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**Summary**

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 EU’s Tobacco Products Directive 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.

**Background**

*E-cigarettes*

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).

‘Heat-not-burn’

Once e-cigarettes became mainstream consumer products, tobacco companies revived their interest in harm reduction. 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.

**Snus**

We should forget that tobacco harm reduction began in Sweden with the rise of ‘snus’ (rhymes with ‘moose’) which has been used in Scandinavia for more than two hundred years, although 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 than 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).

**On health**

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).

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).

**The gateway theory and other red herrings**

When e-cigarettes first became popular in Britain 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 motorcyles, 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.

Has there been a spike in underage smoking since vaping became popular? Far from it. Smoking prevalence was falling steadily between 2004 and 2011 among US high school students but fell sharply after e-cigarettes became popular between 2012 and 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.

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 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. 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 (Eurobarometer 2017: 8).

**On regulation**

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. 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 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.1

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.

1 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).
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 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).\(^2\) 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

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\(^2\) 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).
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.

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.

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[For references, see Vaping Solutions by Christopher Snowdon (IEA)]