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The Vapour Revolution:
How Bottom-Up Innovation Is Saving Lives

by Julian Morris and Amir Ullah Khan

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Executive Summary

After the discovery that smokers tend to die early from various diseases, including lung cancer and heart disease, governments, health professionals and tobacco companies sought to develop "safer" cigarettes. By the 1970s, it was clear that the problem with smoking was the smoke, which contains about 7,000 chemicals, many of which are toxic. Nicotine, the chemical in cigarettes that is most associated with pleasure, is largely benign. As British psychiatrist Michael Russell put it, people "smoke for the nicotine but die from the tar." While some advances were made during the 1970s and 1980s in the development of products that delivered nicotine in a less harmful way, consumer uptake was generally poor.

Then, in 2003, Beijing-based pharmacist Hon Lik invented a new device that vapourized liquid nicotine in a base of propylene glycol, mixed with flavorings. Mr Hon called these devices "electronic cigarettes" and, in 2004, his company began selling them under the brand Ruyan, which means "smoke like." From 2005, Ruyan began exporting its devices.

These early "cigalike" vape devices attracted the interest of smokers, some of whom used them to quit, while others used them to cut the number of cigarettes they smoked. As demand grew, competitors entered the market, developing new devices that sought to offer consumers a better experience at a lower price. In 2008, Taz and Umer Sheikh developed a new cigalike vape device that was more effective at delivering nicotine; it did this by surrounding the atomizer that creates the vapour with polyfill containing the liquid; they called this combined device a "cartomizer."

Enthusiastic vapers created online forums for discussing all aspects of these new devices—including how to modify them. Experimentation at home, combined with sharing of insights through these forums resulted in more-effective devices. One particularly important innovation was the development of a way to connect cartomizers to larger batteries. The vape community then advocated for the use of a standardized thread for this connection, in order to create competition among suppliers.

The adoption of thread standards, first for smaller devices and then for larger devices, enabled interchangeability. Companies, fiercely competing with one another, rapidly innovated more effective components, including larger batteries and new ways to store and heat "e-liquid." Soon, vapers were able to buy ready-made "mods" that were higher quality than they could achieve through their own modifications. And innovation has continued, with the development of variable power devices, temperature controlled heating coils, and lower cost vape pens for the mass market. At the same time, many companies, from tiny vape shops to large-scale online retailers, compete to supply e-liquids.

In combination, the wide—and expanding—variety of devices and liquids is attracting an increasing number of people to switch from smoking to vaping. It is no exaggeration to describe this process as a revolution from the bottom-up: It was driven by consumers from the beginning (Hon Lik was motivated to develop the first cigalike because his father died from lung cancer and he himself smoked, and wanted to develop a safer way to consume nicotine)—and it continues to be driven by consumers. In response to the large and increasing proportion of smokers who have switched to vaping in many countries, tobacco companies now see vaping as the future and are developing new products to meet this demand. At least two companies have developed innovative products that create a vapour by heating—but not burning—tobacco; these may well offer a more attractive and effective solution for smokers who do not wish to switch to e-liquid-based vapes.

The public health impact of the vapour revolution has already been profound. Millions of smokers have switched entirely to vaping, and millions more are using vaping to reduce the amount they smoke. Experts who have assessed vapour produced by heating e-liquids in a vape device have found that it contains only a tiny fraction of the number of chemicals in tobacco smoke—and most of those chemicals are harmless. The best estimate so far produced puts the risk posed by vaping at approximately 5% that posed by smoking. This estimate was produced by a highly esteemed independent team of doctors, pharmacologists, economists and others. It was acknowledged as the best estimate by both Public Health England and the Royal College of Physicians in the UK.

While vaping is thus widely acknowledged to be safer than smoking, concerns have been raised as to whether vaping might be leading to an increase in youth initiation of smoking. However, the evidence does not support this contention. While a few studies suggest that some youths who experiment with vaping seem to be more likely to experiment with smoking, this is likely largely because such youths have a higher propensity to engage in novelty-seeking and/or risky behaviours. In other words, many of those youths who tried vaping and then tried smoking probably would have tried smoking even if they hadn't tried vaping. Since most youth vaping occurs using nicotine-free liquids, it seems most unlikely that the youths are smoking because they are hooked on nicotine.

In addition, interviews with youths who regularly vape suggest that vaping is considered quite different to and less risky than smoking. Moreover, surveys suggest that as more youths vape, fewer smoke. And while there has been a general decline in youth smoking in the US, in those jurisdictions where access to vape products is legally restricted, the rate of decline has been lower, presumably because in these locations fewer youths are vaping as a substitute for smoking. It seems reasonable to conclude from this evidence that while some youths probably do take up smoking after experimenting with vaping, considerably more youths are vaping instead of smoking. As a result, in places where vaping has become widespread, fewer youths are smoking and those who are smoking are smoking less. Thus, vaping is displacing smoking, with potentially enormous public health benefits.

Given time and further innovation, vaping has the potential to continue dramatically to reduce both the number of people who smoke and the number of cigarettes smoked by those who choose to continue to smoke. Over the course of the next two to three decades, vaping might gradually replace smoking altogether, thereby saving most of the billion lives—and perhaps 8 of the 10 billion life years—that otherwise would be lost to smoking over the coming century.

For the vapour revolution to continue, however, it is important that the production, sale and use of vape products remain legal. The evidence suggests that in jurisdictions where vape products are regulated as consumer products (that is, not subject to product-specific regulation either as medicines/medical devices or as tobacco products), producers have innovated rapidly and been highly responsive to perceived concerns of vapers. If innovation is to continue to deliver better, safer, less expansive products—and thereby attract more smokers to switch—it is essential that producers, retailers and consumers be free of excessive regulatory intervention.

The World Health Organization and its Framework Convention on Tobacco Control (FCTC) exert considerable influence on domestic policies towards tobacco in many countries. In 2014, at the 6th Conference of the Parties to the FCTC, parties left open how best to regulate vape products. Since then, the evidence of public health benefits from vape products has been mounting -- as documented in this study. It is important that governments meeting for the seventh Conference of the Parties to the FCTC, which will take place in Delhi in November 2016, take on board this new evidence and support policies that do not impose unnecessary impediments to the development, promotion, sale, and use of vape products.

Introduction

In 2003, Chinese pharmacist Hon Lik patented a device that resembled a cigarette in appearance, but instead of burning tobacco it vapourized a mixture of liquid nicotine, water, propylene glycol and flavourings. The aim was to simulate the look and feel of a cigarette, while delivering nicotine to users as a vapour without the toxic effects that result from inhaling burnt tobacco.

Mr Hon's company began selling "electronic cigarettes" in China under the brand name Ruyan ("smoke like"). These were also soon exported to Europe and the US. From about 2008, competitors entered the market. Various innovations, including important modifications by users, resulted in devices with improved characteristics. (Many of these devices look nothing like cigarettes, so to avoid confusion we shall refer to devices that *look* similar to cigarettes as "cigalikes" and to the general class of devices and liquids as "vape products."[1] Meanwhile, we shall refer to the act of using vape products as "vaping"—a term now in widespread use—and to those who use them as "vapers.")

Consumers responded positively to these innovations, with demand for vape products rising dramatically over the past few years. In the UK, Action on Smoking and Health estimates that the number of adults who regularly vape increased from 700,000 in 2012 to 2.8 million in 2016.[2] Of these, about half (1.4 million) are current smokers, down from two-thirds in 2014, while slightly less than half (1.3 million) are ex-smokers, up from one-third in 2014. The increase in the proportion of ex-smokers vaping suggests that vaping is increasingly a substitute for smoking.

Demand for vape products has also exploded in other European countries over the past few years. A 2014 Eurobarometer Survey of all 28 EU states found that rates of vaping among current smokers was high in the UK (11%), France (8%), Denmark and the Netherlands (both 7%).[3] Meanwhile, rates of vaping among ex-smokers was highest in the UK (8%), Ireland (6%) and France (6%).[4]

A report based on a 2014 survey undertaken by France's National Institute of Prevention and Education for Health (INPES) found that about 6% of the French population vape, half of them daily.[5] The authors also concluded that about 400,000 people in France had quit smoking by switching to vaping.

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[1] In some circles, the term electronic nicotine delivery system, or ENDS, is used. But that term presumes nicotine delivery. The problem is not solved by creating another category of electronic non-nicotine delivery systems (ENNDS), since some devices may be both ENDS and ENNDS. "Vape products" is thus more accurate. It is also more precise, since all the devices discussed in this report function by releasing vapour.

[2] Action on Smoking and Health, "Use of Electronic Cigarettes Among Adults in the United Kingdom," ASH Fact Sheet, May 2016, Available at: http://www.ash.org.uk/files/documents/ASH_891.pdf, accessed 5/22/2016.

[3] Eurobarometer, "Attitudes of Europeans towards tobacco and electronic cigarettes," Brussels: European Commission, Special Eurobarometer, Number 429, 2015.

[4] Ibid.

[5] Rachael Andler, R. Guignard, J.L. Wilquin, F. Beck, J.B. Richard and V. Nguyen-Thanh, "Electronic cigarette use in France in 2014," *International Journal of Public Health*, 2016, Vol. 61(2), pp. 159–165. doi: 10.1007/s00038-015-0773-9.

Vaping is also popular in many Asian countries. Estimates put the number of vapers in Malaysia by the end of 2015 at between 500,000 and one million.[6] In Japan, about one million smokers have bought a tobacco-based vape product developed by Philip Morris International called iQOS.[7] Meanwhile, Japan Tobacco recently released a tobacco-based vape product called Ploom that seems also to be very popular.[8]

Vape products seem to be reducing rates of smoking among youth as well. In 2011, 15.8% of US high school students reported smoking cigarettes in the past month. By 2015, the proportion had fallen to 9.3%.[9] And this decline mirrors the increase in vaping, with 16% of high school students reporting that they vaped in the past month in 2015 compared with only 1.5% in 2011.

Surveys by Action on Smoking and Health UK (ASHUK) found that the proportion of children in the UK aged 11–15 who are regular smokers fell from 5% in 2010 to 3% in 2015.[10] Meanwhile, another ASHUK survey of British children (aged 11–18) found that 93% were aware of "electronic cigarettes" (up from 67% in 2013) and 12% had used them (but only 2.4% said they vape once a month or more, including 0.5% who vape weekly).[11]

At the same time, there is little evidence that non-smokers are taking up vaping. In 2016, only about 2% of regular adult vapers in the UK were previously non-smokers.[12] A 2014 Eurobarometer survey found that across the EU only 2.3% of adult vapers were previously non-smokers; meanwhile, only about half of those (1.3%) vaped with nicotine and only 0.1% reported daily nicotine use.[13]

As demand for vape products has risen, so has interest in and concern over their potential health effects. And along with these concerns has come attention from governments seeking to regulate and/or tax vape products. This study seeks to put those concerns into context. It begins by describing the development of vape products and their uptake by consumers, presented in the context of "harm reduction" and earlier attempts to produce safer cigarettes. It then considers the potential benefits and risks associated with vaping. Finally, it evaluates some actions taken by governments and considers which policies would be most effective in ensuring continued beneficial innovation in and availability of vape products that offer safer alternatives to smoking.

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[6] But recent reports suggest that number may have fallen.

[7] http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MzMyNjU5fENoaWxkSUQ9LTF8VHlwZT0z&t=1&cb=635979711864006385

[8] http://www.reuters.com/article/us-japan-tobacco-idUSKCN0WV0GQ

[9] Tushar Singh, René A. Arrazola, Catherine G. Corey, Corinne G. Husten, Linda J. Neff, David M. Homa and Brian A. King, "Tobacco Use Among Middle and High School Students — United States, 2011–2015," *U.S. Centers for Disease Control Morbidity and Mortality Weekly Report*, April 15, 2016, Vol. 65 (14); pp. 361–367

[10] http://ash.org.uk/files/documents/ASH_108.pdf

[11] Action on Smoking and Health, "Use of Electronic Cigarettes Among Adults in the United Kingdom."

[12] Ibid.

[13] Konstantinos E Farsalinos, Konstantinos Poulas, Vassilis Voudris and Jacques Le Houezec, "Electronic cigarette use in the European Union: analysis of a representative sample of 27,460 Europeans from 28 countries," *Addiction,* 2016, Jun 24. doi: 10.1111/add.13506

1. A Revolution in Tobacco Harm Reduction

Smoking is indubitably a pleasurable activity for many. Much of this pleasure comes from nicotine, the most important psychoactive ingredient in tobacco smoke, which has effects similar to those of caffeine: it increases alertness and stimulates the brain's main "reward" system.[14]

But nicotine is not the only reason people smoke. The act of smoking itself provides oral gratification, sensory pleasure and social camaraderie.[15] As former smoker Lorien Jollye puts it: "There is so much pleasure around smoking in terms of when you can do it, the treat element, the flavor, the sensation, the inhale and the exhale."[16]

Unfortunately, regularly inhaling burnt tobacco in large quantities over a long period also has adverse consequences for most people. Long-term smokers are more likely to suffer from various lung disorders, ranging from emphysema and bronchitis to chronic obstructive pulmonary disorder.[17] They are also more likely to develop cancer of the lung, oesophagus, pancreas and various other organs.[18] And they are more likely to suffer from cardiovascular diseases, including heart disease, stroke and peripheral arterial disease. [19]

Such concerns are hardly new. In 1836, Samuel Green warned that "thousands and tens of thousands die of diseases of the lungs generally brought on by tobacco smoking."[20] By the mid-1950s, epidemiological evidence had become practically incontrovertible, with Richard Doll and Bradford Hill in the UK and Ernest Wynder and Evarts Graham in the US showing that smoking was associated with a significant increase in lung cancer.[21] Doll and Hill also showed that smoking was associated with a range of other diseases, including various other cancers, emphysema and heart disease.[22]

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[14] William S. Griesar, Daniel P. Zajdel and Barry S. Oken, "Nicotine effects on alertness and spatial attention in non-smokers," Nicotine and Tobacco Research, 2005, Vol. 4(2), pp. 185-194, abstract available at: http://ntr.oxfordjournals.org/content/4/2/185.abstract, accessed 5/21/2016; Manoranjan S. D'Souza and Athina Markou, "Neuronal Mechanisms Underlying Development of Nicotine Dependence: Implications for Novel Smoking-Cessation Treatments," *Addict Science Clinical Practice*, 2011 vol. 6(1), pp. 4–16. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3188825/#b17-ascp-06-1-4, accessed 5/21/2016

[15] https://www.sciencedaily.com/releases/2010/07/100713144920.htm

[16] https://www.youtube.com/watch?v=IWyX47PcDH0 (Jollye is a trustee of New Nicotine Alliance and was a smoker for 23 years before she switched to vaping.)

[17] See e.g. U.S. Surgeon General: *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General,* Atlanta, GA: Centers for Disease Control and Prevention, 2010

[18] Ibid.

[19] Ibid.

[20] Samuel Green, *Smoking,* New England Almanack and Farmers' Friend, 1836, New London, CT, pp. 25–2.Cited in by James S. Powers and Martha Wetteman, "On the Hazards of Smoking: Statement from 1836," *American Journal of Public Health*, April 1979, Vol 69(4), at p. 389.

[21] Richard Doll and A. Bradford Hill, "Smoking and Carcinoma of the Lung: Preliminary Report," *British Medical Journal*, September 30, 1950, pp. 739–748. Ernest L. Wynder and Evarts A. Graham, "Tobacco Smoking as a Possible Etiologic Factor in Bronchiogenic Carcinoma: A Study of Six Hundred and Eighty Four Proved Cases," *Journal of the American Medical Association*, May 27, 1950, pp. 329–336.

[22] Richard Doll and A. Bradford Hill, "The Mortality of Doctors in Relation to their Smoking Habits: A Preliminary Report," *British Medical Journal*, June 26, 1954, pp. 1451–1455. See also Richard Doll and A. Bradford Hill, "A Study of the Aetiology of Carcinoma of the Lung," *British Medical Journal*, December 13, 1952, pp. 1271–1280.

During the 1950s, as understanding of the harmful effects of smoking became apparent, there was a surge in demand for cigarettes with filter tips that removed some of the tar.[23] This in turn led to numerous innovations in filter design, ranging from a chlorophyll impregnated filter to complex designs such as the selective filter on Brown & Williamson's Fact Brand.[24] While some of these filter designs did reduce the toxic constituents of the smoke, they also removed nicotine, so smokers compensated by drawing more heavily and consuming more cigarettes. Meanwhile, some filters probably did more harm than good (such as the asbestos filters used for a period on Kent's Micronite cigarettes).[25]

In the 1960s, the US government, tobacco companies and public health groups all advocated the development of safer cigarettes, as Amy Fairchild and James Colgrove document:

> *Surgeon General Luther Terry, who issued the watershed 1964 report definitively linking smoking with cancer, saw "the development of better filters or more selective filters [a]s a promising avenue for further development." In 1964, with the assistance of $1.5 million in congressional funding, the NCI and the Public Health Service (PHS) announced plans to "'work closely' with tobacco researchers from the Department of Agriculture" to try to develop new varieties of tobacco to determine whether they are "less hazardous, more hazardous or show no change from the present ones." NCI head Kenneth Endicott said that the group's "first and foremost" objective would be to reduce the danger of smoking. The NCI spent $6 million a year in pursuit of a safer tobacco product*.[26]

While little came of that NCI investment, at least one tobacco company did develop what appears to have been a safer cigarette. In the 1970s, Liggett & Myers developed a new cigarette containing the rare metallic element palladium, which had been shown to reduce tumor formation in rodent experiments. The cigarette was never marketed, however, as Chris Snowdon relates:

> *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. Ultimately, 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 it from the market. Epic was held back by the same factors that would hinder 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 antismoking campaigners who feared that safer products would deter smokers from quitting,*

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[23] The rolled crepe paper filter had been invented in 1927 by Boris Aviaz and was originally patented in the UK, then, later, in the US. See: http://www.google.com/patents/US2064239

[24] http://www.google.com/patents/US2774354

[25] During the 1950s, Lorillard developed an asbestos based filter, which it used on its Kent Micronite brand of cigarettes between 1952 and 1956. While the filter promised to protect the health of smokers, the use of blue asbestos likely more than offset any reduction in risk from the toxic constituents of burnt tobacco. (See e.g.: http://www.asbestos.com/products/general/cigarette-filters.php)

[26] Amy Fairchild and James Colgrove, "Out of the Ashes: The Life, Death, and Rebirth of the "Safer" Cigarette in the United States." *American Journal of Public Health*, Vol. 94(2), pp. 192–204, 2004 PMCID: PMC1448228

> *and the industry's own reluctance to implicate conventional cigarettes as unsafe for fear of accepting liability.*[27]

In the 1970s, Michael Russell, a psychiatrist based at the Addiction Research Unit at the Institute of Psychiatry of the Maudsley Hospital in London, published a series of papers that developed a new approach to address the problems resulting from smoking tobacco.[28] Central to Russell's approach was the acknowledgement that people smoke in large part because they are addicted to the nicotine, but are made sick mainly by the other constituents of the smoke—or as he put it most succinctly, "People smoke for the nicotine but die from the tar."[29]

Russell argued that what was needed was a means of supplying nicotine in ways that are less harmful. To that end, he surveyed the cigarettes then available on the UK market and showed that levels of nicotine were generally correlated with levels of tar—but that some cigarettes provided a higher ratio of nicotine to tar. In the short-term, he suggested that smokers might be encouraged to choose, from among available brands, those that delivered sufficient nicotine to satisfy their craving (estimated to be approximately 1 mcg per cigarette) with the least amount of tar. In the longer term, he encouraged companies to develop cigarettes that had sufficient nicotine to quench smokers' cravings but with much lower levels of tar.

In spite of the failure of earlier attempts to produce dramatically less harmful cigarettes, companies continued to innovate. In the 1980s, several companies developed cigarettes that heated tobacco in order to release a vapour, instead of burning it to produce smoke. Although the basic idea is sound—and as we will discuss later, more-recent versions of heat-not-burn products show some promise—the early devices, such as R.J. Reynold's Eclipse and Philip Morris' Accord, were not commercially successful and were withdrawn.[30]

Another category of nicotine-containing products was developed explicitly as quitting aids. These products—which include gum and patches—do seem to be effective in assisting some people to quit smoking.[31] But they lack other characteristics of cigarettes that appeal to smokers.

1.1 The Invention of Vape Products

In 1927, Joseph Robinson filed a patent application for an "electric vaporizer" for medicinal products.[32] In 1954, Otto Lobl filed a patent application for a "tubular inhaler simulating a smoking

[27] Chris Snowden, Free Market Solutions in Health, London: Institute of Economic Affairs, 2013, Available at: http://www.iea.org.uk/sites/default/files/publications/files/Free%20Market%20Solutions%20in%20Health.pdf, accessed 5/10/2016.

[28] Michael A. H. Russell, "Low-tar medium-nicotine cigarettes: a new approach to safer smoking," *British Medical Journal*, 12 June 1976, pp 1430-1433.

[29] Michael A. H. Russell, "Low-tar medium-nicotine cigarettes: a new approach to safer smoking," *British Medical Journal*, 12 June 1976, pp 1430-1433, at 1431.

[30] In 1988, R. J. Reynolds introduced a heat-not-burn cigarette called Premier in two test cities in the U.S., St Louis, Missouri, and Phoenix, Arizona; it was not a hit with consumers. In 1998, Philip Morris introduced a heat-not-burn product called Accord that it test marketed in Richmond, Virginia and Tokyo, Japan. After eight years, it withdrew the product due to poor consumer uptake. (see: http://tobaccoproducts.org/index.php/Accord)

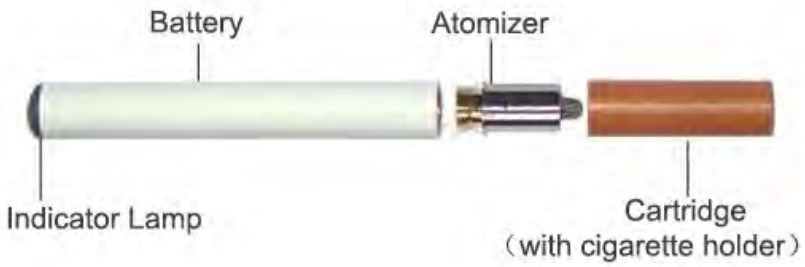
[31] Kate Cahill, Sarah Stevens, Rafael Perera, and Tim Lancaster, "Pharmacological interventions for smoking cessation: an overview and network meta-analysis," *Cochrane Database of Systematic Reviews*, 2013, Issue 5. DOI: 10.1002/14651858.CD009329.pub2.

device."[33] And in 1963, Herbert Gilbert filed a patent application for a "smokeless non-tobacco cigarette."[34] Unfortunately, the technologies necessary to produce an effective smokeless cigarette did not exist in 1963. In particular, miniature, high-density batteries were decades away and the only devices built at that time were too cumbersome to be carried around, making them impractical. Also—and perhaps equally important—none of the patented devices were intended to deliver nicotine.

In 2001, Hon Lik, a pharmacist and executive at a company called Golden Dragon Group (Holdings) in Beijing, China, applied the ideas developed by Robinson, Lobl and Gilbert to the delivery of nicotine.[35] Mr Hon's original patent for an "electronic cigarette" had much of the outward appearance of a conventional cigarette but rather than burning or even heating tobacco, instead it used a high frequency ionizer and piezoelectric atomizer to produce an inhalable vapour from a mixture containing nicotine and propylene glycol.[36]

Hon Lik subsequently modified his design, replacing the piezoelectric atomizer and ionizer with a simpler system that created a vapour by heating a mixture of nicotine, water, propylene glycol and flavours using an electric coil, drawing the liquid from a chamber using a wick. This design became the basis for practically all subsequent vape products.

Figure 1: Ruyan Cigalike



Starting in 2004, Mr Hon's cigalikes were sold under the brand name Ruyan, which translates as "smoke like" (Figure 1). (Golden Dragon Group subsequently changed its name to Ruyan and then Dragonlite.[37]) From 2005, Ruyan began exporting its cigalikes.[38] These early cigalikes quickly became popular with smokers, many of whom found them to be an effective alternative to conventional cigarettes.

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[32] http://www.google.com/patents/US1775947

[33] In 1955, Lobl was granted U.S. patent # 2721551. See: http://www.google.com/patents/US2721551, accessed 4/25/2016

[34] 1963 US patent application # 3200819A. See: http://www.google.com/patents/US3200819, accessed 4/25/2016

[35] Hon Lik is the Cantonese form – and is the form that has been used in patent applications in the US and elsewhere, so we follow that convention. The Mandarin form of the name is Han Li.

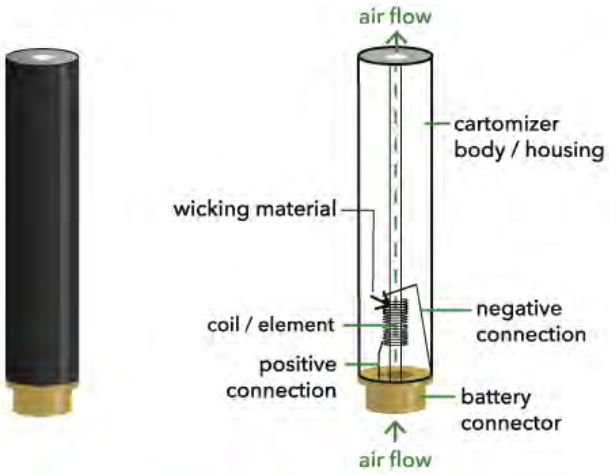
[36] See: http://www.google.com/patents/US20060196518

[37] http://www.prnewswire.com/news-releases/dragonite-international-limited-formerly-ruyan-group-holdings-limited-hong-kong-stock-code-329----change-of-company-name-and-capital-reorganization-100103219.html

[38] http://stephenvandulken.blogspot.co.uk/2014/01/the-patents-for-e-cigarettes.html

Subsequent innovations resulted in a range of devices with improved nicotine delivery and other characteristics. Among the most important early innovations was the "cartomizer", which combined the tank, wick and heating element in a single, disposable unit (Figure 2). This was developed by Gamucci, a company founded by two British Asians, Taz and Umer Sheikh.[39]

Figure 2: Cartomizer



While popular, the early cigalikes delivered relatively small amounts of nicotine to the lungs, blood and brains of users. In response, users began discussing ways to build more effective vape products. Much of this discussion took place in online forums such as E-Cig-Reviews.com and UKVaper.org.[40] Some of the participants in these forums developed their own homemade "mod" devices.

Among the most successful and celebrated of these is the "Screwdriver", developed by father-and-son team Matt and Ted Rogers, which consists of a larger rechargeable battery (originally taken from a flashlight) that connects to a cartomizer.[41]

Next came the refillable cartomizer and the development of a range of "e-liquids", which typically consist of a mixture of nicotine, propylene glycol and/or glycerine, and flavourings.

The combination of larger batteries and refillable cartomizers with more powerful coils enabled devices that could deliver more vapour than the original cigalikes—thereby increasing the amount of nicotine that could be delivered in a single draw, via the lungs to users' blood and thence brain.

Realizing that production of vape devices would benefit from a standardized way to connect batteries to cartomizers, members of the vaping community adopted a standard thread, known as the 510, which had been used on a cigalike manufactured by Joyetech since December 2008.[42] By encouraging the use

[39] Ibid.

[40] See e.g. http://www.engadget.com/2014/10/01/inside-story-e-cig-modding-uk/, accessed 5/22/2016

[41] https://www.wakeandvape.com/blog/the-history-of-vaping, accessed 5/23/2016

[42] http://social.joyetech.com/showthread.php?pid=4391

of this standard, the vapers intentionally promoted competition among diverse manufacturers—with the expectation that this would ensure a diversity of supply.[43] Responding to this opportunity, numerous companies soon began developing ready-made batteries and refillable cartomizers using the 510 thread.

In October 2009, Joyetech developed another thread, known as the eGo, which was designed for larger batteries. It incorporated this thread into its own eGo battery and vape pen, which can be seen in Figure 3. As with the 510, this was promoted as a standard thread by vapers. Vape batteries typically have a 510 thread on the inside and an eGo thread on the outside—see Figure 4.

Figure 3: Battery Head with Dual 510/eGo Threads

http://www.discountvapers.com/ego-vs-510-thread-what-is-the-difference/)

Figure 4: eGo Vape Pen

The open thread standards had the intended effect—and diverse suppliers were soon competing with one another, innovating better products of higher quality at lower cost. As vape devices capable of delivering larger amounts of nicotine were developed, including third and fourth generation "mod" devices,[44] many users switched away from the original "cigalikes"—and demand grew, suggesting that these more powerful vape devices were better substitutes than the cigalikes, even though their

[43] I am grateful to Luc van Daele, one of the main members of the vape community responsible for developing the standard, for explaining the origin of the 510 thread.

[44] For an overview of the different devices, see: http://ecigclopedia.com/the-4-generations-of-electronic-cigarettes/, accessed 5/9/2016.

appearance is quite different to conventional cigarettes. At the same time, a new culture grew around vaping and entrepreneurs establishing vape shops selling devices and a range of "e-liquids", some of which were blended in-house.

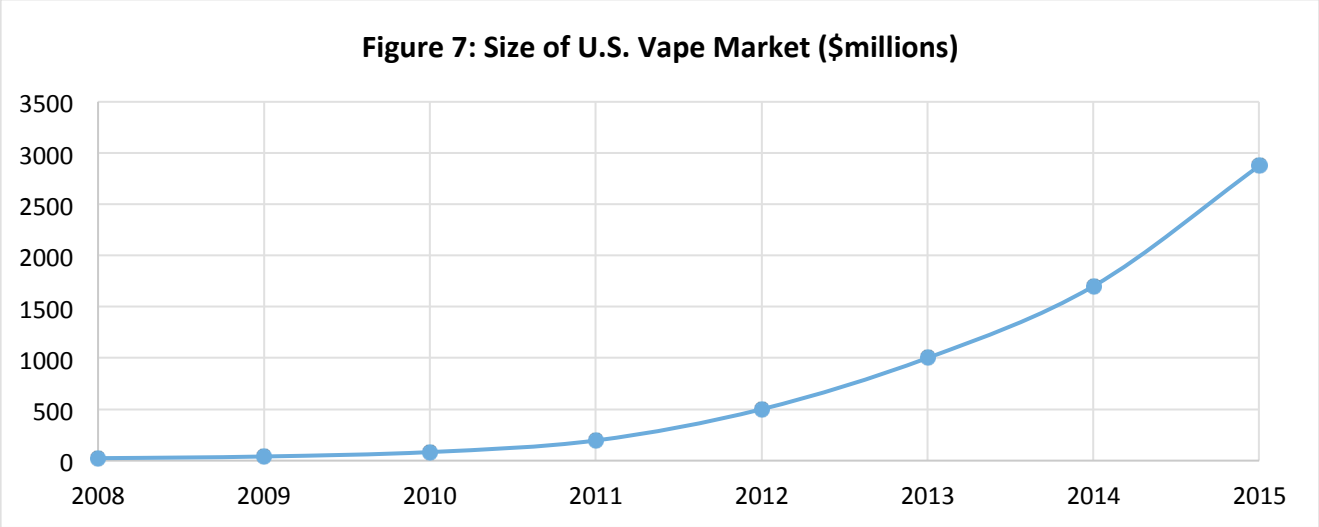
Figure 5: 3RD and 4TH Generation Vape Devices

Figure 6: Examples of E-liquids

As the vape market grew, cigarette manufacturers recognized that they posed both a threat to their traditional market and an opportunity. In response, they either built their own vape product lines or bought existing companies—and then used their marketing muscle to get them on shelves in convenience stores, supermarkets, pharmacies, and tobacconists.

Initially, most of the devices sold by larger tobacco companies were first generation cigalikes. But with vapers increasingly switching to more powerful tank models, several companies developed new, reformulated cigalikes, with delivery systems that increased nicotine absorption, thereby more effectively replicating the cigarette experience.

Ambitious vape-only companies also innovated better cigalikes. An example is the Njoy Daily, which includes lactic acid in the liquid to increase nicotine absorption, uses a liquid mix containing 4.5% nicotine by weight, and also has a larger battery than its predecessor, and a sophisticated pulse mechanism for delivering large amounts of nicotine during the initial puff.[45]



At the same time, at least two cigarette manufacturers, Philip Morris International and Japan Tobacco, have developed vapour products that use heating technology to produce a vapour from tobacco. Both report strong sales of these products, especially in Japan. Analyst Bonnie Herzog of Wells Fargo estimates that these heat-not-burn tobacco vapour products could displace 30% of the traditional cigarette market by 2025.[46]

Conclusions of Section 1

Since the invention of the first cigalike by Hon Lik, in 2003, vape technology has developed rapidly. Vapers have been crucial to this process, as consumers, innovators, and standard setters. Through their early enthusiasm, vapers drove demand for cigalikes, encouraging competitors to enter the market, resulting in innovations such as Gamucci's cartomizer. Experimentation at home and sharing of insights through online forums resulted in the development of more effective devices. Adoption of standards for battery threads by the vape community resulted in further competition among companies to supply increasingly sophisticated batteries, tanks, coils and other elements of vape devices. At the same time, many companies, from tiny vape shops to large-scale online retailers, compete to supply e-liquids. In combination, the wide—and expanding—variety of devices and liquids is attracting an increasing number of people to switch from smoking to vaping.

[45] https://www.njoy.com/global/daily

[46] The Economist, "Smoke signals: Philip Morris, health company?" Apr 23rd 2016.

It is no exaggeration to describe this process as a revolution from the bottom-up: It was driven by consumers from the beginning (Hon Lik was motivated to develop the first cigalike because his father died from lung cancer and he himself smoked, and wanted to develop a safer way to consume nicotine)—and it continues to be driven by consumers. In response to the large and increasing proportion of smokers who have switched to vaping in many countries, tobacco companies now see vaping as the future and are developing new products to meet this demand.

2. The Health Effects of Vaping

The vapour revolution has been driven in large part by a belief that vaping is safer than smoking. Long-term smoking is known to cause or exacerbate many diseases, including: debilitating and often fatal lung diseases, such as chronic obstructive pulmonary disease (COPD), emphysema, tuberculosis; lung, mouth, and various other types of cancer; and numerous cardiovascular diseases, such as coronary heart disease, stroke, peripheral arterial disease, and abdominal aortic aneurysm.[47] These diseases exert an enormous toll. In a 2014 article in the *New England Journal of Medicine*, Prabhat Jha and Richard Peto state:

> *There were about 100 million deaths from tobacco in the 20th century, most in developed countries. If current smoking patterns persist, tobacco will kill about 1 billion people this century, mostly in low- and middle-income countries. About half of these deaths will occur before 70 years of age*.[48]

Jha and Peto, who are respectively Professor of Epidemiology at the University of Toronto's Dalla Lana School of Public Health and Professor of Medical Statistics and Epidemiology at the University of Oxford, cite reliable evidence that smoking throughout adulthood reduces life expectancy by about 10 years.[49] By contrast, those who quit by age 40 face a reduction in risk of smoking-related death of about 90% -- which might crudely be translated into a saving of 9 years of life on average. Those who quit later still benefit from a reduced risk of smoking-related disease and death, but less so: quitting at age 50, for example, reduces risk by a little over 50%.[50]

While premature death is arguably the most severe consequence of continued smoking, smokers also typically suffer more debilitating health problems than non-smokers while they are alive, leading to diminished quality of life.[51]

Proponents of vaping have argued that it can dramatically reduce the harms associated with smoking, with potentially enormous benefits to smokers and society. This section assesses the evidence for such an effect. It begins with a summary of the evidence on the relative risk of smoking and vaping. This is followed by an assessment of the extent to which smokers are switching to vaping. It ends with an assessment of whether vaping is likely to lead to an increase in smoking initiation or vice versa.

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[47] See e.g. U.S. Surgeon General: *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General,* Atlanta, GA: Centers for Disease Control and Prevention, 2010

[48] Prabhat Jha and Richard Peto, "Global Effects of Smoking, of Quitting, and of Taxing Tobacco,"

New England Journal of Medicine, 2014, Vol. 370, pp. 60-68. DOI: 10.1056/NEJMra1308383

[49] Assuming smoking starts around age 19.

[50] Ibid.

[51] Matthew Goldenberg, Itai Danovitch, and Waguih William IsHak, "Quality of life and smoking," *American Journal of Addiction*, 2014, Vol. 23(6), pp. 540-62. doi: 10.1111/j.1521-0391.2014.12148.x.

2.1 The Relative Risk of Vaping Compared with Smoking

The health effects of smoking are almost entirely a consequence of long-term inhalation of smoke, which contains over 7,000 chemicals, including polycyclic aromatic hydrocarbons, nitrosamines, formaldehyde, and various heavy metals. More than 70 of these chemicals are known carcinogens and many contribute to cardiovascular disease.[52]

In contrast, the vapour inhaled by vapers contains only a tiny fraction of the chemicals present in tobacco smoke (the exact number depends on the device and the liquid being used, but most analyses suggest that there are fewer than 100 chemicals in any quantity).[53] In 2014, the journal *Therapeutic Advances in Drug Safety* published a comprehensive review of the available evidence concerning the potential health effects of vaping, written by Dr Konstantinos Farsalinos, a research cardiologist at the Onassis Cardiac Surgery Center in Athens-Greece and at the Medical Imaging Research Center, University Hospital Gathuisberg in Leuven, Belgium, and Riccardo Polosa, Director of the Center for the Prevention and Cure of Tobacco-related Disease at the University of Catania in Italy. The review, which assessed 97 studies, concluded that "Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes."[54]

One misconception addressed by Farsalinos and Polosa is the risk associated with consuming nicotine. While acknowledging that nicotine is addictive, they note that it is, "not classified as a carcinogen by the International Agency for Research on Cancer."[55] More importantly, they observe:

> *A major misconception, commonly supported even by physicians, is that nicotine promotes cardiovascular disease. However, it has been established that nicotine itself has minimal effect in initiating and promoting atherosclerotic heart disease. It does not promote platelet aggregation, does not affect coronary circulation and does not adversely alter the lipid profile. An observational study of more than 33,000 smokers found no evidence of increased risk for myocardial infarction or acute stroke after NRT subscription, although follow up was only 56 days. Up to 5 years of nicotine gum use in the Lung Health Study was unrelated to cardiovascular diseases or other serious side effects. A meta-analysis of 35 clinical trials found no evidence of cardiovascular or other life-threatening adverse effects caused by nicotine intake. Even in patients with established cardiovascular disease, nicotine use in the form of NRTs does not increase cardiovascular risk.*[56]

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[52] http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297981.pdf

[53] For example, an analysis by Jason S. Herrington, Colton Myers, and Amanda Rigdon or Restek Corporation ("Analysis of Nicotine and Impurities in Electronic Cigarette Solutions and Vapor," No Date, Available at: http://www.restek.com/pdfs/FFAN2127-UNV.pdf) found 82 chemicals in vapour from a first generation cigalike vape device. A recent analysis found over 250 chemicals in e-liquid vapour but most of these were present in minute quantities at power settings likely to be used by vapers: Diego Garcia-Gomez, Thomas Gaisl, Cesar Barrios-Collado, Guillermo Vidal de Miguel, Malcolm Kohler, and Renato Zenobi, "Real-Time Chemical Analysis of E-Cigarette Aerosols By Means Of Secondary Electrospray Ionization Mass Spectrometry," *Chemistry – A European Journal*, 2016, Vol. 22(7):2452-7. doi: 10.1002/chem.201504450.

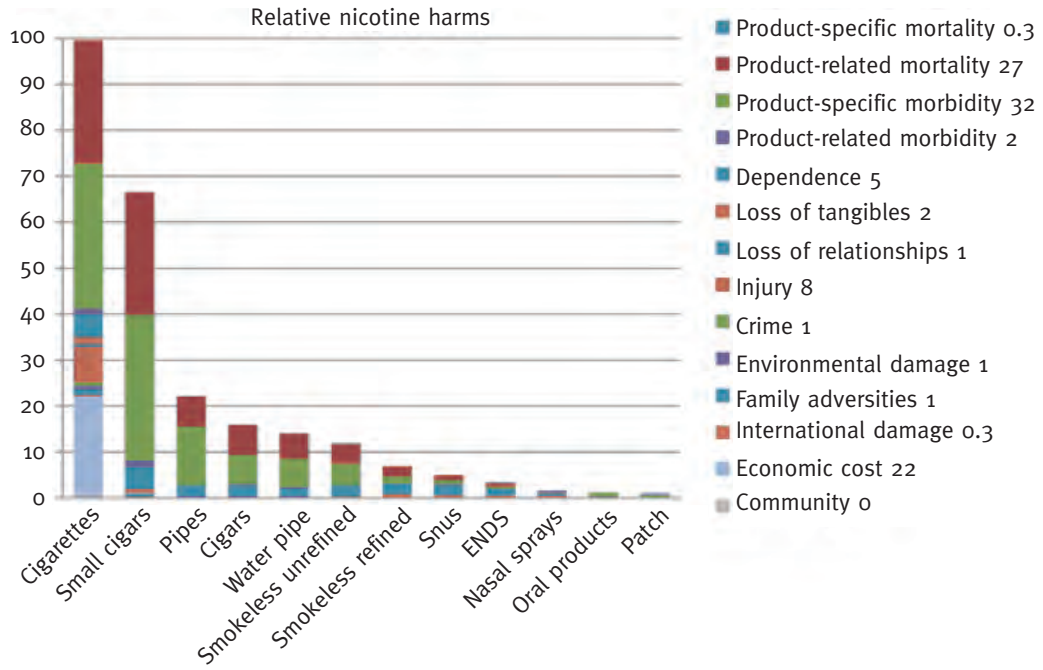
[54] Konstantinos E. Farsalinos and Riccardo Polosa, "Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review," *Therapeutic Advances in Drug Safety*, Vol. 5(2), 2014, pp. 67-86, at. P. 67.

[55] Ibid at p. 69.

[56] Ibid. at 69.

Also in 2014, *European Addiction Research* published an estimate of the harms of various nicotine-containing products, including electronic nicotine delivery systems (ENDS), i.e. vapour products containing nicotine.[57] The estimate was produced by an international team led by Professor David Nutt of Imperial College London and included, among others, Martin Dockrell, who was then with Action on Smoking and Health UK, Riccardo Polosa, and two representatives of the World Medical Association, Kgosi Letlape (South Africa) and Anders Milton (Sweden). The estimate, summarized in Figure 8, was based on a range of factors, including mortality, morbidity, dependence, "family adversities" (negative impact on the economic well-being of families of users, including prospects for children) and economic cost (the impact on the wider economy through e.g. reduced productivity and increased healthcare costs).

Figure 8: Relative harms of various nicotine-containing products



Source: Nutt et al. "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach," *European Addiction Research*, Vol. 20, 2014, pp. 218-225.

As Figure 8 shows, cigarettes are far and away the most harmful source of nicotine, with a score of approximately 100, while ENDS were among the least harmful products, with a score of just 4. When considering only harm to users, ENDS were estimated to have about 5% of the harm of combustible cigarettes.

[57] David J. Nutt, Lawrence D. Phillips, David Balfour, H. Valerie Curran, Martin Dockrell, Jonathan Foulds, Karl Fagerstrom, Kgosi Letlape, Anders Milton, Riccardo Polosa, John Ramsey, and David Sweanor, "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach," *European Addiction Research*, Vol. 20, 2014, pp. 218-225.

In 2015, Public Health England, an autonomous agency of Britain's Department of Health, published a report entitled *E-cigarettes: an evidence update*, written by a team led by Ann McNeill, Professor of Tobacco Addiction in the National Addiction Centre at the Institute of Psychiatry, Psychology and Neuroscience, Kings College, University of London, and Deputy Director of the UK Center for Tobacco and Alcohol Studies.[58] The report sought to evaluate all the then-available studies on the health effects of vaping.

Of particular interest was a study published in January 2015 in the *New England Journal of Medicine* (NEJM) that purported to find higher levels of formaldehyde in vapour than in cigarette smoke. After reviewing the evidence presented in the NEJM study and other studies that investigated the effects it described, the Public Health England report concluded that the formaldehyde found in the NEJM study was caused by a phenomenon called "dry puff", which occurs when there is either too little liquid in the device or the power on a (third generation) vape device is set too high. In either case, the result is an extremely unpleasant tasting vapour. In real-world settings, experienced vapers (the vast majority of users of such devices) stop vaping when they experience a dry puff.[59] The Public Health England report states that "At normal settings, there was no or negligible formaldehyde release." So the risk of vapers being exposed to toxic doses of formaldehyde from vapour is likely very low.

The Public Health England report also reviewed studies that compared levels of other aldehydes (the class of chemical that includes formaldehyde) in the urine of vapers and cigarette smokers. These chemicals are present in tobacco smoke and are also produced in varying quantities as breakdown products when propylene glycol or glycerin are heated. The report concluded that vapers (including those who were also still smoking some cigarettes—so called "dual users") had far lower levels of various aldehydes than smokers. In summary, the Public Health England report found "no indication" that vapers are "exposed to dangerous levels of aldehydes".[60]

After considering all the available evidence, the Public Health England report concluded that "the current best estimate" is that vaping is "around 95% safer than smoking."

In April 2016, the Royal College of Physicians produced a report entitled "Nicotine without smoke: tobacco harm reduction," which covered much the same ground as the Public Health England report and came to similar conclusions.

[58] Anne McNeill, L.S. Brose, R. Calder, S.C. Hitchman, P. Hajek, H. McRobbie, *E-Cigarettes: an evidence update. A report commissioned by Public Health England*. London: Public Health England, 2015.

[59] Konstantinos Farsalinos, Vassilis Voudris, and Konstantinos Poulas, "E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions," *Addiction*, 2015, Vol. 10(8). DOI: 10.1111/add.12942

[60] Ibid at 78.

2.2 How Effective Is Vaping as an Aid to Reducing Smoking?

In 2011, Dr Pasquale Caponnetto and Professor Riccardo Polosa, along with colleagues from the Center for the Prevention and Cessation of Tobacco Related Disease at the University of Catania in Italy, published case study reports on five heavy smokers who had switched to vaping.[61] All five subjects had repeatedly tried and failed to quit smoking, including by attending the authors' smoking cessation clinic (where they were prescribed nicotine replacement therapy, among other interventions). In routine follow-up calls, representatives of the clinic discovered that while the clinics' own treatments had failed, the five had subsequently quit smoking after experimenting with the use of a cigalike vape device.

The discovery that some of their patients were quitting spontaneously by using vape products led Dr Caponnetto and Professor Polosa to undertake a trial to investigate whether vape products might be more widely effective as an alternative to traditional quit aids. In a six-month investigation, their team provided free cigalike vape products to 40 smokers who were not intending to quit. They found that after 24 weeks, 9 of the participants (22.5 percent) remained abstinent, while a further 13 (32.5 percent) had cut their cigarette consumption by 50%.[62]

A potential problem with this first study, known as a "cohort study," is the lack of a "control" group, which makes it difficult to discern whether the effects found were merely the consequence of a "placebo effect." In an attempt to overcome this problem, Caponnetto and Polosa undertook a randomized, controlled trial, in which 300 subjects were split into three groups of 100: two "treatment" groups that received cigalike vape products containing differing amounts of nicotine (half had cartridges with 7.2 mg nicotine for 12 weeks; the other had cartridges with 7.2 mg nicotine for 6 weeks followed by 5.4 mg of nicotine for 6 weeks) and a "control" group given cigalike vape products without nicotine. In all groups, the number of cigarettes smoked declined by between 20% and 26% at week 12 and by between 9% and 12% at week 52 (40 weeks after the end of treatment).[63] As the authors observe, "This was unpredicted, bringing into question the key function of nicotine in cigarette dependence and suggesting that other factors such as the rituals associated with cigarette handling and manipulation may also play an important role."[64]

The story is even more complicated when it comes to quitting, however. Among the groups that received cigalikes containing nicotine, quit rates of 11% and 17% were observed at week 12 and 13% and 9% at week 52. By contrast, in the group whose cigalikes contained no nicotine, quit rates of just 4% were observed. But the authors attribute this difference to the less acceptable taste of the no

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[61] Pasquale Caponnetto, Riccardo Polosa, Cristina Russo, Carmelo Leotta, and Davide Campagna, "Successful smoking cessation with electronic cigarettes in smokers with a documented history of recurring relapses: a case series," *Journal of Medical Case Reports*, Vol. 5, 2011; Pasquale Caponnetto, Riccardo Polosa, Roberta Auditore, Cristina Russo, and Davide Campagna, "Smoking Cessation with E-Cigarettes in Smokers with a Documented History of Depression and Recurring Relapses," *International Journal of Clinical Medicine*, Vol. 2, pp. 281-284, 2011.

[62] Riccardo Polosa, Pasquale Caponnetto, Jaymin B Morjaria, Gabriella Papale, Davide Campagna and Cristina Russo, "Effect of an electronic nicotine delivery device (e-Cigarette) on smoking reduction and cessation: a prospective 6-month pilot study," *BMC Public Health,* Vol.11, pp. 786-, 2011. DOI: 10.1186/1471-2458-11-786

[63] Pasquale Caponnetto, Davide Campagna, Fabio Cibella, Jaymin B. Morjaria, Massimo Caruso, Cristina Russo, Riccardo Polosa, "EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study," PLoS ONE, vol. 8(6): e66317. doi:10.1371/journal.pone.0066317.

[64] Ibid at p. 9.

nicotine cigalike and conclude that "In our opinion, it is likely that with this underperforming model all three study groups were similarly behaving as controls."[65]

Another randomized controlled trial, conducted in New Zealand and led by Professor Chris Bullen, Director of the National Institute for Health Innovation at the University of Auckland, sought to compare the effectiveness of a first generation cigalike vape device with a nicotine patch as quit aids among 657 smokers intending to quit.[66] In the trial, 7.3% of participants who vaped with a nicotine cigalike remained abstinent from smoking 12 weeks after their target quit date, compared with 5.8% of those who used a nicotine patch and 4.1% using a cigalike with no nicotine. The authors determined that any difference in outcome between the groups was not significant. By contrast, the proportion of those who reduced their cigarette consumption by more than 50% *was* significantly greater among those vaping with a nicotine cigalike than those who used a nicotine patch or a zero nicotine cigalike.

In December 2014, the Cochrane Library published a systematic review of the efficacy of vaping for smoking cessation and reduction.[67] Undertaken by an international team led by Dr Hayden McRobbie, Professor in Public Health Interventions at the Centre for Environmental and Preventive Medicine, Queen Mary University of London, the review considered the two randomised controlled trials discussed above, as well as several cohort studies, including the one conducted by Caponnetto, Polosa, et al. The authors concluded that:

> *There is evidence from two trials that ECs help smokers to stop smoking long-term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low' by GRADE standards. The lack of difference between the effect of ECs compared with nicotine patches found in one trial is uncertain for similar reasons. ECs appear to help smokers unable to stop smoking altogether to reduce their cigarette consumption when compared with placebo ECs and nicotine patches, but the above limitations also affect certainty in this finding. In addition, lack of biochemical assessment of the actual reduction in smoke intake further limits this evidence. No evidence emerged that short-term EC use is associated with health risk.*[68]

A further randomised controlled trial was carried out in 2013 and 2014 by a team led by Donna Shelley, co-director of the Center for Drug Use and HIV Research at New York University. The study considered the effectiveness of vape products (cigalikes) as a substitute for cigarettes among, "a diverse young adult sample of current everyday smokers, who were not ready to quit."[69] The

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[65] Ibid at p. 10.

[66] Dr Christopher Bullen, Colin Howe, Murray Laugesen, Hayden McRobbie, Varsha Parag, Jonathan Williman, and Natalie Walker, "Electronic cigarettes for smoking cessation: a randomised controlled trial," *The Lancet*, Volume 382, No. 9905, pp. 1629–1637, 16 November 2013. DOI: http://dx.doi.org/10.1016/S0140-6736(13)61842-5

[67] Hayden McRobbie, Chris Bullen, Jamie Hartmann-Boyce, and Peter Hajek, *Electronic cigarettes for smoking cessation and reduction*, Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD010216.

DOI: 10.1002/14651858.CD010216.pub2.

[68] Ibid

[69] Tuo-Yen Tseng, Jamie S. Ostroff, Alena Campo, Meghan Gerard, Thomas Kirchner, John Rotrosen, and Donna Shelley, "A Randomized Trial Comparing the Effect of Nicotine Versus Placebo Electronic Cigarettes on Smoking Reduction Among Young Adult Smokers," Nicotine and Tobacco Research, 2016, published online: http://ntr.oxfordjournals.org/content/early/2016/02/03/ntr.ntw017.abstract

researchers found that vaping with either zero nicotine ("placebo") cigalikes or cigalikes that delivered 4.5 percent nicotine all resulted in a significant reduction in the number of cigarettes consumed per day. In line with the conclusions of the Cochrane study, the researchers found that smokers who vaped cigalikes with nicotine consumed significantly fewer cigarettes on average than those who vaped zero nicotine cigalikes.

In addition to these trial-based studies, several researchers have used survey-based evidence to investigate the effects of vaping on cigarette consumptions. A 2014 study led by Jamie Brown of the Cancer Research UK Health Behavior Research Center at University College London, compared the effectiveness of vapour products to conventional NRT as a means of stopping smoking. Researchers used responses from surveys conducted in England between 2009 and 2014, from which they identified 5,863 adults who "had smoked within the previous 12 months and made at least one quit attempt during that period." Of those, 464 (8%) had attempted to quit with the aid of vaping, 1,922 (33%) had used over-the-counter NRT, and 3,477 (59%) had used no aid. The researchers found that vapers were significantly more likely to remain abstinent from smoking for 20 weeks or more than were people using NRT or no aid.[70]

A 2015 study led by Professor Cristine Delnevo of the Center for Tobacco Studies at Rutgers University, using data from the 2014 National Health Interview Survey, found that 13 percent of U.S. adults who quit smoking cigarettes during the previous year vaped on a daily basis—four times the proportion of current smokers who did so—providing more evidence that vaping is being used widely and effectively as an alternative to smoking.[71]

A study from France found that about a quarter (23.4%) of 15,635 adults (aged 15-75) surveyed by telephone in 2014 had tried vaping, about a quarter of *those* (6% of all adults) were current vapers, and half of those (3% of all adults) vaped on a daily basis.[72] The survey found that nearly all vapers were smokers (83%) or former smokers (15%) and that 80% of vapers believed vaping had reduced their cigarette consumption. The researchers who undertook the survey concluded that, if the survey is representative of the country as a whole, then approximately 400,000 people in France have switched from smoking to vaping.

Between April and July 2013, Konstantinos Farsalinos and his team undertook a worldwide online survey of "dedicated" vapers. In their subsequent analyses, they included 19,414 responses, of which only 88 (0.5%) reported not being smokers at the time they began vaping.[73] Of those participants, 81% reported quitting smoking altogether by substituting vaping, while those still smoking had on average reduced their cigarette consumption from 20 to 4 per day. A majority of former smokers had

[70] Jamie Brown, Emma Beard, Daniel Kotz, Susan Michie and Robert West, "Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study," *Addiction*, 2014, pp. 1531-1540. doi:10.1111/add.12623

[71] Cristine Delnevo, Daniel Giovenco, Michael Steinberg, Andrea Villanti, Jennifer Pearson, Raymond Niaura, and David B. Abrams, "Patterns of Electronic Cigarette Use Among Adults in the United States," *Nicotine and Tobacco Research*, 2015, (published online first). doi: 10.1093/ntr/ntv237

[72] Rachael Andler, R. Guignard, J.L. Wilquin, F. Beck, J.B. Richard, V. Nguyen-Thanh, "Electronic cigarette use in France in 2014," *International Journal of Public Health*, 2016, Vol. 61(2), pp. 159-65. doi: 10.1007/s00038-015-0773-9.

[73] Konstantinos E. Farsalinos, Giorgio Romagna, Dimitris Tsiapras, Stamatis Kyrzopoulos, and Vassilis Voudris, "Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers," *International Journal of Environmental Research and Public Health*, 2014, Vol. 11, pp. 4356-4373; doi:10.3390/ijerph110404356

been highly dependent on cigarettes, smoking on average 21 per day. Most participants said they had switched to vaping for health reasons and many participants experienced health benefits including improvements in various pre-existing disease conditions such as asthma and chronic obstructive pulmonary disease. Farsalinos et al. concluded that vaping, "can be effective even in highly-dependent smokers and are used as long-term substitutes for smoking."[74] They also note that "High levels of nicotine are used at initiation; subsequently, users try to reduce nicotine consumption, with only a small minority using non-nicotine liquids."

In a recently published study, Konstantinos Farsalinos and three co-authors reviewed data from a representative survey of 27,460 people aged 15 and older in 28 EU countries, undertaken in 2014.[75] They found that approximately 31% of current smokers, 11% of former smokers and 2% of "never" smokers had "ever" vaped. About three-quarters of those who had vaped reported using nicotine. However, initiation of nicotine consumption by vaping was under 1% of those who had ever used a tobacco product. Among those who reported vaping with nicotine on a daily basis, 70.4% were current smokers, 27.7% were former smokers, and 1.9% were never smokers. Farsalinos et al. found that of those who had ever vaped, 14% reported that they had quit smoking and another 21% reported that they had reduced their cigarette consumption. By extrapolating these results to the whole EU population, Farsalinos et al. estimate that 6.1 million EU citizens had, by 2014, quit smoking by switching to vaping, while a further 9.2 million had reduced the amount they smoked. The rates of quitting and reduction were higher for current vapers, at 35% and 32% respectively.

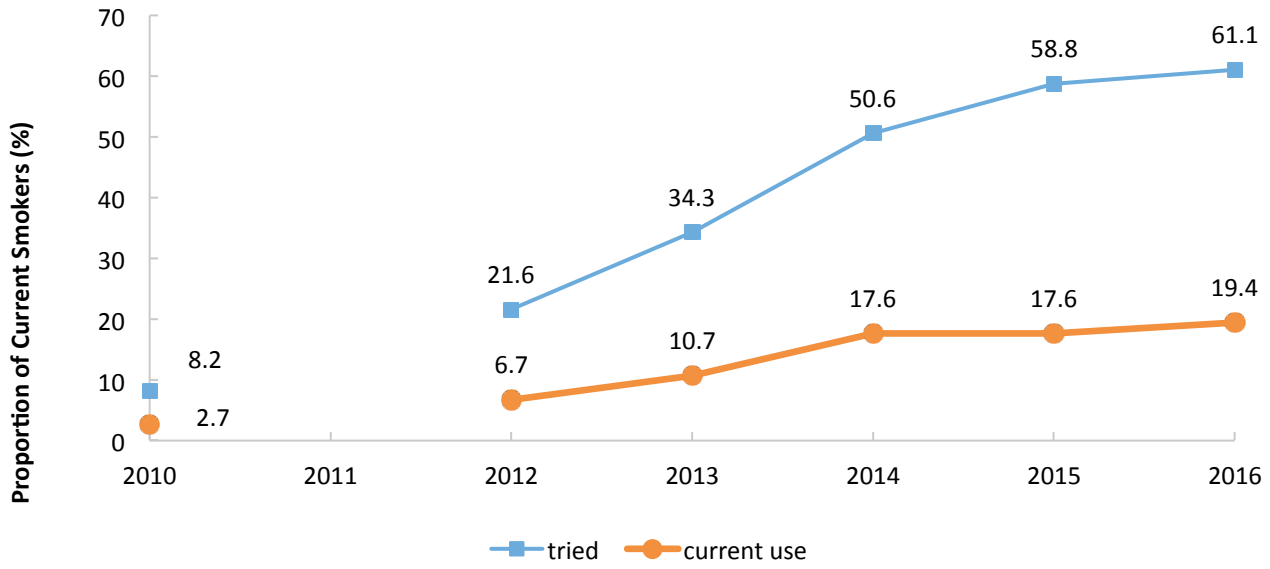
In seeking an answer to the question as to whether vaping helps smokers quit, perhaps the most relevant surveys are those that have been undertaken by Action on Smoking and Health UK (ASHUK). These began in 2010 with a survey of smokers, who were asked various questions about their use of vape devices. Since 2012, questions about the use of vape products have been asked each year in a representative survey of the general population. Figure 9 shows how experimentation and use of vape products has increased since 2010.

Meanwhile, as Figure 10 shows, the proportion of vapers in the UK who are smokers has declined from 65% in 2013 to 51% in 2016, while the proportion of vapers who are ex-smokers has risen from 30% in 2013 to 47% in 2016. In addition, 67% of ex-smokers and 35% of current smokers say the reason they vape is "To help me stop smoking tobacco entirely." For current smokers, a slightly larger proportion, 41%, say that they vape "To help me reduce the amount of tobacco I use, but not stop completely."

[74] Ibid.

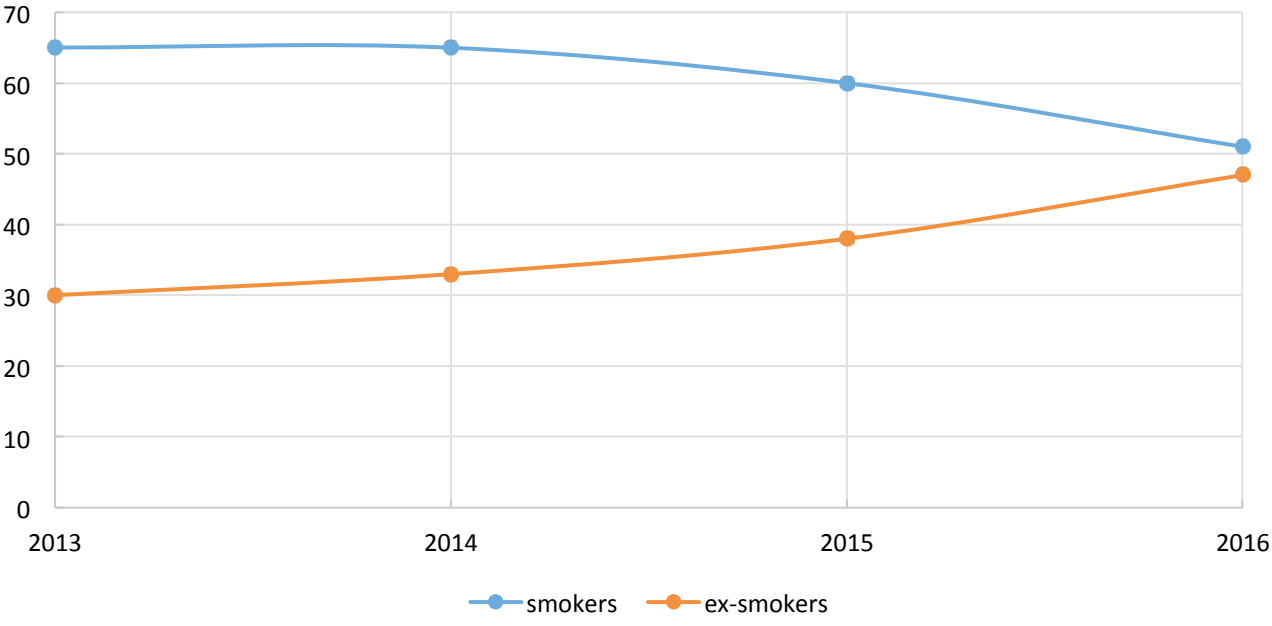
[75] Konstantinos E Farsalinos, Konstantinos Poulas, Vassilis Voudris, and Jacques Le Houezec, "Electronic cigarette use in the European Union: analysis of a representative sample of 27,460 Europeans from 28 countries," *Addiction*, 2016, Jun 24; doi: 10.1111/add.13506.

Figure 9: Use of Vape Products Among Current Cigarette Smokers in Great Britain



Taken together, these data provide a strong indication that a large proportion of people in the UK who take up vaping do so in order to quit smoking and that a significant proportion of current smokers in the UK are vaping in order to quit smoking. Based on these survey data, ASHUK estimates that by the time of the 2016 survey there were 2.8 million vapers in the UK, of whom approximately 1.3 million are ex-smokers.

Figure 10: Proportion of vapers in the UK who are smokers or ex-smokers



Source: ASH 891 May 2016

2.3 Innovation and the Effectiveness of Vaping Devices as Substitutes for Cigarettes

One of the challenges facing researchers investigating the effectiveness of vape products is the fact that there has been considerable innovation in these products over the course of the past decade, resulting in a wide array of different products with highly varied characteristics. So, conclusions drawn from investigations using one product might not be applicable to other products.

Take nicotine delivery, for example. In 2014, Megan Schroeder and Allison Hoffman of the U.S. Food and Drug Administration Center for Tobacco Products reviewed studies of nicotine delivery from various different vapour products.[76] They found that nicotine delivery from vapour products was substantially different from cigarettes but varied considerably depending on the type of device. All vapour products included in the review delivered nicotine more slowly than cigarettes. For first generation cigalikes, the maximum blood plasma concentration remained lower than for cigarettes even after (unrealistically) intensive puffing. By contrast, people vaping on second generation devices were able to achieve blood plasma concentrations similar to the peak concentrations smokers achieve.

Konstantinos Farsalinos and his team at the Onassis Cardiac Surgery Center in Kallithea, Greece, investigated the relative effectiveness of two vape devices in delivering nicotine: a first generation cigalike and a second generation tank system. In both cases, the same liquid was used; a solution of 18 mg/ml of nicotine in a base of approximately 65% glycerol and 35% propylene glycol.[77] The effectiveness of the two devices in delivering nicotine—and a comparison with combustible cigarettes—may be seen in Figure 11. Combustible cigarettes deliver peak nicotine concentrations in about five minutes, whereas the vape devices take over 30 minutes. While the first generation vape device achieves a peak blood nicotine concentration of about 11 ng/ml, the second generation device achieves a peak blood nicotine concentration of nearly 18.5 ng/ml, which is very similar to the peak level from smoking a cigarette (18.8 ng/ml). Farsalinos et al. conclude that while newer devices are able to deliver more nicotine due to the higher power heating coils and larger batteries, higher concentrations of nicotine in liquids might "make them more successful for smoking substitutes."

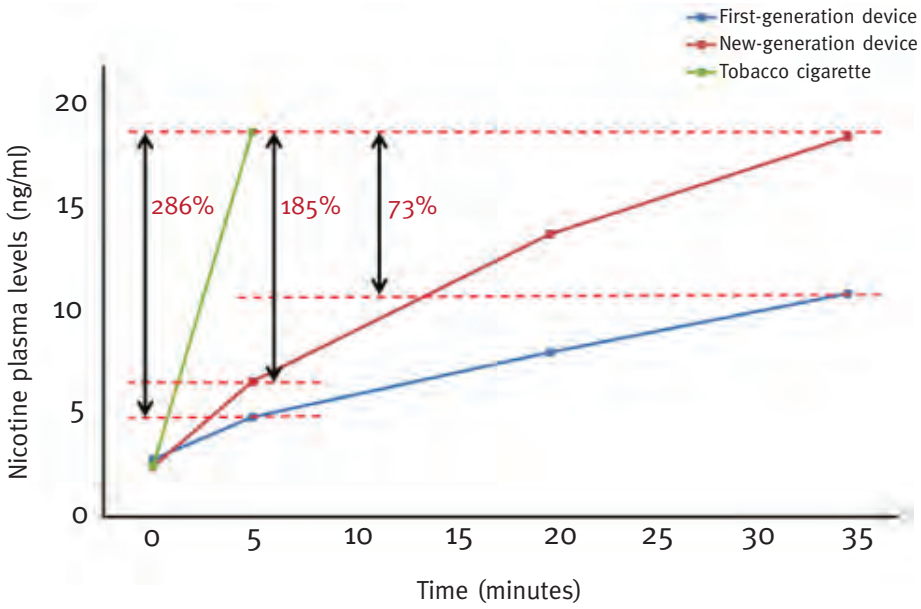
These conclusions are supported by research conducted by a team led by Sara Hitchman of the Department of Addictions at the Institute of Psychiatry, Psychology and Neuroscience at Kings College London, which undertook an online longitudinal survey of smokers in Great Britain, and found that people using tank models had a significantly higher quit rate than those using cigalikes.[78]

[76] Megan J Schroeder, Allison C Hoffman, "Electronic cigarettes and nicotine clinical pharmacology," *Tobacco Control,* 2014, Vol. 23, pp. ii30–ii35. doi:10.1136/tobaccocontrol-2013-051469

[77] Konstantinos Farsalinos, Alketa Spyrou, Kalliroi Tsimopoulou, Christos Stefopoulos, Giorgio Romagna and Vassilis Voudris, "Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices," *Scientific Reports*, 2014, Vol. 4, Article Number 4133, doi:10.1038/srep04133.

[78] Sara C. Hitchman, Leonie S. Brose, Jamie Brown, Debbie Robson, and Ann McNeill, "Associations Between E-Cigarette Type, Frequency of Use, and Quitting Smoking: Findings From a Longitudinal Online Panel Survey in Great Britain," *Nicotine and Tobacco Research*, 2015, Vol. 17(10), pp. 1187–1194. doi: 10.1093/ntr/ntv078

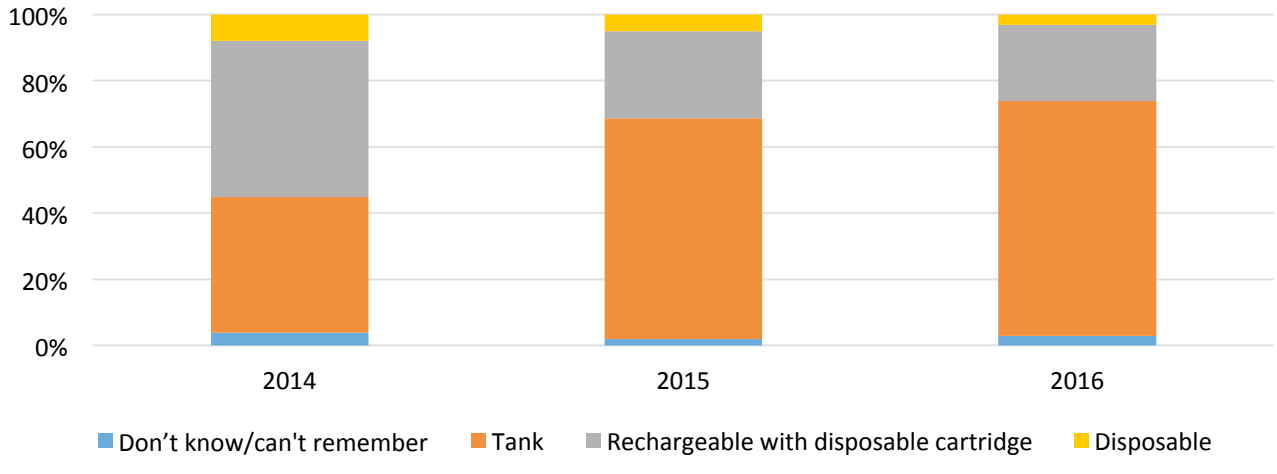
Figure 11: Effectiveness of First and New Generation Vape Devices in Nicotine Delivery, Compared to Cigarettes



Source: Farsalinos et al. "Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices," *Scientific Reports*, 2014, Vol. 4, Article Number 4133, doi:10.1038/srep04133.

In addition, there have been numerous surveys looking at the proportion of people who vape, what type of device they use and other characteristics of their vaping habits. The ASHUK surveys discussed above show that the proportion of vapers using tank models has increased from 41% in 2014 to 71% in 2016. In the US, a 2015 survey put the use of tank models at 60%.

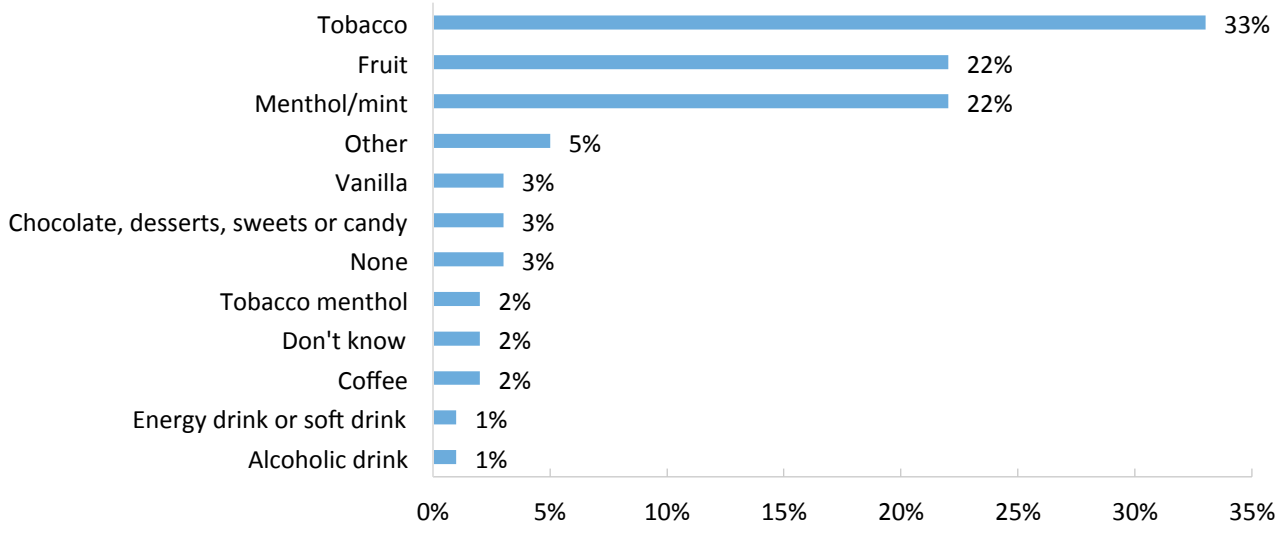
Figure 12: Most Popular Devices Used by UK Vapers



Source: ASHUK, Use of electronic cigarettes (vapourisers) among adults in Great Britain, 2016.

Surveys also show that vapers like a wide variety of different flavours. The most recent ASHUK survey, for example, found that while the most popular flavour of vape liquid remains tobacco, the second most popular flavour *among adults* is fruit flavour—see Figure 13.

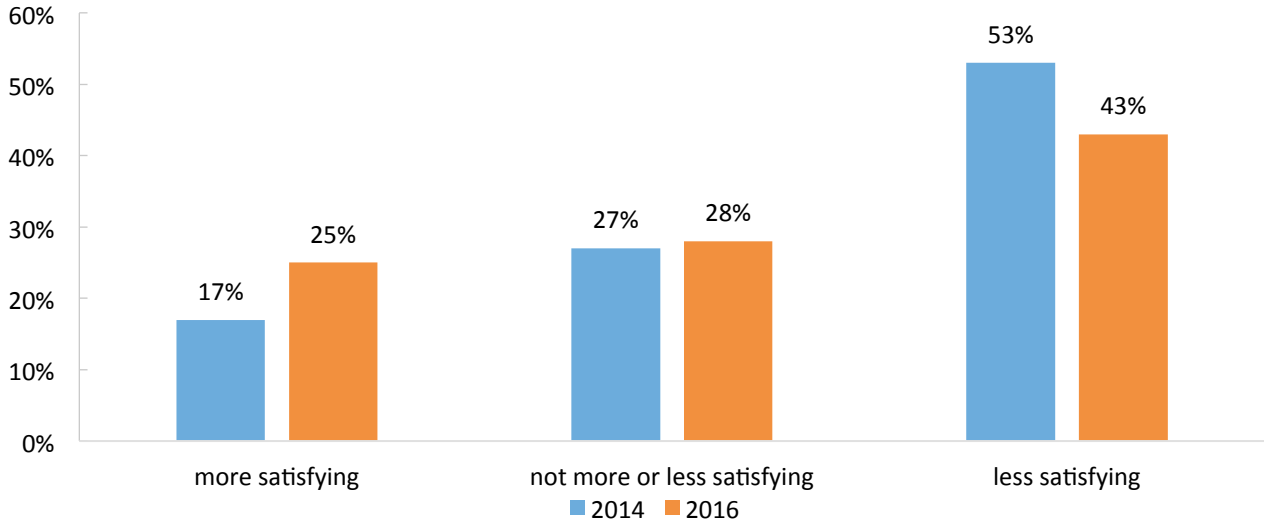
Figure 13: Flavours most often used by current vapers



Source: ASHUK, Use of electronic cigarettes (vapourisers) among adults in Great Britain, 2016.

The ASHUK surveys also found that 25% of vapers are now more likely to find vaping more satisfying than smoking, compared with only 17% in 2014. Meanwhile, the proportion of vapers who found vaping less satisfying has fallen from 53% to 43%. (See Figure 14.)

Figure 14: Current vapers' satisfaction with vaping compared with smoking



Source: ASHUK, Use of electronic cigarettes (vapourisers) among adults in Great Britain, 2016.

Conclusions of sections 2.1-2.3

From this review of the evidence, it seems reasonable to draw the following conclusions:

1. First, effective nicotine delivery is an important characteristic of vaping for some but not all people who choose to use vape devices as a means of quitting smoking.
2. Second, effective delivery of nicotine has been both a goal and an outcome of the development of many new devices.
3. Third, while newer tank model vape devices are able to deliver similar levels of nicotine to cigarettes, they typically do so more slowly.
4. Fourth, the increasing popularity of newer tank models suggests that vapers prefer the experience of vaping using such models; for many consumers, this is at least partly due to the ability of those models to deliver nicotine more effectively.
5. Fifth, the existence of a diversity of flavours of liquid has almost certainly enhanced the attractiveness of vaping as an alternative to smoking.

More generally, and more importantly, innovations that have improved the quality and expanded the diversity of both vape devices and liquids have played an important role in making vaping a more attractive alternative to smoking. As a result, millions of smokers have switched entirely to vaping and millions more are using vaping to reduce their smoking. Given time and further innovation, vaping has the potential to continue dramatically to reduce both the number of people who smoke and the number of cigarettes smoked by those who choose to continue to smoke.

2.4 Does Vaping Encourage or Discourage Youth Smoking Initiation?

Some researchers have raised concerns that vape devices might "renormalize" smoking and lead to an increase in the number of people addicted to nicotine. The evidence presented above suggests that such worries are not justified with respect to adult vapers, the vast majority of whom are smokers or ex-smokers motivated to reduce their consumption of cigarettes or stop smoking altogether. But is there reason to be concerned about youth initiating smoking after vaping?

In 2015, the *Journal of the American Medical Association* published a study by a team of ten researchers, led by Adam Leventhal of the Department of Preventative Medicine at the University of Southern California, that reported an association between vaping by youths and subsequent smoking six months and one year later. Specifically, they found that from a total sample of 3,326 ninth graders (average age, 14.1 years) in the Los Angeles area, 617 said they had "ever" vaped and, of those, 392 said they had used one or more forms of combustible tobacco and 225 said they had never used any combustible tobacco. At follow-up, only youths who said they had "never" smoked in the original survey were included; with attrition, the total sample fell to 2,530, of whom 222 had "ever" vaped. At 6 months, 249 of those students said they had smoked in the previous six months, of whom 67 were "ever" vapers. At 12 months, 264 students said they had smoked in the previous six months, of whom

54 were "ever" vapers. The authors concluded on the basis of this evidence that a greater proportion of youths who had tried vaping prior to the survey went on to try smoking—and inferred that experimenting with vaping leads to smoking.[79]

An alternative explanation for the apparent association between youths trying vaping and then trying smoking is that those youths had certain characteristics that made them more likely to engage in both types of behaviour. Indeed, the researchers found just that; youth smoking was associated with: "lower parental education and baseline peer smoking, impulsivity, ever use of non-nicotine or tobacco substances, delinquent behaviour, and smoking expectancies." And the same factors, "also were associated with baseline e-cigarette ever use."[80]

Three subsequent studies made similar findings.[81] From these studies, it seems reasonable to conclude that some young people who experiment with vaping are also likely to experiment with smoking. Whether vaping leads to smoking is less clear. One problem with all four studies is that they only investigated whether experimenting with vaping leads to experimenting with smoking, they did not investigate whether frequent vaping leads to frequent smoking. While some attempt was made in three of the studies to account for the fact that people who vape likely share certain characteristics, such as a propensity to engage in novelty-seeking and/or risky behaviour, it remains quite possible that these characteristics, rather than a desire for nicotine primed by vaping, explains much of the observed subsequent smoking among "ever" vapers.

Another problem with the studies is that they did not investigate whether youth smokers switch to vaping, which seems like a highly relevant question. One way to try to answer this question is to look at smoking trends and vaping trends among youth. The U.S. National Institutes of Health conducts an annual survey of approximately 50,000 8th, 10th and 12th grade children that includes questions on smoking habits.[82] Since the mid-1990s, that survey has found that smoking rates have declined dramatically and continuously.[83] Although the rate of decline slowed in the mid-2000s, it picked up again about five years ago, just as rates of vaping began rising. In the most recent survey, more teenagers reported vaping "in the past 30 days" than reported smoking in the same period.[84] (However, there is inadequate data on the number of teenagers who vape regularly in the U.S.[85])

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[79] Adam Leventhal, David Strong, Matthew Kirkpatrick, Jennifer Unger, Steve Sussman, Nathaniel Riggs, Matthew Stone, Rubin Khoddam, Jonathan Samet, and Janet Audrain-McGovern, "Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence," *Journal of the American Medical Association*, 2015, Vol. 314(7), pp. 700-707. doi:10.1001/jama.2015.8950

[80] Ibid.

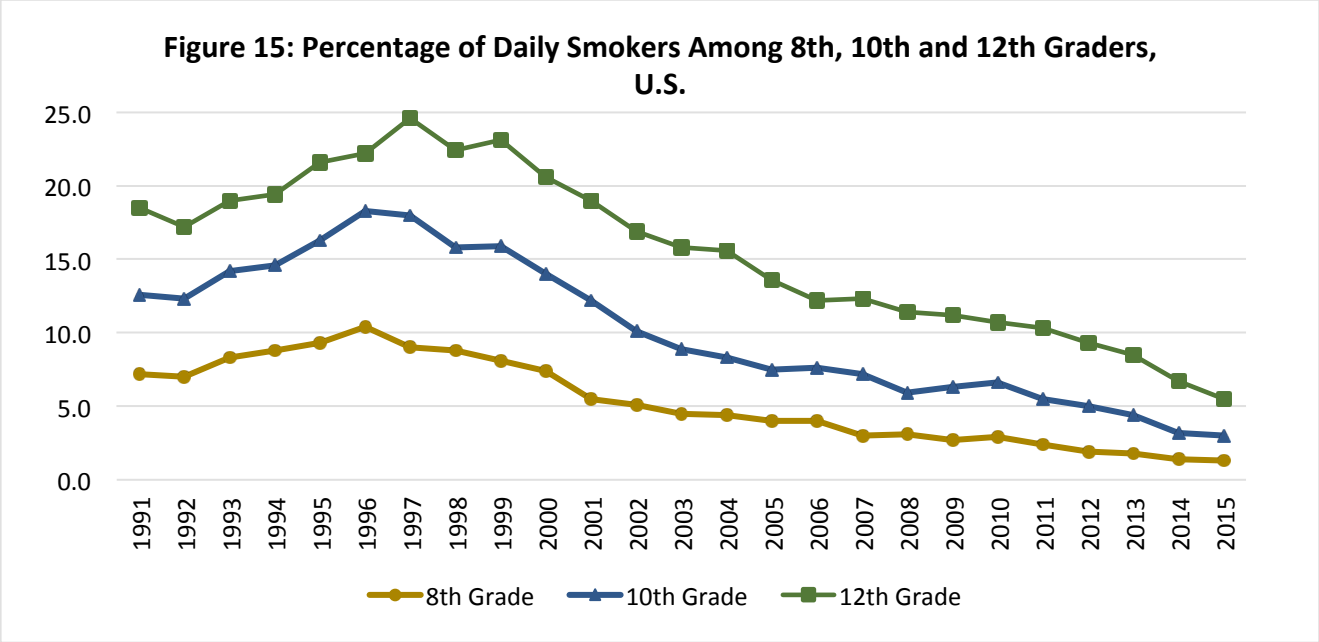
[81] Thomas Wills, Rebecca Knight, James Sargent, Frederick Gibbons, Ian Pagano, and Rebecca Williams, "Longitudinal study of e-cigarette use and onset of cigarette smoking among high school students in Hawaii," *Tobacco Control*, doi:10.1136/tobaccocontrol-2015-052705; Jessica L. Barrington-Trimis, Robert Urman, Kiros Berhane, Jennifer Unger, Tess Boley Cruz, Mary Ann Pentz, Jonathan Samet, Adam Leventhal, and Rob McConnell, "E-Cigarettes and Future Cigarette Use," *Pediatrics*, 2016, Vol. 138(1):e20160379

[82] www.monitoringthefuture.org.

[83] Data from: http://www.monitoringthefuture.org/data/15data/15cigtbl1.pdf

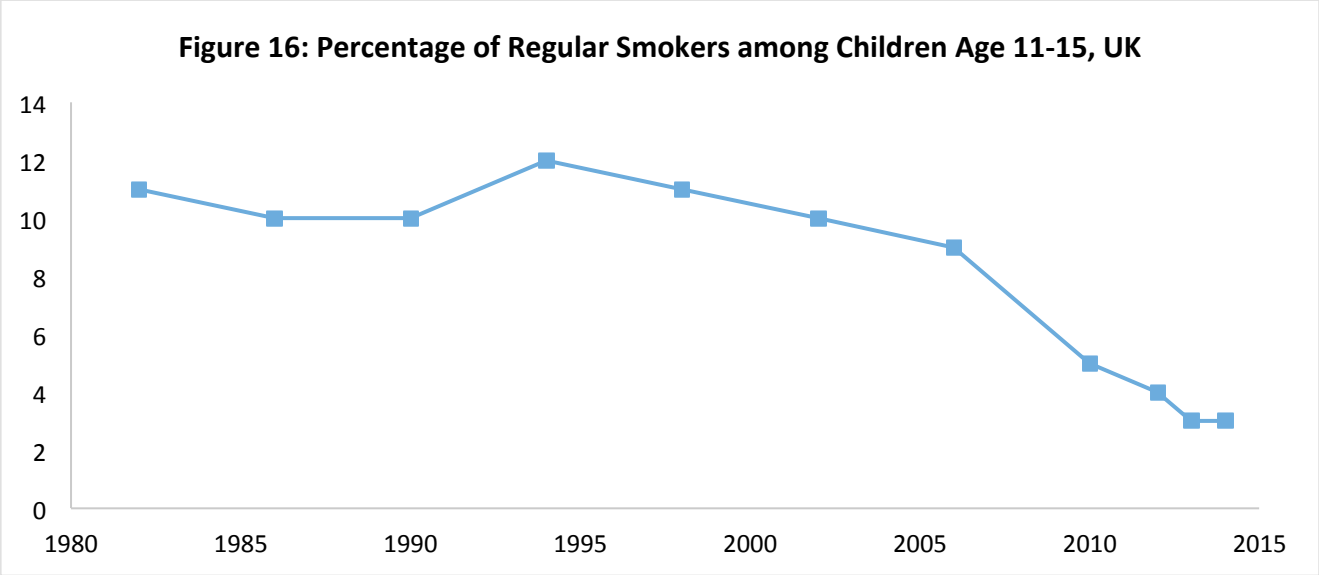
[84] For vaping, "30-day prevalence was 9.5%, 14.0%, and 16.2% in 8th, 10th, and 12th grade. The corresponding prevalence for tobacco cigarettes was 3.6%, 6.3%, and 11.4%." Lloyd Johnston, Patrick O'Malley, Richard Miech, Jerald G. Bachman, and John E. Schulenberg, *Monitoring the Future 2015 Overview, sponsored by the National Institute on Drug Abuse and National Institutes of Health*, Michigan: Institute for Social Research, The University of Michigan, Ann Arbor, Michigan, February 2016, at p. 41.

[85] Jonathan Foulds, "Use of Electronic Cigarettes by Adolescents," *Journal of Adolescent Health*, 2015, Vol. 57, pp. 569-570.



Source: Monitoring the Future survey, U.S. National Institutes of Health, 2016.

A similar picture emerges in the UK. A 2015 survey of 11-18 year old Brits commissioned by ASHUK found that only 4 percent of youth "ever" vapers were "never" smokers; this fell to 0.1% for those who vaped once per month or more.[86] (ASHUK also reports on several other surveys from the UK that likewise found extremely low levels of vaping among never smokers, with two surveys finding rates of "at least monthly" use of levels below 0.1% and one of 0.3%.). Meanwhile, rates of daily smoking among children age 11-15 have declined dramatically in the past 5 years, as can be seen in Figure 16.



Source: Action on Smoking and Health UK, *Young People and Smoking*, Fact Sheet, July 2015.

[86] Action on Smoking and Health UK, *Use of electronic cigarettes among children in Great Britain*, August 2015. (www.ash.org.uk)

A study by Abigail Friedman of the Department of Health Policy Management at Yale University sought to investigate the substitution of vaping for smoking among minors. To do this, Dr Friedman looked at how state bans on the sale of vape products to minors influence smoking rates among 12 to 17 year olds. She found that "such bans yield a statistically significant 0.9 percentage point increase in recent smoking in this age group, relative to states without such bans." She also notes that "This effect is both consistent with e-cigarette access reducing smoking among minors, and large: banning electronic cigarette sales to minors counteracts 70 percent of the downward pre-trend in teen cigarette smoking for a given two-year period." One interpretation of this is that use of vape products explains as much as 70% of the recent downward trend in cigarette consumption.

Another study, by Dr Michael Pesko and colleagues at the Department of Healthcare Policy and Research at Cornell University, likewise found that regular smoking by minors was nearly 1% higher in states with restrictions on the sale of vapour products to youths.[87]

There are also problems with one of the alleged mechanisms by which vaping is supposed to lead to smoking, namely exposure to nicotine. In its 2015 Monitoring the Future survey, the U.S. National Institutes of Health found that only 20% of youths who reported vaping stated that the device they used contained nicotine. While this may underestimate the proportion that in fact vaped with nicotine, it does indicate that nicotine is not—consciously at least—the reason these youths are vaping.[88] And if 80% of youth are not vaping for the nicotine—or don't associate vaping with nicotine—why would they then smoke for the nicotine?

Given the significant declines in youth smoking coincident with the increase in youth vaping, the evidence actually indicates that vaping is more likely to reduce youth smoking than to increase it. This conclusion is reinforced by work by Dr Neil McKegany and colleagues at the Centre for Substance Use Research at Glasgow University, who interviewed young vapers to discover how they viewed vaping compared with smoking.[89] Their conclusions are revealing:

> *The young people we were interviewing saw vaping and smoking as being associated with very different harms and whilst some were focussed on nicotine others were more focussed on flavours and plumes. The predominant view was that vaping had made smoking less likely not more likely and it had not for the most part re-normalised smoking. The transition from vaping to smoking would involve the individual in engaging in a form of drug use (smoking) which was accepted as being substantially more harmful and dissimilar to the form of drug use (vaping) in which they were presently engaging.*

[87] Michael Pesko, , Jenna Hughes, and Fatima Faisal, "The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use," *Preventative Medicine*, 2016, Vol. 87, pp. 207-212.

[88] As the authors of the *Monitoring the Future* study point out: "Overall, the finding that youth vape 'just flavoring' more than all other substances combined suggests that the recent, exponential increase in adolescent vaporizer use does not necessarily indicate a corresponding jump in use of substances such as nicotine or marijuana, as has been feared. See: Lloyd Johnston, Patrick O'Malley, Richard Miech, Jerald G. Bachman, John E. Schulenberg, *Monitoring the Future 2015 Overview, sponsored by the National Institute on Drug Abuse and National Institutes of Health*, Michigan: Institute for Social Research, The University of Michigan, Ann Arbor, Michigan, February 2016, at p. 41. See also: https://www.nih.gov/news-events/news-releases/drug-use-trends-remain-stable-or-decline-among-teens

[89] Neil McKeganey Ph.D Marina Barnard Ph.D Christopher Russell Ph.D Centre for Substance Use Research Glasgow

Conclusions of section 2.4

Youths who experiment with vaping seem to be more likely to experiment with smoking. Probably, such youths have a higher propensity to engage in novelty-seeking and/or risky behaviours, as well as sharing other characteristics. Interviews with youths who regularly vape, however, suggests that vaping is considered quite different to and less risky than smoking. Surveys suggest that as more youths vape, fewer smoke. And while there has been a general decline in youth smoking in the US, in those jurisdictions where access to vape products is legally restricted the rate of decline has been lower, presumably because in these locations fewer youths are vaping as a substitute for smoking.

It seems reasonable to conclude from this evidence that while some youths probably do take up smoking after experimenting with vaping, considerably more youths are vaping *instead* of smoking. As a result, in places where vaping has become widespread, fewer youths are smoking and those who are smoking are smoking less. Thus, vaping is displacing smoking, with potentially enormous public health benefits.

2.5 Long-Term Effects of Switching to Vaping: Lessons from the Use of Snus

Vape products have been in widespread use for less than a decade and data on the implications of long-term use have not yet been collected. But there is a less harmful tobacco product that has been in use for several decades, from which inferences might be drawn. Snus, a form of pasteurized wet snuff—a smokeless tobacco—that is kept refrigerated, was developed by Swedish Match in the 1970s. Since then, it has become very popular in Sweden and, more recently, in Norway.

In 2003, *Tobacco Control* published a study by Dr Jonathan Foulds, then at the Tobacco Dependence Institute of the University of Medicine and Dentistry in New Jersey, and three co-authors, published a review of the effect of Snus use in Sweden.[90] The authors noted that "Snus is manufactured and stored in a manner that causes it to deliver lower concentrations of some harmful chemicals than other tobacco products, although it can deliver high doses of nicotine. It is dependence forming, but does not appear to cause cancer or respiratory diseases. It may cause a slight increase in cardiovascular risks and is likely to be harmful to the unborn fetus, although these risks are lower than those caused by smoking." Moreover, Foulds et al. noted that as a result of increased use of Snus in Sweden:

> *There has been a larger drop in male daily smoking (from 40% in 1976 to 15% in 2002) than female daily smoking (34% in 1976 to 20% in 2002) in Sweden, with a substantial proportion (around 30%) of male ex-smokers using snus when quitting smoking. Over the same time period, rates of lung cancer and myocardial infarction have dropped significantly faster among Swedish men than women and remain at low levels as compared with other developed countries with a long history of tobacco use.*

[90] Jonathan Foulds, Lars Ramstrom, M Burke, and Karl Fagerström, "Effect of smokeless tobacco (snus) on smoking and public health in Sweden," *Tobacco Control*, 2003, Vol. 12, pp. 349-359 doi:10.1136/tc.12.4.349.

In a subsequent paper also published in *Tobacco Control*, Lars Ramstrom and Jonathan Foulds report on a survey of 6,752 adult Swedes, undertaken in 2001-2002, in which they found that "16% of the men started daily tobacco use as a snus user. Among these primary snus users 20% started daily smoking compared to 47% among non-primary snus users (OR 0.28, 95% CI 0.22 to 0.36). Thus, the odds of initiating daily smoking were significantly lower for those who had started using snus than for those who had not."[91] While there are clearly very significant differences between using snus and vaping, this finding suggests that, for those who want to consume nicotine, regular consumption of a non-combustible nicotine product may *reduce* the likelihood of initiating regular use of a combustible product.

2.6 Potential Health Benefits of Vaping

Based on the evidence summarized above, it is clear that vaping has the potential to help improve and extend the lives of tens of millions—possibly hundreds of millions—of people. It is extremely difficult to be more precise because that will depend on consumer acceptance of vaping as an alternative to smoking. Notwithstanding that caveat, this section offers a first approximation of the possible health benefits of vaping.

As noted above, Jha and Peto estimate that smokers who quit before the age of 40 reduce their likelihood of dying from smoking by 90%. If, as Nutt et al. estimate, vaping with e-liquid is 95% safer than smoking, then a person who switches from smoking to vaping e-liquid at age 40 will reduce their likelihood of dying from smoking by 85%. Since smoking on average reduces life expectancy by about 10 years, then, very crudely, switching to vaping at age 40 saves about 8.5 life years.

There are currently approximately 1 billion smokers. If all those smokers switched to vaping and all potential smokers chose to vape instead, then, again very crudely, vaping might be responsible for saving 8.5 billion life-years.[92] That is, of course, unlikely. But even if, over the next decade, only 10% of smokers were to switch and 20% of potential smokers chose vaping over smoking, it is possible that a billion or more life-years could be saved.

[91] Lars Ramstrom and Jonathan Foulds, "Role of snus in initiation and cessation of tobacco smoking in Sweden," *Tobacco Control*, 2006, Vol. 15(3), pp. 210–214. doi: 10.1136/tc.2005.014969.

[92] The actual impact would depend on the age at which smokers switch. In this crude estimate, we assume that on average smokers are 40 years old.

Conclusions of section 2

This section has reviewed evidence regarding the relative health effects of vaping compared to smoking, the rate at which adult smokers have been switching to vaping, and the effect of availability of vape products on rates of teen smoking and vaping. The picture that emerges is a very positive one from a health perspective:

- Vaping with e-liquid is estimated to be about 95% safer than smoking;
- Smokers appear to be switching to vaping at a rapid rate, with new devices attracting additional converts year-on-year;
- Those smokers who take up vaping but do not quit smoking, tend dramatically to cut down their cigarette consumption;
- Availability of vape products appears to reduce smoking initiation among young people;
- On present rates of switching and initiation-prevention, vaping may result in the saving of a billion or more life-years.

3. Government Responses to Vape Products and Vaping

Governments' responses to vaping have varied considerably, with some countries imposing very few if any restrictions on the sale, possession and use of vape products and others imposing outright bans. This section presents a brief review of the regulation of vaping and vape products—and discusses their implications.

In March 2008, Turkey became the first country to ban the sale of vape devices. According to a report in *Hurriyet Daily News*, the Director of the Ministry of Drugs and Pharmacy, Mahmut Tokaç, claimed that the devices could cause cardiovascular disease and high blood pressure, asserting that "There is nicotine in this product and it is seriously harmful to health."[93] The action by Turkey's Ministry of Health was supported by Turkey's Foundation for Combatting Smoking, whose Vice President, Kıyas Güngör, reportedly asserted that nicotine is the most harmful of 4,800 chemicals in tobacco smoke, and claimed that nothing that contains nicotine can help people quit smoking. "Quitting smoking is possible only if one can stay away from nicotine, but these electronic cigarettes increase addiction."

Ruyan, at that time the sole manufacturer of vape devices, responded to Turkey's ban on import and sale of their devices by releasing a statement in which it asserted that it had not been informed of the decision by the Turkish Ministry of Health. Ruyan's Turkish representative, Selahattin Aygüler, is reported to have said that "Electronic cigarettes are based on World Health Organization approved nicotine treatment methods."[94]

On 19 September 2008, the World Health Organisation released a statement in which Dr Ala Alwan, Assistant Director-General of WHO's Noncommunicable Diseases and Mental Health Cluster, asserted that: "The electronic cigarette is not a proven nicotine replacement therapy. WHO has no scientific evidence to confirm the product's safety and efficacy. Its marketers should immediately remove from their web sites and other informational materials any suggestion that WHO considers it to be a safe and effective smoking cessation aid."[95]

In March 2009, the U.S. Food and Drug Administration (FDA) sought to ban imports of vape devices, notifying Smoking Everywhere that shipments of its devices have been refused entry on the grounds that they are unlicensed drug-delivery devices. (This decision was overturned as a result of a lawsuit filed by Smoking Everywhere and Sottera (now Njoy).)

Also in March 2009, Health Canada issued a "Notice - To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada," in which it noted that any such device

[93] "Electronic Cigarettes Go Up in Smoke," Turkish Daily News, 1/3/2008, available at: http://www.hurriyetdailynews.com/electronic-cigarettes-go-up-in-deep-smoke.aspx?pageID=438&n=electronic-cigarettes-go-up-in-deep-smoke-2008-01-03, accessed 5/17/2016.

[94] Ibid.

[95] "Makers of electronic cigarettes should halt unapproved therapy claims," News Release, Geneva: World Health Organisation, 19 September 2008, available at: http://www.who.int/mediacentre/news/releases/2008/pr34/en/

containing nicotine would be regulated as a drug and medical device—and that no vape devices had yet been authorized as such.[96]

And in the same month, the Hong Kong Department of Health issued a notice that vape products containing nicotine were prohibited under the Special Administrative Region's Pharmacy and Poisons Ordinance.[97]

Numerous other countries subsequently imposed restrictions on the importation and sale of vapour products. Other than countries that have imposed outright bans, regulation typically takes one of the following forms: (1) Regulation of nicotine as a poison or medicinal product; (2) Regulation as tobacco products; or (3) No special regulation—governed by standard product regulation, as well as other laws (contract and tort). The form regulation takes can have significant effects, as discussed below.

3.1 Nicotine Regulated as a Poison/Restricted Medical Product

In many countries, including Canada, Australia and New Zealand, nicotine is classified as a poison and may only be sold legally if it is licensed as a medical product—such as a patch, gum or inhaler. In most such jurisdictions, these restrictions apply only to nicotine itself or products *containing* nicotine, so tank systems may be sold legally, often with few or no restrictions. Zero nicotine liquid may also typically be sold legally in those countries.[98] As a result, many consumers purchase tanks and zero-nicotine liquid legally. Those who want to vape with nicotine typically purchase it overseas and then mix it with the flavoured base liquid.

In Australia, under federal legislation, importation of nicotine liquid for personal use is technically legal but domestic possession and sale is subject to state legislation that classifies it as a poison.[99] Many vapers have chosen simply to flout the law in order to switch to a product that is far less harmful than smoking. At the Global Nicotine Forum in Warsaw, we spoke with a vaper from Australia who told us that in spite of having chronic obstructive pulmonary disease (COPD), an often-fatal lung condition, she had continued to smoke because she simply couldn't give up; then, when she found out about vaping, she enthusiastically switched—and her condition has since gone into remission.

This situation is clearly absurd and iniquitous. Apart from making criminals of people who are causing harm to no one, while improving their own lives, it almost certainly results in consumers obtaining lower quality and less consistent liquids, as well as being exposed to greater risks, because they are forced to mix their own liquids. Worse, by regulating nicotine as a medicinal product, governments effectively drive up the cost of switching from smoking to vaping. As a result, fewer people switch.

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[96] http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.php

[97] https://www.tco.gov.hk/textonly/english/infostation/infostation_04032009.html

[98] Some Australian states have restricted the sale of non-nicotine vape products.

[99] https://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes

Perhaps recognizing the absurdity and iniquity of the current situation, New Zealand's government recently announced that it proposes to legalize the sale of vape devices containing nicotine.[100]

3.2 Regulation of Vape Products as Tobacco Products

The US and EU have chosen to regulate vape products as tobacco products. However, their approaches differ substantially. Under the EU's Tobacco Products Directive, for each product, vape producers must provide:[101]

- a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;
- information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;

In addition, the TPD requires that:

- vape devices and e-liquid containers must be child-proof, protect against breakage and leakage, and have a mechanism that enables users to refill devices without leakage;
- e-liquid containers may not be larger than 10ml
- the nicotine concentration of e-liquid may not exceed 20mg/ml
- ingredients not listed may only be present in trade quantities
- ingredients "of high purity" are used in the manufacture of the nicotine-containing liquid
- except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;
- vape devices deliver the nicotine doses at consistent levels under normal conditions of use;

These requirements will almost certainly raise the cost of vape products and reduce competition. Both directly through its obligations on producers and indirectly through its effect on competition, the TPD will reduce both innovation and the diversity of products available to consumers.

But the effect of the TPD is likely to be mild compared to the Food and Drug Administration's rule "deeming" vape products to be tobacco products. Under the "deeming" rule, vape products that were not for sale on 15th February 2007 are required to obtain regulatory approval by one of two routes:

[100] http://m.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11685868

[101] Article 20 of: Directive 2014/40/EU Of The European parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

either by showing that the product is "substantially equivalent" to a product on the market on 15th February 2007, or by completing a premarket tobacco application (PMTA).

Since there were few if any vape products on the market the US in 2007, it seems unlikely that the substantial equivalence route will be widely available. So, once the rules finally come fully into effect (after 8th August 2018), only products for which manufacturers have submitted a PMTA will be permitted to be on the market. The cost of producing a PMTA is not yet known, but the FDA estimates that for an e-liquid, the cost of an initial PMTA is likely to range from $180,000 to $2 million, while for devices, the cost of an initial PMTA is likely to range from $285,000 to $2.5 million.[102] It hardly needs stating that small producers of low-volume products will not be able to afford to spend such enormous sums on a PMTA. As a result, the number of products on the market is likely to fall dramatically. There is also likely to be considerable consolidation in the industry, as subsequent PMTAs will likely be able to take advantage of information gathered during the initial process, so manufacturers using the same base liquid for multiple products will have lower average costs. But that almost certainly means there will be less competition—and, hence, less innovation.

In light of the evidence presented above, the FDA's deeming rule is utterly perverse. Until now, competition between producers and a fluid interplay between producers and consumers has led to rapid improvements in vape products, resulting in devices that are both safer and more effective as quit aids. By requiring pre-market approval (or at best proof of "substantial equivalence"), the FDA will impede that process: producers will be forced to spend hundreds of thousands of dollars and wait many months to obtain approval for each product; also, they will no longer receive rapid feedback from consumers, enabling them to tweak products to meet felt needs. So, instead of experimenting with small innovations, producers will seek regulatory approval for successful products already on the market. Meanwhile, innovation will shift to countries with less onerous regulations, where feedback will remain possible. Producers of products that are successful in those other markets might then apply for pre-market approval in the US.

Ironically, a recently published study funded by the FDA came to exactly that conclusion, warning that heavy regulation and taxation of e-cigarettes will counteract the benefit that these products can provide.[103]

[102] Office of the Commissioner, Department Of Health And Human Services Food and Drug Administration, *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements: Final Regulatory Impact Analysis; Final Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis;* Office of Policy, Planning, Legislation and Analysis, Docket No. FDA-2014-N-0189, May 2016, at pp. 87-91. Available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf, accessed 8/9/2016.

[103] David T. Levy, K. Michael Cummings, Andrea C. Villanti, Ray Niaura, David B. Abrams, Geoffrey T. Fong, and Ron Borland, "A framework for evaluating the public health impact of e-cigarettes and other vaporized nicotine products," *Addiction*, April 2016, doi:10.1111/add.13394

3.3 Regulating Vape Products as Consumer Products

While the knee-jerk reaction of many governments has been to impose stringent regulation on vape products, especially those that contain nicotine, some governments have shown remarkable restraint—at least until recently. Prior to the implementation of the TPD, vape products in the UK were regulated like any other consumer product. Similarly, in the US, between early 2010 (when the attempt by the FDA to regulate vape products as drug/delivery devices was ruled illegal) and August 2016 (when the FDA regulations "deeming" vape products to be tobacco products kicked in), vape products were regulated as consumer products.

For the most part, regulation as consumer products has meant that devices and liquids have been subject to the requirement that they are fit for purpose and did not cause immediate harm to users or others. In addition, certain items used in vape products have been subject to specific regulations. For example, in the UK (and throughout the EU), products containing batteries are subject to specific regulations.[104] And the International Air Transport Association has imposed a prohibition on passengers placing lithium batteries (which are used in all tank model vape devices) in the hold of planes.[105]

The liquids used in vape devices have been subject to regulation as food products. Since the liquids are inhaled rather than eaten or drunk, those standards may not be appropriate. Concerns have been raised about some of the chemicals present in the vapour from some liquids. As noted above, when vapers overheat liquid, it is possible to generate a "dry puff" that can contain relatively large quantities of aldehydes. However, when used appropriately, vape devices do not produce these chemicals in appreciable quantities. Moreover, in some more recent devices, it is possible to set the maximum temperature of the coil, thereby obviating this risk.

When producers and retailers compete to supply consumers, they have strong incentives to ensure that the goods they sell are of reliable quality. First and foremost, these incentives come from the desire to build a loyal, repeat customer base. Any company seeking to win customers must offer a value proposition that differentiates it positively from its competitors. For vape devices, that value proposition might be more-effective nicotine delivery, or a larger volume of vapour, or—for liquids and composite products—better or more interesting flavours, or simply lower price. But given that a core feature of vaping is its relative safety compared to smoking, it seems likely that most vapers will require that vendors seek to ensure that their products are safe.

Several popular retailers of e-liquids have invested considerable resources testing the liquids they sell in order to ensure that they do not contain chemicals that might cause harm to consumers. In late 2014, Konstantinos Farsalinos and his team published a study highlighting the presence of two chemicals associated with "popcorn lung" (diacetyl and acetyl propionyl) in many brands of e-liquid.[106] Shortly

[104] https://www.gov.uk/guidance/waste-batteries-producer-responsibility

[105] http://www.iata.org/whatwedo/cargo/dgr/Documents/lithium-battery-guidance-document-2016-en.pdf

[106] Konstantinos Farsalinos, Kurt Kistler, Gene Gillman, and Vassilis Voudris, "Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins," *Nicotine and Tobacco Research*, 2015, Vol. 17(2), pp. 168–174. (Published online 2014 Sep 1.) doi: 10.1093/ntr/ntu176.

afterwards, one of the largest online retailers of e-liquids, VaporShark, tested all the liquids it sells for the presence of both substances and made the results of these tests available online.[107] Another retailer, VapeWild, has tested vapour from several of the liquids it sells for the presence of a range of potentially toxic chemicals—but it also notes that in each case the amounts of these chemicals is hundreds or even thousands of times greater in tobacco smoke.[108] Yet another producer/retailer, The Clean Vape, markets itself as a vendor of "diketone free" e-liquid.[109]

Producers in the U.S. formed an industry association to develop standards for liquids. The resultant organisation, AEMSA, certifies e-liquids that comply with its standards, which require, among other things: verification of the nicotine content; nicotine purity of at least 99%; base liquids (propylene glycol and/or glycerine) to be certified to US pharmacopeia (USP) grade; liquids containing diketones to be tested annually for the presence of diacryl and acetyl propionyl; and prohibit the use of whole tobacco alkaloids, caffeine, and various other substances.[110] In France, the standard setting agency, AFNOR, developed standards for both e-liquids and vape devices.[111] Meanwhile, in the UK, the British Standards Institute developed a wide ranging standard for vape devices and e-liquids that covers practically all aspects of these products.[112]

It seems fair to conclude that in markets where vape products have been regulated as consumer products, producers and retailers of both devices and liquids have been highly responsive to the felt needs of consumers. It is perhaps not surprising that much of the innovation in vape products has been driven by these markets and especially by the UK and US.

Since many of these innovations have resulted in improvements that have made products more acceptable as alternatives to smoking, while others have reduced their potential to cause harm, it seems likely that regulation of vape products as consumer products has had far greater benefits to health than regulations that have been more restrictive.

3.4 Provision of Information by Government Bodies

In addition to product regulation, many governments are involved in communicating health risks to consumers. As noted above, reports from the US and UK governments played an important role in improving public understanding of the dangers of smoking cigarettes.

Government bodies in many countries provide information on vaping. The quality of that information, however, is highly variable. In the UK, Public Health England has produced a series of reports that

[107] https://www.scribd.com/doc/268974991/VaporShark-E-Liquid-Testing

[108] http://www.vapewild.com/the-wild-blogger/vapewild-test-results/

[109] http://thecleanvape.com/diacetyl-acetyl-propionyl-and-acetoin/

[110] http://www.aemsa.org/standards/

[111] http://www.afnor.org/en/news/news/2015/avril-2015/afnor-publishes-the-world-s-first-voluntary-standards-for-electronic-cigarettes-and-e-liquids

[112] See the summary here: http://ecita.org.uk/ecita-blog/summary-british-standards-institute-pas-54115

have sought to investigate in a substantive and impartial manner the evidence regarding the effects of vaping on health. The most recent report agreed that the best available evidence supports the conclusion that vaping is, on balance—and taking into account all the adverse effects—95 percent safer than smoking.

In the US, the Centers for Disease Control, by comparison, has not attempted to offer such an impartial analysis. Instead, it simply contrasts what it sees as the beneficial and harmful effects of vape products without any attempt to weigh these against one another. Specifically, it sees vape products as potentially having public health benefits if:

- Individual adult smokers switch completely from combustible tobacco products to e-cigarettes.
- They assist in rapid transition to a society with little or no combustible tobacco use.

However, vape products are seen by the CDC as harming public health if they:

- Lead to use of nicotine and/or other tobacco products by youth and non-tobacco users.
- Are used by pregnant women.
- Lead former smokers to relapse to nicotine use or use of other tobacco products.
- Delay complete smoking cessation among current smokers.
- Result in nicotine poisonings (e.g., through ingestion of e-cigarette liquid, absorption of e-cigarette liquid through the skin, or inhalation of e-cigarette aerosol).
- Expose nonusers to secondhand aerosol.

While the CDC raises some legitimate concerns regarding potential negative public health effects of vaping, it does so without offering any perspective on the relative importance of these effects or the trade-offs they entail. For example, if a few former smokers or non-smokers begin vaping, it is possible that they might suffer some harm as a result of their decision (but at a personal level, they may believe that the risk of harm is worthwhile because of the benefits they experience from vaping). However, if many people vape instead of smoking, the overall incidence of tobacco-related disease is likely to fall.

To put the trade-off into context: If vaping is 95% less harmful then smoking, then about 20 times as many non-smokers would have to take up vaping compared with the number of smokers who switch from smoking to vaping in order to generate a neutral effect on “public health”. Since the evidence suggests the numbers of adult non-smokers and former smokers taking up vaping is a tiny fraction of all vapers, the net impact of vaping on public health is likely very positive.

The CDC also ignores the potential for allegedly harmful instances of vaping actually to represent *beneficial* offsetting behaviour. For example, if youth and pregnant women vape *instead* of smoking, then there are likely to be public health *benefits*.

In general, the CDC’s concerns seem to be motivated by a religious adherence to a “quit or die” philosophy that ignores the reality of human behaviour. For example, the concern that vaping might

"delay complete cessation by current smokers" seems to ignore the reality that smoking cessation is a process and that many vapers begin with dual use and gradually switch. In addition, while switching entirely to vaping almost certainly is healthier than continuing to smoke even one cigarette a day, the evidence (discussed above) suggests that dual users have improved lung function and are ingesting significantly fewer harmful chemicals than exclusive smokers. Thus, the CDC's abject rejection of dual use is likely dangerous to public health.

Concerns about nicotine poisonings should also be put into context: the Association of Poison Control Centers collects annual data on poisonings in the U.S. In 2014, the latest year for which data are available, 50 children under 5 years died from poisoning; of those, 10 were caused by "fumes/gases/vapors" unrelated to eliquid or vape products, 7 were caused by analgesics, 7 by household cleaning substances, and one caused by ingestion of nicotine eliquid.

Ironically, the FDA Deeming regulations might result in an increase in nicotine poisonings—if vapers follow the pattern in Australia, New Zealand and other countries where sale of e-liquids have been heavily restricted. The reason is simple: vapers will buy highly concentrated nicotine in bulk and mix it at home. Under such circumstances, the likelihood of infants inadvertently consuming dangerous and even lethal amounts of nicotine is far higher than if nicotine is mixed and dispensed in small childproof bottles by manufacturers and retailers.

The CDC approach exists in stark contrast to that of Public Health England, which has sought to weigh the benefits and harms that might result from widespread adoption of vaping as an alternative to smoking—and has concluded that such an outcome presents a risk that is 95% lower than smoking. Public Health England also emphasizes the need to communicate *to smokers* the benefits of switching to vaping. The stance taken by Public Health England has been reinforced by the National Health Service, which now actively encourages smokers to consider vaping instead of smoking—and advocates vaping as one of the main ways of quitting smoking.[113]

3.5 The World Health Organisation

The World Health Organisation (WHO) has generally been supportive of harm reduction—except when it comes to tobacco. In a 2006 paper, the WHO asserted that: "a recent review of smokeless tobacco by the International Agency for Research on Cancer concluded that smokeless tobacco is carcinogenic, making no exception for Swedish snus." Yet this WHO paper came out three years after *Tobacco Control* had published the above-mentioned study by Jonathan Foulds et al. showing that snus is not carcinogenic and that its use had reduced the use of combustible tobacco.

The WHO has been similarly hostile to vape products. For example, at the conclusion of the sixth Conference of the Parties to the Framework Convention on Tobacco Control, in October 2014 it issued

[113] http://www.nhs.uk/conditions/smoking-(quitting)/Pages/Treatment.aspx

a press release stating that "Another milestone in tobacco control was adoption of the decision on electronic nicotine (and non-nicotine) delivery systems, also known as electronic cigarettes. This rather novel product was first launched by independent companies, but many of them are now being controlled by multinational tobacco companies. The decision acknowledges the need for regulations along the lines of policies concerning other tobacco products, including banning or restricting promotion, advertising and sponsorship of ENDS."[114]

This is actually a misrepresentation of the decision that was taken, which states that it "INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health."[115] In other words, the parties meeting actually were not committed specifically to regulating the devices "along the lines of policies concerning other tobacco products" but rather offered a wide range of possible forms of regulation, including as consumer products. The blatant misrepresentation of the Decision language is, however, indicative of the bias shown by the WHO against tobacco harm reduction in general and vape products in particular.

Conclusions of section 3 and the study

The public health impact of the vapour revolution has already been profound. Millions of smokers have switched entirely to vaping and millions more are vaping in order to reduce the amount they smoke. According to the best estimate so far produced, vaping is 95% safer than smoking. So those millions of vapers can expect to live years longer than otherwise would have been the case. In aggregate, the vapour revolution may already have added 100 million or more years of healthy, productive life to the lifespans of vapers. Even among minors, vaping is displacing smoking, with potentially enormous public health benefits.

Given time and further innovation, vaping has the potential to continue dramatically to reduce both the number of people who smoke and the number of cigarettes smoked by those who continue to smoke. The potential scale is enormous. If product quality and diversity continue to increase, and costs continue to fall, within 20 years vaping could cut smoking rates by 50% or more. In 30 years, it might eliminate smoking altogether. If that were to happen, it would effectively save most of the billion lives – and perhaps 8 of the 10 billion life-years – that might otherwise be lost to smoking.

For the vapour revolution to continue, however, it is important that the production, promotion, sale and use of vape products remain legal. In jurisdictions where vape products are regulated as consumer products, producers have innovated rapidly and have been more responsive to perceived concerns of vapers. The ability of consumers to share and acquire information online puts pressure on companies to ensure their products are of high standard – and to respond to challenges resulting from new

[114] World Health Organisation, *News release: WHO tobacco treaty makes significant progress despite mounting pressure from tobacco industry*, 18 October 2014, Available at: http://www.who.int/mediacentre/news/releases/2014/cop6-tobacco-control/en/, accessed 8/9/2016.

[115] Conference of the Parties to the WHO Framework Convention on Tobacco Control Sixth session, Moscow, Russian Federation, 13–18 October 2014, *DECISION FCTC/COP6(9) Electronic nicotine delivery systems and electronic non-nicotine delivery systems*, 18 October 2014. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf, accessed 8/9/2016.

information, as illustrated by the rapid response of vape retailers and producers to concerns raised regarding the presence of diacetyl and acetyl propionyl in e-liquids. If innovation is to continue to deliver better, safer, less expensive products – and thereby attract more smokers to switch – it is essential that producers, retailers and consumers not be subject to excessive regulatory intervention.

Private companies and standard setting bodies are able to respond in a flexible and dynamic way to changing information and so are likely better suited to the job of regulating quality than government regulatory agencies. Standard-setting bodies have already developed standards for vape products that likely are more effective and useful than the regulations being implemented in the EU and US.

In countries where vaping has become popular, the public in general and smokers in particular are generally aware of the existence of vape products. However, a large proportion of the public remain unaware of the relative risks of vaping compared with smoking. It is important, therefore, that producers, retailers and third parties should be permitted to promote vape products, including by making truthful statements about the (much) lower risk of vaping compared to smoking.

Governments should be cautious about imposing restrictions on the promotion of vape products, including limits on advertising and even the distribution of free samples. Such restrictions are likely to reduce the rate at which smokers switch to vaping, with potentially enormous negative consequences for public health.

Finally, governments should be cautious about imposing taxes on vape products. One of the reasons vapers give for switching is the lower cost of vaping. Taxes on vape products would reduce the differential between smoking and vaping, thereby making the latter relatively less attractive. Since vaping is likely to reduce considerably the burden of tobacco-related disease and thereby reduce the cost to taxpayers of government funded healthcare, there is a strong public finance argument for keeping taxes on vape products low.

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