall: bystanders are exposed to far lower levels of toxicants and for much less time. Three things are very different and toxic exposure to bystanders depends on all three:

- The quantity emitted. Most of the inhaled vapour is absorbed by the user and only a small fraction is exhaled (15% or less, depending on the constituent). In contrast, about four times as much environmental tobacco smoke comes directly from the burning tip of the cigarette than is exhaled by the smoker. There is no equivalent of this "sidestream smoke" for vaping.
- 2. The toxicity of the emissions. Tobacco smoke contains hundreds of toxic products of combustion that are either not present or present at very low levels in vapour aerosol. Vapour emissions do not have toxicants present at levels that pose a material risk to health. Exposure to nicotine, itself relatively benign, is unlikely to reach a level of pharmacological or clinical relevance.
- 3. The time that the emissions remain in the atmosphere. Environmental tobacco smoke persists for far longer in the environment (about 20-40 minutes per exhalation). The vapour aerosol droplets evaporate in less than a minute and the gas phase disperses in less than 2 minutes.

[With thanks to Roberto Sussman]

Further reading

Avino et al. Second-hand Aerosol From Tobacco and Electronic Cigarettes: Evaluation
of the Smoker Emission Rates and Doses and Lung Cancer Risk of Passive Smokers and
Vapers. 2018 [link] "...excess life cancer risk (ELCR) for second-hand smokers was five
orders of magnitude larger than for second-hand vapers."

## **6.2 Should vaping be banned by law in public places and workplaces?**

No. There is a (contested) case to ban indoor *smoking* as there is science showing that second-hand cigarette smoke exposure is harmful to bystanders. However, e-cigarette vapour is quite different chemically and physically. The evidence suggests vaping creates exposures far below thresholds that would be allowed for occupational health limits, for example. The force of law should be reserved for protecting people from material harm caused by others. Vaping may still be disagreeable to some people, but it is primarily a matter of etiquette and respect for the preferences of others. E-cigarette policy should be decided, therefore, by the owners and managers of premises (hotels, bars, restaurants, shops, transportation, offices, public buildings etc). The hospitality industry may be more open to vaping and to welcome vapers, but public buildings will be most likely to prohibit it. The point is that owners and managers should be able to make the decisions that are right for them and their clientele.

## 7. Marketing – what marketing freedoms or constraints are appropriate?

### 7.1 Are vaping products aggressively marketed to teens?

There is no sign of this in reality. Just because teens take to something does not mean that it was 'aggressively marketed' to them. For example in 2017, one in five (19.8%) of US adolescents were cannabis users, but there has been very little marketing of cannabis to anyone. Nor is it enough to point to marketing that uses childish images, cartoons or brand names. It is a myth that arises from a dual misunderstanding: (1) that adults don't like sweet things or don't have nostalgia for childish things, and (2) that adolescents are somehow trying to reinforce their childish identity when they are more likely doing the opposite. Also, adolescents make very poor customers for vaping companies – the large market of adult smokers is much more lucrative because those users will displace smoking by vaping daily and more intensively, have more disposable income and are likely to remain as customers. Teen users also cause vape companies immense political pain, don't make that much use of the products and most will give up – they just are not worth pursuing with marketing budgets. Controls on content and placement could reinforce the already poor incentives to pursue young customers.

### 7.2 Should advertising for reduced-risk products be banned?

No, absolutely not. This type of advertising actually functions as anti-smoking advertising – promoting a smoking cessation pathway, and at no expense to the taxpayer. It allows the new 'entrant' products to gain the attention of smokers and compete with cigarettes, the dominant 'incumbent'. Advertising and promotion is key to the disruption of the cigarette oligopoly. It works by informing consumers, developing confidence in brands, creating a buzz around an alternative "value proposition" to smoking. To ban the advertising of low-risk alternatives has the effect of protecting the cigarette trade.

#### **Further reading**

- Dave D, Dench D, Grossman M, Kenkel DS, Saffer H. *Does e-cigarette advertising encourage adult smokers to quit?* Journal of Health Economics. 2019. [link]
- Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [link]

## 7.3 How to maximise the benefit to smokers and would-be smokers, while minimising the potential to recruit non-users of nicotine

Controls on access, marketing and information should be used for targeting any particular sub-populations, such as youth.

Rather than ban vape advertising, a good policy would control content (what sort of messages) and placement (where and when the advertiser can advertise). Several jurisdictions control *alcohol* advertising in this way, for example, see UK code on non-broadcast and broadcast advertising of alcohol.

But the question may contain a flawed premise, in my view. It is too narrowly short-term to conceptualise vaping as a smoking cessation option for adult smokers. Why should it somehow be a prerequisite to smoke before vaping? Vaping products will bring on the obsolescence of cigarettes – the 'endgame' as some call it – and with it the epidemic of disease and death caused by *smoking*. The rise of vaping is better understood as an emerging technology transition within the consumer nicotine market, in which nicotine use is decoupled from the driver of disease, smoking.

## 8. Retailing - who should sell and under what conditions?

## 8.1 Where should e-cigarettes and other reduced-risk products be sold and not sold?

Alternatives to cigarettes should be at least as widely available as cigarettes and other combustible tobacco products. It makes no sense to withdraw the much safer nicotine products from certain retail environments while leaving cigarettes in place. Of course, a government cannot force retailers it does not own to stock particular product lines, but it should not use its powers or influence to make cigarettes more available in some environments. In addition, there is a case for making effective alternatives available in settings where there may be an opportunity for behaviour change – for example, in hospital shops.

## 8.2 Should e-cigarettes be available only through pharmacies or on prescription or over-the-counter everywhere?

No. They should be available everywhere cigarettes are – convenience stores, petrol stations, supermarkets – and more besides. The alternatives to smoking need to be just as easy to access as the harmful incumbent product, cigarettes. It is important not to place barriers in the way of easy access: if people cannot access them easily there is less chance they will try and more chance they will fail and relapse back to smoking. Vape shops are especially important as they combined diverse personalised product options with expert advice – offering what amounts to a smoking cessation service. Vaping products are now available in some hospital shops in England – this is to encourage patients, visitors and staff to try a permanent switch from smoking.

### 8.3 Should vaping products be available on-line?

Yes. Particularly in areas of sparse population, specialist vape shops selling diverse products would not be viable (the inventory costs would be too high) and many people also like the convenience and wide choice of online shopping and bargain hunting. Again, this is an area where vaping can and should outcompete smoking. Online sales present barriers to youth access through the requirement to make card payments and stronger systems of age verification are possible in some jurisdictions.

## 9. Tobacco industry - pariahs, predators or player?

## 9.1 Are e-cigarettes a tobacco industry ploy to keep people smoking?

No. Modern e-cigarettes were not invented by the tobacco industry and there are thousands of suppliers who are not part of the tobacco industry. The tobacco industry has realised that its customers want to switch to these products and has entered the market. The industry deserves to be treated with great scepticism and should always be handled with caution. However, it is *positive* that the industry is marketing low-risk alternatives to its core product, the cigarette – there is no reason to want the industry to remain exclusively focussed on selling cigarettes. A long-term transition of the industry from selling combustible products to non-combustible is in the interests of public health and is the most likely and rapid way to end the worldwide epidemic of smoking-related disease.

## 9.2 Should tobacco control authorities collaborate with tobaccorelated industries in pursuit of public health objectives?

Yes, of course – if the companies have something to offer that would benefit health. Imagine a situation where a deal could be done between a government and a tobacco company to include an insert and/or voucher for e-cigarettes in each pack of cigarettes it sells. Suppose they want to run this as area controlled trial to see if this works to reduce smoking and increase switching. What would be the consequences of <u>not</u> collaborating? It could mean health opportunities are lost and more harm is caused. That cannot be justified. The

marketplace is changing radically and I think everyone in public health has a 'duty of curiosity' to find ways to exploit these opportunities to the greatest possible extent, even if that means 'talking to the enemy'. Dogmatic inflexible positions that are oblivious to changes in the real world positions are the enemy of progress and liable to cause more harm than good.

## 9.3 If tobacco companies want to reduce the harm caused by cigarettes, why don't they just stop selling cigarettes?

This is more of an empty campaigning posture than a plausible way to make progress. No public company could do this unilaterally. The management has a legal duty to its shareholders not to destroy the value of their equity (shares). If a management team tried it they would be fired and replaced by the board or shareholders. If somehow they succeeded, the company would be taken over or its profitable assets and brands sold to another company. Somebody would end up selling the cigarettes. There are two other ways in which it could happen: (1) a government-led legal ban on cigarettes or its equivalent (reducing nicotine levels to near-zero). (2) a technology transition, reinforced by risk-proportionate regulation, in which cigarettes become an obsolete niche product. I doubt the first will work and no-one has so far tried it. The second is already underway but obstructed by tobacco control activism. The most pragmatic way to get rid of smoking is to have a much better alternative.

#### **Further reading**

- Clive Bates. Pariahs, predators or players? The tobacco industry and the end of smoking, 2017 [link]
- David Sweanor, Tobacco Companies' best friends, Tobacco Truth (2019) [link]
  - David Sweanor, Big Tobacco's little helpers, 2015 [link]

## 10. Rapid responses to the biggest myths about vaping etc.

Here are some quick-fire responses to common myths. Let me borrow this image from Charles Gardner on Twitter to organise the reactions. He sets out 14 examples of widely propagated myths.



- 1. Don't help smokers quit
- 2. Cause cancer, heart and lung disease
- 3. More addictive than cigarettes
- 4. Aggressively marketed to teens
- 5. Epidemic among teens
- 6. Gateway to teen smoking
- 7. Damage teens' brains
- 8. A plot by Big Tobacco
- 9. Flavors only attract teens
- 10. Adults don't like flavors
- 11. Promoted as safe/safer
- 12. 5 million teens are addicted
- 13. Toxins & "ultra-fine particles"
- 14. Most vapers are dual users

## 10.1 Don't help smokers quit

Evidence from randomised controlled trials, observational studies, population data, and user testimonies converge on showing vaping is an effective approach to smoking cessation.

Studies that claim to show no effect suffer a range of shortcomings and biases, for example by including people who were not trying to quit or fail to recognise that people using ecigarettes may be using them because they are more nicotine dependent (and would have already quit otherwise).

### 10.2 Cause cancer, heart and lung disease

There is no evidence that these products present a material risk of disease at this stage. There are studies that show *effects* of vaping, but these do not show that these effects are sufficient to cause serious disease or to overwhelm the natural defences of the body. Many studies are also confounded by prior smoking, given almost all adult vapers are former smokers. It is, however, possible that there will some risk – this is a harm *reduction* approach, so we are expecting there will be some residual risk.

### 10.3. More addictive than cigarettes

Not so. Cigarettes are capable of delivering more nicotine to the brain more rapidly than almost any e-cigarette, though some e-cigarettes are now drawing level. There are also other psychoactive substances in tobacco smoke, for example, MAOIs, that may increase the reward and reinforcing properties of cigarettes acting in concert with nicotine.

### 10.4 Aggressively marketed to teens

There is no sign of this in reality. Young people take up things for reasons other than marketing – for example, about 1 in 5 American adolescents use cannabis at least once a month, but there is negligible marketing. Teens make terrible customers for vape businesses compared to adult smokers – a ton of political grief, not much consumption (and hence revenue) and most are unlikely to persist for long. It is not enough to point at branding that has a childish theme and then conclude it is targeted at kids – most adolescents are not trying to reinforce a childish image and many adults like youthful nostalgia.

## 10.5 Epidemic amongst teens

No, the rise in teen vaping in the United States does not meet the definition of an epidemic. More importantly, drilling down into the headline numbers we find most teen users are making relatively trivial experimental use – a few days each month ('party users'). Among the regular teen vapers, almost all were prior tobacco users, mostly smokers. For them, teen vaping may be a good thing – a diversion from smoking. Also, there is little sign of dependence in users who were not prior tobacco users. The data is also complicated by the switch to vaping among cannabis users – the surveys do not handle this clearly.

## 10.6 Gateway to smoking

No credible evidence for this. It is true, however, that teen vapers are more likely to smoke, and this has become an anti-vaping activist talking point. However, those moving from vaping to smoking may have gone on to smoke in the absence of vaping. The most likely cause of this relationship is that whatever inclines people to vape also inclines them to smoke – factors such as genetics, liking nicotine, parental background, home environment, mental health status etc. This is the rival 'common liability' theory to the 'gateway effect'. Scientists who claim they can isolate a gateway effect from common liability do not really understand the problem of confounding.

## 10.7 Damage to teen brains

No. We would have seen in this in multiple generations of smokers who were exposed to high doses of nicotine as adolescent smokers. The evidence cited to claim nicotine damages teen brains is based on a few rodent studies.

## 10.8. A plot by Big Tobacco

Vaping is a *threat* to the highly lucrative dominance of the cigarette oligopoly and it was developed outside the tobacco industry. Tobacco companies are all competing vigorously with each other to attract consumers who are keen to switch from long-established cigarette brands. They are driven to develop (or acquire) the best products they can or risk losing customers to competitors. It is generally a good thing that tobacco companies diversify away from only selling the most harmful products. The main risk comes from regulators severely limiting the customer appeal of e-cigarettes and, in doing so, protect the cigarette trade from competition.

### 10.9 Flavours only attract teens

It is a meaningless assertion. Flavours are integral to vaping in the same way toppings are integral to pizza – so remove all the flavours and vaping become less appealing to everyone. The majority of adults prefer flavours and many are trying to get away from tobacco flavour. Anti-vaping activists used to highlight 'kiddie appealing' flavours like Gummy Bear and Cotton Candy. However, when Juul took off they started to define any flavour that isn't tobacco as appealing to kids – Juul comes in flavours like creme, mango, cucumber, mint, menthol.

### 10.11 Promoted as safe/safer

They should not be promoted as 'safe' – very little of anything can meet a literal interpretation of the word 'safe'. However, they are not just *promoted* as safer, e-cigarettes are much safer beyond any reasonable doubt. This is because vaping products do not involve combustion and the chemistry of vapour aerosol is much simpler and more predictable than the smoke from burning tobacco in cigarettes. Comparisons of vapour and smoke toxicity suggest nicotine vaping is likely to be at least 95% lower risk than cigarette smoking.

#### 10.12 Five million teens addicted

No this is a baseless US activist talking point. It conflates <u>product use</u>, no matter how occasional or irregular with 'addiction'. There is very little sign of dependence among adolescent vapers who were not already using other tobacco products. Addiction is a pejorative and emotive word, but it usually implies some sort of harm is caused to the addicted user and that they continue despite the harm. Vaping is not obviously causing its users any harm and many users report that they really enjoy it and are happy vaping.

## 10.13 Toxicants and ultrafine particles

Everyone should remember the maxim of Paracelsus, the original toxicologist: "the dose makes the poison". Far too many studies are able to *detect* toxicants at some very low level (this is a function of the detection equipment). But the risk depends not only on the presence of a hazardous agent but on the user's exposure to it. Yes, there are some 'ultrafine particles' in vape aerosol, but these are chemically and physically completely different to the fine particles produced by combustion like cigarette smoke, diesel engines, power stations etc.

## 10.14 Most vapers are dual users

Dual-use means using both e-cigarettes and cigarettes. It includes very different behaviours, vaping most of the time but having an occasional cigarette and smoking all the time and vaping when that is not possible. In the UK, most vapers are not dual users and the proportion of dual users has been falling. In the US, the proportion of dual users has also been falling and has almost reached 50% in 2019. Dual-use is often a sign of a user on a journey from smoking to vaping and can be an encouraging sign. One of the reasons for dual-use is that smokers have been misled about the benefits of vaping compared to smoking. Ultimately what makes the difference is overall efficacy in switching smokers from cigarettes to vaping – and e-cigarettes score highly on that: if NRT is half as effective, it leaves more people smoking.

#### Further reading and viewing

- Clive Bates. Vaping risk compared to smoking: challenging a false and dangerous claim by Professor Stanton Glantz, August 2019 [link]
  - Clive Bates. Ten perverse intellectual contortions: a guide to the sophistry of antivaping activists [link]

#### Postscript. Vaping: what people are getting wrong, The Economist

Vaping: what people are getting wrong, a great primer from The Economist (13 mins)