Current Controversies No. 54

VAPING SOLUTIONS

An easy Brexit win

By Christopher Snowdon

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The first two chapters of this Current Controversies Paper contain some revised sections from the 2013 Discussion Paper Free Market Solutions in Health.

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Snowdon is the editor of the Nanny State Index and the author of five books: '*Killjoys*' (2017), '*Selfishness, Greed and Capitalism*' (2015), '*The Art of Suppression*' (2011), '*The Spirit Level Delusion*' (2010) and '*Velvet Glove, Iron Fist*' (2009). He has also written more than a dozen reports for the Institute of Economic Affairs including '*Drinking, Fast and Slow*', '*The Proof of the Pudding: Denmark's Fat Tax Fiasco*', '*Cheap as Chips*', '*Sock Puppets*' and '*Closing Time: Who's killing the British pub?*'.

Executive Summary

- The UK and Sweden have the lowest smoking rates in the European Union as a result of consumers switching from cigarettes to low risk nicotine products: specifically, e-cigarettes and snus, respectively.

- Public Health England and other health organisations have concluded that the health risks of vaping are unlikely to exceed five per cent of the risks of smoking. Early fears about e-cigarettes acting as a ‘gateway’ to smoking appear to be unfounded.

- The British experience with e-cigarettes is an example of the free market finding solutions to health risks. Vaping products have reduced the costs associated with nicotine use (i.e. health risks) while maintaining most or all of the benefits (i.e. pleasure). They emerged spontaneously without the initial support of governments and ‘public health’ campaigners.

- Recent EU regulation of vaping has led to higher prices, more waste, smaller narrower product ranges, less innovation and heavy restrictions on how they can be promoted, even by government agencies. There is no evidence that these regulations have led to any positive outcomes. On the contrary, they have reduced the appeal of e-cigarettes to existing smokers and raised the costs for existing vapers.

- Snus, meanwhile, is banned by the EU in every member state except Sweden despite its well documented role in reducing smoking prevalence in Scandinavia.

- A third of smokers in the UK have still not tried vaping and many of those who have tried it continue to smoke. Further innovation in the industry could encourage more smokers to switch, but progress is hampered by EU regulation.

- Brexit offers an opportunity to return to a more liberal regulatory regime to the benefit of consumers and British businesses. Repealing the regulations that have been stipulated by EU's Tobacco Products Directives (TPD) is a relatively simple process and would not require primary legislation.

- After Brexit, the UK should regulate e-cigarettes, snus and other reduced-risk nicotine products in a way that does nothing to discourage smokers from switching to them.

1. The search for a safer cigarette - a brief history

The health hazards of cigarette smoking are so well known that they require no preface here. Those risks have been almost universally acknowledged for decades, and yet more than one in five adults smoke in most developed countries. We are unlikely to see mass abstinence in the short or medium term, and supply-side policies designed to reduce smoking rates, such as high taxes, have the unwelcome side effects of fuelling the black market and creating secondary poverty. By contrast, safer nicotine products, such as e-cigarettes, provide hardened smokers with a pleasurable, low-risk alternative to smoking without any significant externalities.

Historically, efforts to reduce the hazards of smoking have been led by the tobacco industry and mostly involved modifying conventional cigarettes. Formal acceptance of the link between smoking and lung cancer by the Royal College of Physicians and the US Surgeon General in the early 1960s made the search for a safer cigarette more urgent and, until around 1980, governments worked alongside industry in this quest. The US National Cancer Institute set up the Tobacco Working Group in 1968 and spent $6 million a year in the search for a safer cigarette (Fairchild and Colgrove 2004). In Britain, the government formed the Independent Scientific Committee on Smoking and Health in 1973 to oversee efforts to reconstitute cigarettes in a less damaging form.

Industry and public health scientists initially believed that it would be possible to identify and remove carcinogenic compounds from cigarettes, but these hopes faded as they began to grasp the enormity of the challenge (Berridge 2007: 92-93). Neutering the harms of smoking requires much more than isolating and expelling one chemical culprit. Burnt tobacco contains too many carcinogens for all to be removed and even if that were possible, carbon monoxide would remain.

One promising avenue was reducing tar yields. Cigarettes typically have ten times as much tar as they do nicotine (e.g. 10mg tar and 1mg nicotine) but since the ratio is fixed, there is a limit on how far tar yields can be reduced without making cigarettes unsatisfying to consumers. In the USA, Dr Gio Gori led an industry-government collaboration to reduce tar yields to the point at which cigarettes would pose a 'tolerable risk', as he put it (Kluger 1996: 448-449). Assuming a linear relationship between tar yields and disease, Gori made some rather simplistic calculations and concluded that 'it is reasonable to expect that the current epidemic proportions of smoking-related diseases could be reduced to minimal levels in slightly over a decade' if smokers shifted en masse to very low tar ('ultra-light') cigarettes (Gori 1976). This was naïve. Smokers increasingly switched to low-tar brands in the 1970s but they tended to compensate for the reduced nicotine by inhaling more deeply and smoking more cigarettes.

Although ultimately fruitless, the billions of dollars spend on research into safer cigarettes in the twentieth century left a few tantalising 'what ifs?' Liggett & Myers developed a new cigarette in the 1970s by adding the rare metallic element palladium to tobacco. Skin painting experiments on mice suggested that the new brand, set to be called Epic, led to 95-100 per cent fewer tumours than ordinary cigarettes. But internal pressure from the rest of the industry (which had not yet publicly accepted that smoking caused cancer), as well as external pressure from the tobacco control movement, led to the company withholding Epic from the market. It was hindered by the same obstacles that would hold back every attempt to reduce the harms of cigarette smoking in the twentieth century: advertising bans which prevented companies from informing the public about putative health benefits, opposition from anti-smoking campaigners who feared that safer products would deter smokers from quitting, and the industry's own reluctance to implicate conventional cigarettes as unsafe for fear of accepting liability. As one Liggett and Myers' executive later said, Epic 'would have been attacked from all sides - the government, health authorities, antismoking groups, and especially our competitors' (Kluger 1996: 461).

The most concerted British initiative of the 1970s was the development of 'tobacco substitutes'. Almost entirely forgotten today, the idea was to replace some of the tobacco in cigarettes with less toxic cellulose. The government, like the tobacco industry, had a financial motive for developing a less hazardous cigarette on British shores. A successful product, if

exported, ‘had the potential of saving foreign currency and ... improving the balance of payments’ (Berridge 2007: 143). The industry invested tens of millions of pounds in tobacco substitutes and the resulting products were cleared for sale in April 1977 after the Independent Scientific Committee on Smoking and Health concluded that ‘there is no doubt that they are a contribution to safety’ (Van Rossum 1978: 3). Three months later, on a date picked by the government, eleven new cigarette brands containing up to 50 per cent tobacco substitutes were put on the market. They were a commercial disaster. A year after being launched, their combined sales made up less than one per cent of the market. The most successful of them, Peer, was finally taken off the shelves in 1984.

Part of the reason for this expensive failure was that smokers were given little reason to switch to the new brands. Advertising restrictions prevented manufacturers from claiming that one cigarette was less hazardous than another and the government decided to levy the same rate of tax on both traditional and modified products. The industry had expected ‘some form of qualified public support’ from the government for the new cigarettes but instead found itself on the end of a ‘campaign of vilification’ (Van Rossum 1978: 3-4). Action on Smoking and Health and the Health Education Council opposed the ‘safer smoking’ initiative, with the latter declaring that shifting from traditional to modified cigarettes was akin to jumping out of the thirty-sixth rather than the thirty-ninth floor of a building. Roland Moyle, the Minister for Health, told the public that ‘cigarettes with or without substitutes can be debilitating and ultimately lethal’ and reaffirmed his commitment to ‘the ultimate objective of a smoke-free society’ (ibid.: 4).

These sudden denunciations stood in contrast to more encouraging noises from the Ministry of Health and the Royal College of Physicians a few years earlier but, by 1977, attitudes were beginning to harden and total abstinence was increasingly seen as the only option in tobacco control. As Berridge (2007: 155) notes of the tobacco substitutes debacle, ‘product modification and “safer” smoking had fallen foul of a major shift in health policy’.

Gio Gori’s work on low-yield cigarettes fell victim to the same attitudinal sea-change in the USA, although the ambitious scientist’s hubris also played a part. In 1978, Gori published an article in the Journal of the American Medical Association in which he asserted that cigarettes were virtually

harmless below a certain tar level and went on to name existing brands which could be smoked in large quantities 'without exceeding tolerable levels' (Gori and Lynch 1978). Sales of the supposedly least hazardous brand soared by 50 per cent after the paper was published and Gori's naïve assumptions drew a hail of criticism from health authorities who feared that Americans were given being carte blanche to carry on smoking (Kluger 1996: 452). The government's interest in developing safer smoking alternatives subsided thereafter.

Heat not burn

From the 1980s, the tobacco industry's efforts at harm reduction focused on non-cigarette products which heated the tobacco as opposed to using combustion, thereby reducing the emission of dangerous toxicants. The American tobacco giant R.J. Reynolds spent hundreds of millions of dollars on its near-smokeless Premier brand and launched it in a few US states in 1988, but smokers were indifferent. With a carbon rod which heated the tobacco to make it smoulder rather than burn, Premier was almost certainly less hazardous to health, but it had so little in common with conventional cigarettes that it required its own instruction manual. Those who tried it in the test markets of St Louis and Phoenix found it unsatisfying, perplexing and smelly. It was swiftly abandoned.

Philip Morris made similar efforts with brands called Next, Accord and Heatbar but they were similarly unsuccessful. When R.J. Reynolds relaunched a heavily modified version of Premier in 1996 under the name Eclipse, even ardent opponents of the tobacco industry, such as Senator Henry A. Waxman, accepted it was 'safer, relatively speaking. That is impressive and could be a big advantage' (Hilts 1994). But all the major US health organisations – bar the Institute of Medicine – rejected it without trial and the American Cancer Society fought for it to be taken off the market, claiming that it 'may be more lethal than other low-tar cigarettes'. The product is still available in the USA, albeit with a negligible customer base.

Pharmaceutical nicotine

By the end of the century, despite the acquisition of hundreds of patents, a commercially viable reduced harm cigarette still eluded the tobacco industry. The only safer nicotine products that had gained the support of anti-smoking campaigners and regulators were pharmaceutical products such as patches and gums. Licensed as a medical product, Nicotine Replacement Therapy (NRT) differs from other alternative nicotine products in that it is marketed as a means of not only giving up smoking but, ultimately, of giving up nicotine. In practice, however, NRT has a very modest track record of helping smokers do either. A 2012 systematic review found that NRT increases the chances of quitting by 50-70 per cent, but with 95 per cent of unaided quit attempts ending in failure, this means that smokers who use the most effective forms of NRT have a less than ten per cent chance of being a nonsmoker after six months (Stead et al. 2012). There are serious questions about NRT's ability to bring about long-term abstinence. Many studies have found relapse rates to be no different between people who take NRT and those who quit 'cold turkey' (e.g. Alberg et al. 2005; Alpert et al. 2013; Carpenter et al. 2011). NRT seems to be particularly ineffective when not accompanied by counselling (Kotz et al. 2014; Pierce and Gilpin 2002).

Although some smokers find NRT helpful, its widespread use over three decades has not had a measurable impact on smoking rates. A study in the Annual Review of Public Health found no correlation between NRT use and smoking cessation rates and concluded that 'there is no evidence that such policies [i.e. recommending that pharmaceutical aids be used in all quit attempts] lead to an increase in successful cessation in the population... That successful smoking cessation has not increased ... despite the increased efforts focused on it suggests that there is an urgent need to revisit current tobacco control policy' (Pierce et al. 2012).

2. The new wave of smoking alternatives

Just when it seemed that efforts by cigarette companies and pharmaceutical firms to produce popular alternatives to smoking had failed, two products appeared from unexpected quarters to revive interest in the field of tobacco harm reduction.

Snus

Snus (rhymes with 'moose') was used in Sweden for more than two hundred years before it fell out of favour in the cigarette age of the mid-twentieth century. It consists of finely cut, moist tobacco in a teabag-like pouch which is placed under the top lip to allow nicotine to absorb through the gum. By the end of the 1960s, it was associated with old men and appeared to be moribund as a consumer product. But growing acceptance of the dangers of cigarette smoking led to a dramatic revival in its fortunes. Between 1970 and 2000, per capita snus consumption more the doubled while per capita cigarette consumption nearly halved (Foulds et al. 2003).

This unprompted mass switchover had a dramatic impact on rates of smoking and smoking-related disease. In 1976, Sweden's male smoking rate was an unexceptional 40 per cent. By the end of the century, it was the lowest in Europe. In 2000, a third of male ex-smokers had used snus as a cessation aid and Sweden was almost unique in having a smoking rate that was higher for women than for men (snus has traditionally been used mainly by men).

Today, only seven per cent of Swedes are smokers, much lower than the EU average of 26 per cent (Eurobarometer 2017: 8), and 41 per cent of Swedes are ex-smokers, against an EU average of 20 per cent (ibid.: 11). Moreover, while more than 80 per cent of smokers in other EU countries smoke every day, this is only true of 52 per cent of Swedish smokers (ibid.: 22). Despite being a massive outlier in the smoking statistics Sweden still

consumes plenty of tobacco. It has more than three times as many snus users as it does smokers (23 per cent of adults are users of smokeless tobacco).

At one time, snus was assumed to increase the risk of oral cancer, but the weight of epidemiological evidence shows no such association (Rosenquist et al. 2005). In 2001, the EU took the unprecedented step of removing the cancer warning from a tobacco product when it changed its regulations for Swedish snus products (European Commission 1999: 43-51). More recently, it has been claimed that snus increases the risk of pancreatic cancer and heart attacks, but rigorous epidemiological research has again failed to support this (Bertuccio et al. 2011; Hansson 2012). Sweden has the lowest rate of pancreatic cancer in the EU and it has one of the lowest rates of oral cancer. It also has the lowest rate of lung cancer (IARC 2012).

Empirical evidence from Sweden and Norway strongly suggests that switching to snus is an effective cessation technique for a significant number of smokers (Gilljam and Galanti 2003). A study of Norwegians found that 48 per cent of smokers who used snus to quit remained abstinent, compared to only 26 per cent of those who used NRT (Scheffels et al. 2012). A small but growing evidence base from countries which have no tradition of using snus also shows that it is an acceptable substitute for many smokers (Joksić et al. 2011).

E-cigarettes

Writing in 2001, the epidemiologist John Britton suggested that it was "necessary to develop nicotine delivery products that can provide the nicotine that the addict wants, and with the speed of delivery achieved by the cigarette, but without the harmful products of tobacco combustion" (Britton et al. 2001: 15). Unbeknownst to him, the Beijing pharmacist Hon Lik was in the process of inventing just such a product. The electronic cigarette, which he patented in 2003, uses a battery and atomiser to vaporise a liquid combination of nicotine, water, propylene glycol and vegetable glycerin is absorbed into the bloodstream via the lungs. Much of its potential as a harm reduction product stems from the way it closely mimics the smoking experience, including the "throat hit" and the rapid nicotine absorption. The vapour contains no burnt matter, no tar, and no carbon monoxide.

The e-cigarette is the kind of product the tobacco industry contemplated for many decades but never brought to market. The idea can be traced back

to 1927 when Joseph Robinson applied for a US patent for his “electric vaporizer” designed to “produce vapors for inhalation” (his prototype is shown as Figure 1 on the opposite page). British American Tobacco (BAT) experimented with vaping-style devices as early as 1960 but despite numerous prototypes and several patents, all their efforts were stillborn, including a non-combustible device called Favor which was found to be “extremely irritating” on the throat and was never brought to market (Proctor 2003: 90).

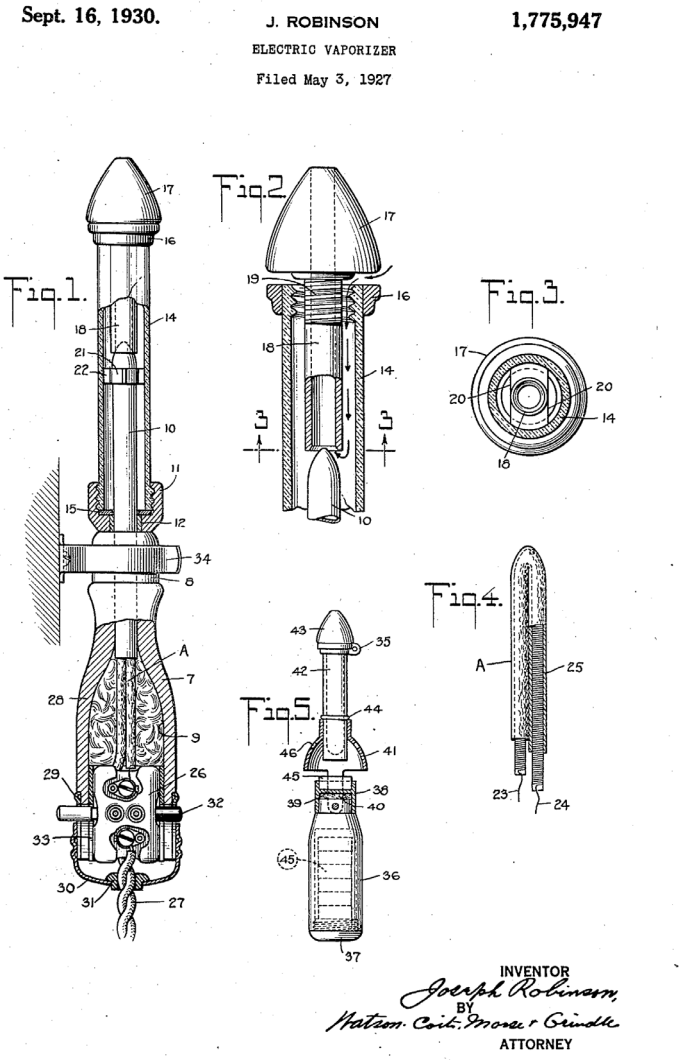

Figure 1: American prototype of a ‘vaporizer’ from 1927.

In the first decade of the millennium, the first generation of commercially available e-cigarettes were manufactured in China and sold by independent companies in the UK and elsewhere, largely on the back of word-of-mouth recommendations. These products typically looked like larger versions of conventional cigarettes and had a limited range of flavours. The market began to grow more rapidly once second generation e-cigarettes with a refillable tank and variable wattage became mainstream from around 2012. These devices allowed consumers to choose the flavour of their vape juice and the amount of nicotine it contained. Regulated under normal consumer protection laws with few restrictions on advertising, an innovative and highly competitive market emerged to provide smokers with a low-cost, bespoke alternative.

By 2016, England had two million ex-smoking vapers who had given up smoking and a further 470,000 vapers who were using e-cigarettes as an aid to quitting (Department of Health 2017: 15). These figures were remarkably high in a country that had begun the vaping era with nine million smokers, but Britain has taken to e-cigarettes more enthusiastically than anywhere else. Five per cent of British adults are current users of e-cigarettes – significantly higher than the EU average of two per cent – and vaping prevalence among ex-smokers is exceptionally high at 14 per cent (the EU average is four per cent - see Figure 2) (Eurobarometer 2017: 107).

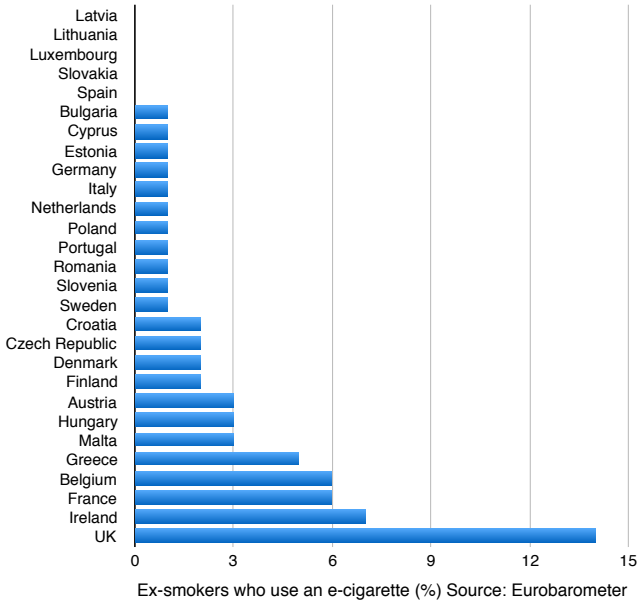

Figure 2: E-cigarette use by ex-smokers

Although e-cigarettes cannot be marketed as smoking cessation devices, academic research confirms that they are being used as such. A recent study found that e-cigarette users in the USA are 73 per cent more likely to succeed in giving up smoking than would-be quitters who do not vape (Zhu et al. 2017). Even with the cruder first generation products, randomised controlled trials found that smokers were twice as likely to quit if they vaped than if they were given a placebo (Bullen et al. 2013; Caponnetto et al. 2013a). A study of vape shop customers found that 41 per cent had quit smoking within a year of taking up e-cigarettes (Polosa et al. 2015) and a clinical trial using second generation e-cigarettes saw 53 per cent of subjects quit smoking (Pacifici et al. 2015). Perhaps most impressively, vaping leads to cessation even among smokers who had no intention of quitting at the outset (Polosa et al. 2011; Caponnetto et al. 2013b).

As for their safety, a study in the Journal of Public Health Policy reported in 2010 that e-cigarettes are “comparable in toxicity to conventional nicotine replacement products”. Harmful tobacco-specific nitrosamines were detected at 0.07-0.02 per cent of the level found in conventional cigarettes (Cahn and Siegel 2010: 18). “Thus far”, write Cahn and Siegel, “none of the more than 10,000 chemicals present in tobacco smoke, including over 40 known carcinogens, has been shown to be present in the cartridges or vapour of electronic cigarettes in anything greater than trace quantities” (ibid: 26). A 2013 study in Tobacco Control found that “levels of toxicants [in e-cigarettes] were 9-450 times lower than in cigarette smoke” (Goniewicz et al. 2013).

In 2015, Public Health England declared that e-cigarettes were “around 95% safer than smoking”. The following year, the Royal College of Physicians (2016: 84) concluded - somewhat more accurately - that the health risks of vaping “are unlikely to exceed 5% of those associated with smoked tobacco”. The five per cent reflects uncertainty rather than any specific risks that have been identified. The long-term effects are, inevitably, unknown but the main ingredients of e-cigarettes are not thought to be harmful and there is no evidence that current vapers have damaged their health by using e-cigarettes (Caponetto et al. 2013b). Moreover, smokers who switch to vaping tend to avoid the side effects that are often associated with smoking cessation, such as weight gain and depression (Caponetto et al. 2013a).

Heat not burn returns

Once e-cigarettes became mainstream consumer products, tobacco companies revived their interest in harm reduction. In 2012, the US tobacco company Lorillard bought Blu Ecigs for $135 million, the first in a series of takeovers of vaping companies by established tobacco corporations. Blu was later sold to Imperial Tobacco and by 2014 every major tobacco company had entered the e-cigarette market with brands such as Vuse (Reynolds), Vype (BAT), MarkTen (PMI) and Logic (JTI).

The involvement of these firms in the emerging vaping market drew the attention of some hardline anti-smoking activists who portrayed e-cigarettes as “new weapons of the tobacco industry” (Neuberger 2015). In truth, tobacco companies had watched from the sidelines until e-cigarettes had demonstrated their popularity and their investments in the vaping market were relatively modest. But their deep pockets allowed them to develop new nicotine products that were neither cigarettes nor e-cigarettes.

In April 2011, British American Tobacco created a standalone company called Nicoventures which developed Voke, a medically licensed nicotine inhaler which contained no tobacco or electronics. In 2014, JTI launched a tobacco-vaping hybrid called Ploom, which gave smokers a more familiar taste by filtering the vapour through a tobacco capsule. In the same year, PMI launched IQOS in Japan and Italy. Based on the same principle as the earlier Eclipse and Premier systems, IQOS heats the tobacco rather than burning it and the company claims that this reduces levels of harmful chemicals by 90-95 per cent. It has since been launched in twenty countries, including the UK. As of May 2017, IQOS had ten per cent of the Japanese tobacco market, a strikingly large share for a new and unfamiliar product (Uranaka and Shimizu 2017) and an indication that the new breed of heat-not-burn products have overcome the problems associated with their predecessors.

3. Arguments against safer products

When e-cigarettes first became popular in Britain, medical opinion was divided. Few denied that they were much less hazardous to health than combustible cigarettes, but there were fears that they could lead to more smoking via two mechanisms. First, it was argued that there could be a “gateway effect” in which consumers who were not inclined to smoke would be introduced to nicotine through vaping and then proceed to start smoking. Second, it was suggested that smokers who would otherwise quit smoking would become “dual users” of both electronic and combustible cigarettes. Exactly the same objections were raised against snus in the 1980s and 1990s to justify its prohibition by the EU (see below).

It should first be said that nonsmokers do not seem to be particularly attracted to e-cigarettes. In the EU, fewer than 0.5 per cent of those who have never smoked use e-cigarettes and 96 per cent of lifelong nonsmokers have never had so much as one puff on them (Eurobarometer 2017: 105). In Britain, where vaping is more popular, the most recent data show that among 11-16 year olds who have never smoked, between four and ten per cent have tried using e-cigarettes at some time but only 0.1 to 0.5 per cent are regular users. Bauld et al. (2017) conclude that “most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low”. Moreover, they find “no evidence of e-cigarettes driving smoking prevalence upwards”.

Opponents of vaping cite a number of studies from the USA which appear to support the gateway hypothesis. These studies typically track the behaviour of young people over a period of a year or two to see how many vapers become smokers. Based on a review of nine studies (some of which are no more than unpublished conference abstracts) Soneji et al. (2017) reported that e-cigarette users are three or four times more likely to become smokers than people who had never tried vaping.

Does this mean that vaping makes people more likely to start smoking? These studies cannot answer that question because they have no counterfactual with which to compare their observations. We do not know whether the teenagers who started smoking after experimenting with vaping would have started smoking if they had never vaped. Teenagers experiment with all sorts of things, and the backgrounds and attitudes of teenagers who are tempted to trying vaping make them more likely to engage in other illicit or risky pursuits. Nicotine use is statistically correlated with riding motorcycles, drinking alcohol and being murdered, but it is extremely unlikely that nicotine causes any of these. The only hypothesis that is really supported by the gateway studies is that "teens who are inclined to experiment with products disapproved by adult leadership are more likely to use both e-cigarettes and cigarettes than kids not prone to such experimentation" (Nitzkin 2017).

The gateway theory seems to have been borrowed from war on drugs rhetoric that was used to oppose marijuana legalisation. Prohibitionists have often cited statistics showing that users of heroin have previously been cannabis smokers and imply that this association is causal. They resort to the gateway argument because the harms associated with cannabis are arguably not sufficient to justify prohibition on its own terms and so a link with more dangerous drugs needs to be found (Phillips 2015: 5440). The gateway theory has fallen into disrepute in the drugs debate because the gateway "effect" can be plausibly explained by the fact that "people who are more vulnerable to drug-taking are simply more likely to start with readily available substances such as marijuana, tobacco, or alcohol" (National Institute on Drug Abuse 2017). Indeed, one of the studies in the Soneji review found that e-cigarette users were not only more likely to smoke cigarettes but were more likely to smoke marijuana (Unger et al. 2016). It would not be surprising to find that they are also more likely to drink alcohol and have unprotected sex, but it would be a stretch to claim that these risky activities are somehow caused by their earlier experiments with vaping.

Just as we cannot be sure whether a smoker who vapes would have smoked in the absence of e-cigarettes, we do not know how many non-smoking vapers would have been smokers in the absence of e-cigarettes. Vaping could make people more likely to smoke, or less likely to smoke, or make no difference at all. As Etter (2017) notes, scientific experiments

that would test the theory properly are impossible for practical and ethical reasons. But we do have highly suggestive data from natural experiments involving whole populations. If vaping increased the likelihood of young people smoking tobacco three or four-fold, we would expect to see this reflected in the smoking rate.

Has there been a spike in underage smoking since vaping became popular? Far from it. Figure 3 shows current use of cigarettes and e-cigarettes by high school students in the USA.[1] Smoking prevalence was falling steadily between 2004 and 2011 but fell sharply after e-cigarettes became popular between 2012 and 2016. (The dotted line in Figure 3 shows what the smoking rate would have been if the secular decline seen between 2004 and 2011 had continued at the same rate until 2016.) It is notable that there was an unusually large decline in cigarette use in 2013 which coincided with a very sharp rise in e-cigarette use. These data are clearly more consistent with the hypothesis that vaping is a substitute for smoking rather than a gateway to smoking.

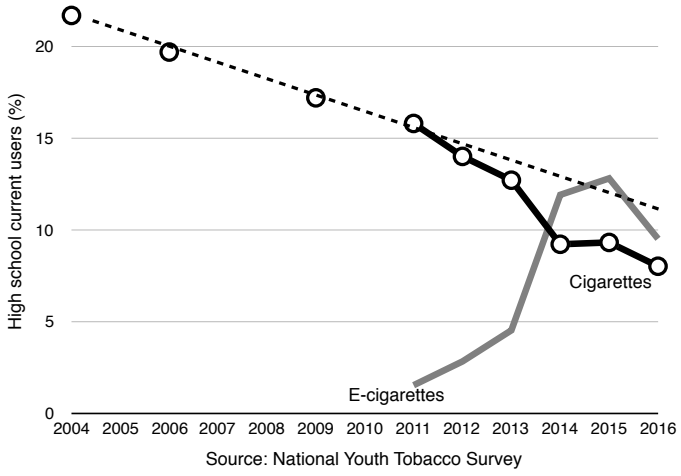

Figure 3: High school use of e-cigarettes and combustible cigarettes (USA)

Adult smoking rates tell a similar story. Between 2013 and 2015, smoking prevalence in the US fell at its fastest rate for many years, dropping from 18 per cent to 15 per cent. In the UK, the adult smoking rate barely moved

1 Current use is defined in the survey as use in the past 30 days.

after the smoking ban was introduced in 2007, but once e-cigarettes became mainstream consumer products it went onto sharp decline, falling from 20.4 per cent in 2012 to just 15.8 per cent per cent in 2016 (see Figure 4).

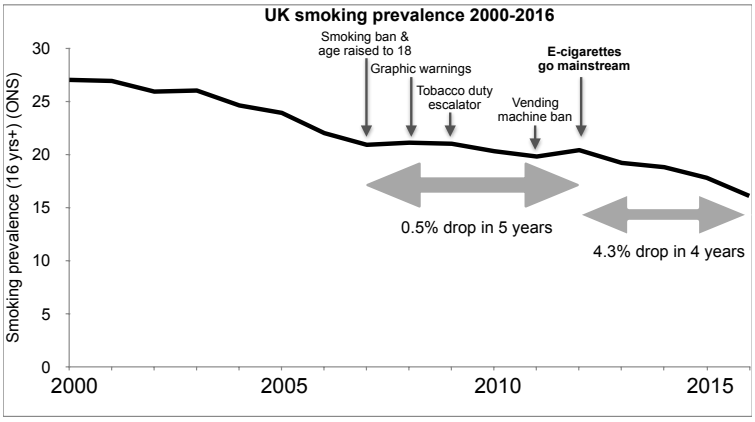

Figure 4: Smoking prevalence 2000-2016 (UK)

None of this is absolute proof that e-cigarettes help large numbers of smokers to quit. Nor does it necessarily show that e-cigarettes are being used by young people who would have otherwise become smokers. But it is certainly inconsistent with the notion that vaping is a gateway to smoking. If never-smoking vapers were really three or four times more likely to take up smoking, we should have seen a rise in the number of smokers by now, particularly among the young. At the very least, we should have seen a deceleration in the rate of decline. Instead we have seen a more rapid decline in smoking prevalence among both the young and the old.

The belief that “dual use” keeps people smoking is also undermined by these figures. There has clearly been no slowdown in the rate of quitting. On the contrary, the evidence suggests that vaping leads to smoking cessation even among those who do not initially intend to quit. It makes more sense to see dual users as smokers who have taken the first step towards quitting. A 2014 study found that 22 per cent of dual users quit smoking within one month and 46 per cent quit within one year (Etter and Bullen 2014).

None of this will come as any surprise to those who are familiar with the Swedish experience with snus. Despite high levels of snus consumption, fears about dual use and the gateway effect have been shown to be baseless (Timberlake et al. 2009; Rodu and Cole 2010). Fifty per cent of Swedes have tried smokeless tobacco but only seven per cent of Swedes smoke (Eurobarometer 2017: T28, 8). Sweden's exceptionally low rate of smoking is more consistent with snus being a gateway to quitting (and an alternative to starting) than as a gateway to smoking (Foulds et al. 2003).

Ultimately, the proof of the pudding is in the eating. It is a striking fact that the two EU countries that have unwittingly hosted natural experiments in tobacco harm reduction - Sweden and the UK - have the lowest smoking rates (see Figure 5) (Eurobarometer 2017: 8).

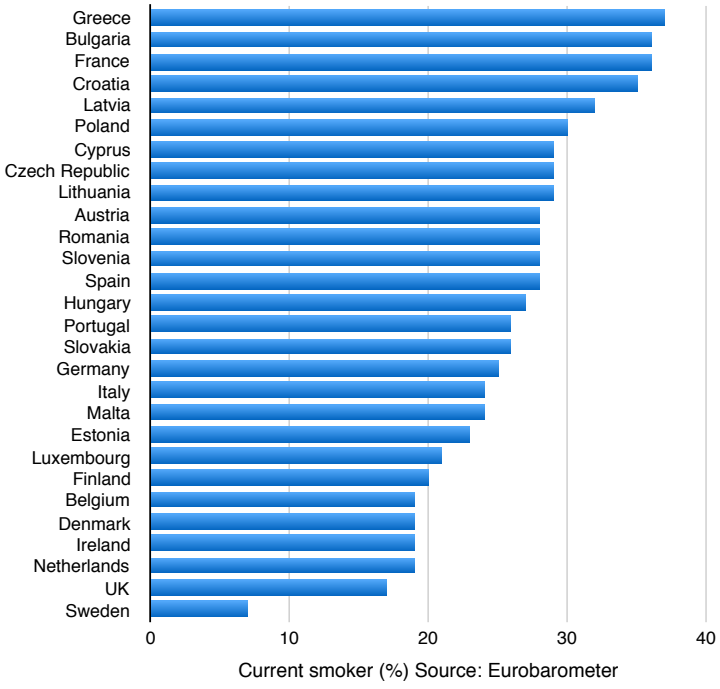

Figure 5: Smoking prevalence in EU member states (2016)

After switching to snus over several decades, Sweden is in a league of its own when it comes to abstinence from cigarettes, with a smoking rate that is barely a quarter of the EU average. This cannot be attributed to Scandinavian culture, since smoking is far more common in neighbouring Finland and Denmark.[2] Nor can it be attributed to anti-smoking legislation; Sweden is ranked in the middle of the league table for tobacco control policies (Joossens and Raw 2017). Snus is the only thing that sets Sweden apart and its role in lowering the smoking rate is now widely acknowledged, including by Public Health England (Selbie 2017).

Britain's natural experiment with vaping is more recent but its effect has also been dramatic. E-cigarette use among ex-smokers is at 14 per cent in the UK, far above the EU average (see Figure 2 above) and only Sweden has a lower smoking rate. This has not always been the case. In 2009, eleven EU countries had lower smoking rates than the UK (Eurobarometer 2010: 9) and as late as 2012, nine EU countries had lower rates (Eurobarometer 2012: 7). The fall in smoking prevalence did not coincide with the slew of anti-smoking legislation from 2007 but with the emergence of e-cigarettes as mainstream products from 2012 (see Figure 4 above).

The British experience with e-cigarettes and the Swedish experience with snus are examples of the free market finding solutions to health risks. These products have reduced the costs associated with nicotine use (i.e. the health risks) while maintaining most of the benefits (i.e. pleasure) and consumers have naturally drifted towards them. They emerged spontaneously and unexpectedly without the support of governments and "public health" campaigners. On the contrary, the anti-smoking lobby has opposed these innovations to varying degrees and, as a result, they have suffered from over-regulation. Snus is banned throughout the EU, except in Sweden, and the e-cigarette market has recently been stifled by the EU's Tobacco Products Directive on the explicit assumption that e-cigarettes "can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption" (European Union 127/7). This legislation is unlikely to be reviewed by the European Commission in the near future, but Brexit offers a chance for the UK to create a more sensible regulatory regime.

2 Norway's smoking prevalence is closer to Sweden's, at 12 per cent (down from 24 per cent in 2006). Snus has become widely used in Norway, with 10 per cent of adults being daily users. One in three Norwegian smokers use snus to quit smoking: https://www.ssb.no/en/royk

4. UK policy after Brexit

The UK shoulders much of the blame for the EU's ban on snus. The British government banned the sale of snus in 1989 after anti-smoking activists led a campaign against an American brand of snus known as Skoal Bandits. There was a presumption that Skoal Bandits caused oral cancer and would encourage young people to start smoking via the "gateway effect". Ireland also banned the sale of oral tobacco and, in 1992, the EEC introduced a ban across the common market. Sweden negotiated an exemption from this ban when it joined the EU in 1995, but it has remained in place for the rest of the single market despite the European Commission's subsequent acknowledgement that snus is not carcinogenic.

In light of the Swedish experience of widespread snus consumption, low smoking rates and low rates of cancer, the EU ban appears dangerously misguided. The EU has had several opportunities to repeal the ban since 1992, most recently with the 2014 Tobacco Products Directive (TPD). But rather than repeal the prohibition on snus, it has doubled down on its opposition to harm reduction by introducing arbitrary and counter-productive regulations for e-cigarettes. A list of these regulations, which came into force in May 2016, can be found in the Appendix of this report.[3] The net effect of the regulations is to increase costs, limit competition, restrict choice, and make vaping less appealing to smokers who might otherwise switch.

This is important because 62 per cent of smokers in the EU have still not tried e-cigarettes and 23 per cent have tried them only once or twice (Eurobarometer 2017: 105). Even in Britain, a third of smokers have never tried using an e-cigarette. It is safe to assume that more smokers would switch to vaping if the e-cigarette market reached its full potential. If this is to happen, retailers and manufacturers must be able to launch a wide range

3 Manufacturers had to abide by the new laws from 20 May 2016 but retailers were able to sell non-compliant stock until 20 May 2017.

of products to suit every preference. The TPD deters innovation, restricts choice and severely limits the ability of vaping companies to communicate with the public. The TPD's advertising restrictions are so severe that the British government is not even able to broadcast smoking cessation commercials that advocate using e-cigarettes as a healthier alternative.[4]

Public Health England acknowledged in 2015 that the TPD "certainly raises the barrier for bringing [e-cigarette] products to market or continuing to market existing products, and will undoubtedly constrain the [e-cigarette] market" (Public Health England 2015: 23). The EU's vaping regulations were fiercely criticised by members of the House of Lords in a debate on 10 May 2016 (Hansard 2016) and an Early Day Motion to repeal them was tabled in the House of Commons in the same month. A case of shutting the stable door after the horse had bolted, perhaps, but it should be remembered that a majority of British MEPs voted against the regulations in the European Parliament at the time.

The government's recently published Tobacco Control Plan for England mentions the opportunities for better regulation of nicotine products that Brexit offers (Department of Health 2017: 27):

> "…the government will review where the UK's exit from the EU offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where EU regulations limit our ability to deal with tobacco.
>
> In particular, the government will assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context."
> Leaving the EU offers an unusually simple solution. The statutory instrument that transposed the TPD into British law is called the Tobacco and Related Products Regulations 2016. It should be repealed at the first opportunity and e-cigarettes should be

4 The TPD states that "commercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited". The law even bans "any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes" (European Union 2014: 27-28).

> regulated under normal product and consumer law, as they were before May 2016. Repealing the TPD would then allow the UK to legalise snus (as New Zealand is in the process of doing) by repealing the Oral Snuff (Safety) Regulations Act (1989) and the Tobacco for Oral Use (Safety) Regulations (1992).

Disentangling British legislation from EU law in this area also requires the repeal of two pieces of legislation which the Tobacco and Related Products Regulations (2016) revoked: the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations (2002) and the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations (2007). The first of these transposed a previous EU tobacco directive into UK law. The latter amended EU law to mandate graphic warnings on tobacco packaging.

Would this lead to the inadvertent repeal of anti-smoking legislation that the government wants to keep? In practice, no. The UK has tended to go beyond EU directives with its tobacco regulation and the Children and Families Act 2014 gives the Secretary of State for Health the ability to regulate (without primary legislation) all aspects of tobacco packaging as well as the shape, size and flavour of cigarettes. The UK's flagship anti-smoking policies, such as the smoking ban, the advertising ban and plain packaging, did not emanate from the EU and would not be affected by the repeal of EU legislation.

The only notable tobacco regulations that would be affected are the ban on ten-packs of cigarettes and the forthcoming ban on menthol cigarettes (which is due to come into effect in 2020), both of which would be revoked by the actions outlined above. It is debatable whether either of these policies are desirable. Behavioural economists have argued that ten-packs are useful for smokers who are trying to give up (Marti and Sindelar 2015) and have even suggested that tobacco companies be forced to manufacture them for this reason (Sunstein 2014: 193).[5] The ban on menthol is an arbitrary prohibition on a product that has a large number of existing customers and is likely to lead to black market activity. But whatever the arguments for and against these bans, it will be for the British government to decide. If it chooses to uphold them, it could do so without primary legislation using the Children and Families Act.

5 When David Cameron was alerted to the EU's proposed ban on ten-packs during Prime Minister's Questions in 2013 he said: 'It does not, on the face of it, sound a very sensible approach' (Hansard 2013).

A free market approach has been shown to be optimal for e-cigarettes and would be revived by the actions listed above. However, the legalisation of snus may require a new regulatory category to be created so that low-risk tobacco products are not regulated as harshly as cigarettes. The Swedish approach has been to tax snus at a lower rate than cigarettes and to allow some point-of-sale advertising. This seems sensible and it is a discussion that needs to be had given the new breed of heat-not-burn products coming on the market.

Conclusion

The new breed of safer nicotine products are substitutes for combustible cigarettes. Policies which deter the use of a safer substitute effectively encourage the use of the less healthy alternative. As former ASH director Clive Bates puts it, “if you over-regulate a new, disruptive, low-risk alternative to the dominant and deadly cigarette, you simply protect the worst products from competition” (Bates 2013).

The TPD was a solution looking for a problem that did not exist. The vaping market functioned better under the relatively laissez-faire regime that preceded it than it has since. The sooner it returns to its previous state, the better for the health, prosperity and liberty of the nation.

Appendix: E-cigarette regulations included in the Tobacco Products Directive

1. Limiting the size of e-cigarette fluid refill containers and devices to 10ml and 2ml respectively.

Justification: Unknown, though possibly to reduce risk if the fluid is drunk.

Consequences: Limiting refill containers to 10ml, which is smaller than the pre-TPD average, uses more resources, creates more waste and reduces economies of scale for consumers. The risk of children (or adults) drinking the fluid has already been addressed by making containers child-proof. There are plenty of fluids that are hazardous if drunk, such as bleach, but few would argue that they should be sold in tiny bottles.

Banning devices that can hold more than 2ml has led to the prohibition of a large part of the market for vaping devices, preventing consumers from using their preferred products and damaging the small and medium sized businesses that manufacture and sell them.

2. Limiting nicotine content in e-cigarette fluid to 20 mg/ml.

Justification: To ensure that vapers do not absorb more nicotine in five minutes than would be delivered by one cigarette.

Consequences: The most commonly used fluids have a nicotine concentration of 18mg/ml, but around a fifth of vapers consumed e-cigarette fluid that is stronger than 20mg/ml in 2013 (Dawkins et al. 2013). Some users, many of whom used to be heavy smokers of cigarettes, find vaping unsatisfying at lower strengths, thus increasing the risk of relapse. Other users will simply consume more fluid, thereby increasing the cost of vaping.

3. Bottles of vape juice must be accompanied with a leaflet with information showing "warnings for specific risk groups", "possible adverse effects" and "addictiveness and toxicity".

Justification: To provide information to consumers.

Consequences: Creation of a large amount of waste paper to supply vapers with information that is almost always superfluous. Pertinent information, such as advice to keep the container out of the way of children, could be easily placed on the exterior packaging or on the container, as with over-the-counter medicines. Other labelling, such as a warning that the product contains nicotine, can be placed on the packaging (indeed, it must be placed on the packaging under Article 20). Mandatory leafleting is bureaucratic overkill and will further inflate prices. Many suppliers did not sell bottles of fluid in boxes before TPD and now need to manufacture boxes just to keep leaflets in.

4. Manufacturers and importers of electronic cigarettes and vape juice must submit written notification to the competent authorities of each Member States six months before placing a product on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. Notification must include contact details, toxicological data and a description of the production process.

Justification: Unclear, but presumably to allow the market to be monitored.

Consequences: Prior to TPD there were many thousands of different e-cigarette fluids on the market. The notification regime places such a heavy administrative cost on businesses that many of products have been withdrawn from the market. For example, one company (Vapemate) says it has reduced its range of fluids from over 60,000 to less than 6,000. Innovation in the e-cigarette market, which had previously been rapid, has slowed considerably. Each fluid now has to undergo expensive tests before reaching the market. Larger companies, including tobacco companies, can afford to do this but smaller competitors cannot.

5. E-cigarette advertising is banned in all media that can cross national borders, including radio, television, print media and the internet.

Justification: To help prevent non-smokers and young people taking up vaping.

Consequences: Advertising bans typically protect incumbent and rival industries. By limiting advertising to a few domestic outlets, such as billboards, the TPD is stifling competition and discouraging innovation. A tobacco-style prohibition on the advertising of vaping products could also give smokers the false impression that e-cigarettes are as dangerous as smoking. It also prevents the Department of Health and local authorities from promoting vaping as an alternative to smoking.

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