HEALTH

SMOKE AND VAPOUR

The changing world of tobacco harm reduction

Jenesa Jeram
Foreword by Oliver Hartwich

THE NEW ZEALAND INITIATIVE

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About the New Zealand Initiative

The New Zealand Initiative is an independent public policy think tank supported by chief executives of major New Zealand businesses, including tobacco companies. We believe in evidence-based policy and are committed to developing policies that work for all New Zealanders.

Our mission is to help build a better, stronger New Zealand. We are taking the initiative to promote a prosperous, free and fair society with a competitive, open and dynamic economy. We develop and contribute bold ideas that will have a profound, positive, long-term impact.

ABOUT THE AUTHOR

Jenesa is a Research Fellow at The New Zealand Initiative, focusing mainly on social issues and lifestyle regulations. She is the author of *Health of the State*, a report that looks at the evidence and ideology behind public health and lifestyle regulations. She has an interest in sugar tax regulations, and has also co-authored publications on poverty, inequality, social impact bonds, economic growth and housing.

She has a Bachelor of Arts with first class Honours from the University of Otago, majoring in Politics, Philosophy and Economics.

ACKNOWLEDGEMENTS

This author would like to recognise the hard work, expertise and advocacy of some brave public health experts. Thank you for helping to move the conversation from that of tobacco control to tobacco harm reduction, even when your colleagues pull in the other direction. Thanks to the vapers and community organisations who have helped spread the word about less harmful alternatives to smoking, and who have fought to have their needs and preferences heard by government. And thanks to the journalists, retailers and other supporters who are changing perceptions: quitting smoking is a process that can actually be enjoyed rather than endured.

This report builds on the knowledge and work of others, in the hope that better options are made available for smokers as we head towards a smoke-free future.

Responsibility for all views expressed and any errors or omissions lies with the author.

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Foreword

I am a strange choice as a foreword contributor to a report on cigarettes.

When I was a child, my parents smoked for a while. I kept pestering them to quit until they finally did. I remember my mother telling me afterwards that I would be in trouble if I ever started smoking myself, having just put them through the traumatic experience of giving up.

For fear of my mother and for my intense dislike of tobacco smoke, I have thus never smoked a single cigarette.

Or maybe it was the simple realisation that I have enough vices that I do not need another one.

That last sentence may sound flippant but it is not.

I understand that in my life I frequently make decisions that are not entirely healthy, at least from a physiological point of view. And if most people were honest, they would admit the same.

I enjoy a good drink, I believe that a lunch without a dessert is incomplete, and you better avoid me in the morning if I have not had my two strong coffees yet.

From a strictly physiological point of view, life without whiskey, panna cotta and flat whites is possible. But to me it would feel pointless.

Or, to be more precise, there is an emotional enjoyment from consuming these products which goes beyond their physiological benefits (or lack thereof).

I can only imagine that some people might feel the same way about smoking.

There must be something in the act of smoking that appeals to smokers. Of course, there is the nicotine which is a proven stimulant. It also reduces appetite and stimulates metabolism (which is the only thing that would make it sound vaguely attractive to me). It might also be the glue which binds people together socially, much in the same way that I like to meet people for coffee or a drink.

The main problem with tobacco though, as Jenesa Jeram reminds us in her report, is the way in which it was traditionally delivered: in clouds of tobacco smoke.

As it is widely known, the majority of smoking's bad health effects result from the combustion of tobacco which releases not just the nicotine but a burst of nasty and toxic by-products.

So the basic thought behind alternatives to conventional cigarettes is the idea of delivering what smokers want but without these toxic by-products.

It is the equivalent of a calorie-free dessert, an alcohol-free whiskey and a caffeine-free (but still stimulatory) coffee. Frankly, if these products existed, I would switch to them.

For nicotine delivery, there are now a range of products and technologies available that allow people to indulge in their nicotine addiction without the dangers resulting from smoking. Even better, there are also products that also deliver the inhalation experience that smokers like but, again, without the nasties of conventional cigarettes.

As Jenesa Jeram explains in this report, if we really care for smokers, we should make it easier for these new products to be used. They are a better alternative to cigarettes. They may even help some people quit altogether.

This is not to stigmatise smokers. Even though I intensely dislike the smell of traditional cigarettes, my other vices make me tolerant enough to respect smokers' choices. As an aside, you can be without vices and still lack the virtue of tolerance.

But it is about allowing smokers a path towards a better alternative. This is what Jenesa Jeram's report is about, and I hope it will inform debates around vaping in New Zealand and beyond.

Dr Oliver Hartwich
Executive Director
The New Zealand Initiative

CHAPTER 1
Introduction

In many parts of New Zealand vaping has become a regular sight, and e-cigarette retailers have been popping up across the country.[1] What might have once been seen as a niche hobby is now properly understood as a viable way of cutting down or quitting smoking. A number of public health experts both in New Zealand and overseas have recognised the role e-cigarettes and other non combustible products can play in complementing anti-smoking measures.

Vaping – the action of inhaling and exhaling the aerosol produced by an e-cigarette – has become so commonplace that some might be surprised to learn that the domestic sale of nicotine e-liquids used in these devices has been illegal in New Zealand, the law just wasn't being enforced.[2] While the previous National-led government had announced an intention to clearly legalise the sale of nicotine e-liquids, smokeless tobacco and other nicotine delivery products, these actions have been stalled by the election of a new government with other policy priorities. Given the law was not being actively enforced,[3] and the National-led government had indicated an intention to legalise, there has been some public confusion about the legal status of these products. As a recent *Herald on Sunday* feature on vaping has pointed out, "e-cigarettes are in the unusual position of the technology having left the science, and the law, far behind."[4]

It has been estimated that there are around 63,000 daily vapers in New Zealand, and vaping is helping many New Zealanders stop smoking,[5] despite the regulatory grey area it currently occupies. It is clear that there are smokers who want access to effective, satisfying and less harmful alternatives to cigarettes. It is also clear that quitting smoking will improve the life expectancy, health outcomes and financial wellbeing of smokers. Thus it is perplexing that some of those committed to reducing the harm of smoking in our community have been so resistant to allowing broader access to these risk-reduced products.

As vaping has grown in New Zealand, so too has the public and expert understanding of tobacco harm reduction. If the stated goal is to have New Zealand 'Smokefree by 2025', it makes sense to listen to the needs and preferences of those affected most by tobacco policies: smokers themselves. Empowering smokers who want to cut down or stop smoking by enabling access to less harmful alternatives would put New Zealand's tobacco control policies miles ahead

1. For those unfamiliar with the jargon: E-cigarettes are the technological device used to deliver the e-liquids. E-liquids are loaded into e-cigarettes and can be either nicotine-containing or non-nicotine. It is the former that cannot be legally sold domestically, though they can be imported from overseas for personal use only. When the e-cigarette heats the e-liquid, it produces a vapour which is inhaled. Hence the action of using an e-cigarette is known as vaping.
2. The Ministry of Health claimed that the existing Smoke-free Environments Act 1990 applies to nicotine e-liquids. The Act bans the import of oral tobacco products for sale and distribution.
3. A reported reason for the lack of enforcement is due to the practical difficulties in obtaining evidence to a criminal law standard that the nicotine in e-liquids is derived from tobacco.
4. Lee Umbers, "Up in smoke: how vaping might save smokers," *Herald on Sunday* (18 February 2018).
5. A Massey University-led survey conducted in 2016 found that of 218 vapers "Almost all had been smokers, but three quarters no longer smoked, with the remainder having significantly reduced their tobacco use." Penelope Truman, Marewa Glover and Trish Fraser, "An Online Survey of New Zealand Vapers," *International Journal of Environmental Research and Public Health* (2018) 15: 222

of many of our international counterparts including Australia,[6] and New Zealand has the opportunity to distinguish our tobacco policies on the world stage as progressive and compassionate.

This report comes at a time when the government will no doubt be facing some pressure and urgency to announce its position regarding e-cigarettes and other reduced risk tobacco products. A recent court judgment[7] regarding heat-not-burn (HNB) products[8] has the potential to propel both the tobacco harm reduction landscape, and the need for public and expert understanding of these products (discussed in section 2.1). The court decision also potentially has implications for legalising the domestic sale and supply of nicotine-containing e-cigarettes. This means the sale of both HNB and e-cigarettes might be legalised but *might* be subject to the same regulations as smoked tobacco products. Section 2.1 discusses why it would be illogical and counterproductive to extend smoked tobacco regulations to products that could help reduce the harms of smoking.

At the same time, the (Opposition) National Party's Hon Nicky Wagner has proposed a members' bill regulating e-cigarettes through amendments to the Smoke-free Environments Act 1990.[9] Though the proposed members' bill would be an important step towards formally legalising the product,[10] the suggested regulations would limit many of the freedoms that currently exist that could contribute to smokers making the switch to less harmful alternatives. Any regulatory framework that is introduced needs to improve on the status quo by enabling better access to these products. Advertising regulations (discussed in section 5.4) and applying smoke-free zones to vaping (discussed in section 5.5) would result in fewer freedoms and access than the status quo.

This report argues that while the government needs to clarify its position, any regulations introduced should neither hinder access to these products, nor misleadingly conflate reduced risk products with the known harms of smoked tobacco products. Accurate and responsible communication of risks and potential benefits is also important, especially addressing the misperception that reduced risk products are as harmful or more harmful than smoking.[11] New Zealand needs legislation that is flexible enough to ensure that improvements in the technology, consumer acceptability and effectiveness of reduced risk products are readily available as they are developed.

These moves from parliament and the judiciary indicate that New Zealand is already behind the legal and regulatory eight-ball. E-cigarettes are just one of many reduced risk products[12] available on the international market, and it is likely the

6. Standing Committee on Health, Aged Care and Sport, "Report on the Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia," Parliament of Australia (2018)
7. Also note at the time of writing, the legal implications of this decision are not clear or well-understood, so discussion on this subject throughout the report is only this author's [non-legal] interpretation. The decision relates to the Smoke-free Environments Act and its implications will be explained in more depth in the next chapter. Judgment of Judge P J Butler, "Ministry of Health v Phillip Morris (New Zealand) Limited," Wellington District Court (12 March 2018)
8. Also known as heated tobacco products. HNB is explained in more depth in section 4.2.
9. "Smoke-free Environments (Regulation of Electronic Cigarettes) Amendment Bill," Proposed members' bill, 52nd Parliament (22 Mar 2018)
10. Assuming, of course, that the bill is not superseded by the aforementioned court judgment.
11. After all, a recent New Zealand-based survey found that 20% of adult respondents disagreed with the statement 'e-cigarettes are safer for your health than tobacco', while 38% agreed. Health Promotion Agency, "Data Release: updated preliminary analysis on 2016 Health and Lifestyle Survey electronic cigarette questions," (2017) www.hpa.org.nz/research-library/research-publications/preliminary-analysis-on-2016-health-and-lifestyles-survey-hls-e-cigarette-questions
12. This report uses the term 'reduced risk products' to refer to all non-combustible forms of nicotine delivery: e.g. e-cigarettes, snus, heat-not-burn.

technology will continue to develop. Though these products have differing risk profiles,[13] the evidence so far suggests that these products are significantly less harmful than smoking.[14]

Although e-cigarettes have worked to help many (who want to) quit or cut down on smoking, they will not work for all. In a regulatory environment of mainly punitive measures against smokers, it is time for a compassionate approach that reduces the harm of smoking while respecting the diverse preferences of smokers.

1.1 What does an economist know about health?

There is no shortage of public health research and commentary in New Zealand. Tobacco control has been a major area of research and advocacy, and efforts are only likely to ramp up as New Zealand approaches the government's 'Smokefree by 2025' target.

A neglected voice in our national conversation has been that of the economist. Perhaps because these issues are literally dealing with life or death, basic economic principles that ought to apply to all public policies are often foregone when it comes to public health.

Whether one agrees with the target and the desired outcome (encourage or force people to quit smoking), an economic analysis can bring something different to the table. Of course, both economists and public health experts are concerned with raising the welfare of society.

However, economics gives a good baseline for interpreting multiple competing interests at the same time. It provides the framework for assessing the costs and benefits of a policy, and how to accommodate different people's preferences. It is concerning how little weight is placed on individual preferences when it comes to tobacco control policy.

When it comes to tobacco harm reduction, the aim is not to ignore or deny the very real harm that smoking causes. Rather, harm reduction recognises that harm elimination in the form of abstinence-only policies will not improve the welfare of those individuals who cannot or do not want to quit. Giving smokers access and encouragement to switch to less harmful substitutes for cigarettes is therefore a priority. As Professor Gerry V. Stimson argues vapers often use the language of "switching" rather than "quitting" or having to give something up. Stimson argues that 'pleasure' has rarely been so explicit in externally led harm reduction interventions.[15] Access to reduced risk products can not only reduce the harm from smoking but might even make the process enjoyable.

The law of diminishing returns will be discussed in Chapter 2. Despite concerted efforts from government to get people to quit smoking, current policies are now having only a marginal

13. The evidence to date suggests that the risks of snus and e-cigarettes are likely to be lower than heat-not-burn products. Rather than view products as simply "safe" and "not safe", products are likely to fit somewhere along a sliding scale of risk, with combustible cigarettes at the "high risk" end, and e-cigarettes closest to the "low risk" end. Alternatively, if a nicotine delivery product is found to be not significantly less harmful than smoking, or the literature evolves to find that some products are riskier than researchers first thought, then they would no longer be considered in the class of "reduced risk".
14. In a synthesis of recent national and international evidence (798 potentially relevant articles were identified) Public Health England found that using e-cigarettes is around 95% less harmful than smoking. While the exact percentage may be contentious, it is a dominant theme in the literature that e-cigarettes release less toxins than combustible cigarettes. A. McNeill, L.S. Brose, R. Calder, S.C. Hitchman, "E-cigarettes: an evidence update: A report commissioned by Public Health England," Public Health England (2015)
15. Gerry V. Stimson, "A tale of two epidemics: drugs harm reduction and tobacco harm reduction in the United Kingdom," *Drugs and Alcohol Today* 16(3)203–211.

effect. Even experts who were involved with the increasing tobacco excise regime or who supported its inception now recognise its limitations and the harms it is causing for some of society's most vulnerable.

Chapter 3 will then argue that the best way to displace smoking and cigarettes is to create an environment where creative destruction can thrive. 'Creative destruction', a term coined by economist Joseph Schumpeter, explains how the free market can encourage innovation, deliver progress and benefit consumers.[16] The theory can be used to explain technologies from the big (establishing a railroad network) to the not-so-big (the smartphone). Trying to slow innovation not only delays benefits to consumers, but is ultimately unsustainable. E-cigarettes are a ground-breaking start to this displacement process, but they are just that: the start.

Chapter 4 discusses two nicotine delivery products that might become legally available for sale in New Zealand: snus and HNB products (at the time of writing, HNB products can legally be sold). These products have the potential to meet the diverse preferences of smokers wanting to switch to less harmful alternatives. The chapter discusses some of the risks and benefits involved with these products, and discusses their uptake in countries where uptake has been significant (Sweden for snus and Japan for HNB).

The rest of this report (Chapter 5) discusses how the risks and benefits of these products should be considered.[17] While both economists and health experts will discuss the costs and benefits of public health policies, the conclusions might be different between the two groups. This report argues that many of the arguments against light-touch regulations on e-cigarettes and other reduced risk products are overly risk averse. Where risks do exist, economists argue that these need to be balanced with potential benefits. Rather than considering risks and benefits in isolation, this report considers them as a contribution to the 'Smokefree 2025' aspiration and the net social welfare of New Zealanders.

16. W. Michael Cox and Richard Alm, "Creative destruction," *The Concise Encyclopedia of Economics* (2008) www.econlib.org/library/Enc/CreativeDestruction.html.

17. Carl V. Phillips has worked extensively on tobacco control and harm reduction. His paper on the economics of tobacco harm reduction is well worth a read for a better understanding of the analytical framework used in this report (the source is particularly accessible to non-economists). Carl V. Phillips, "Understanding the basic economics of tobacco harm reduction," Institute of Economics Affairs (IEA Discussion Paper no.72: 2016).

CHAPTER 2

Getting NZ smoke-free by 2025

The main or most aggressive mechanism used by successive governments to reach the 'Smokefree by 2025' has been through rises in tobacco excise. Plain (standardised) packaging was also introduced this year, though there is little evidence that the policy has been effective in Australia, where plain packaging has been in place for five years.[18]

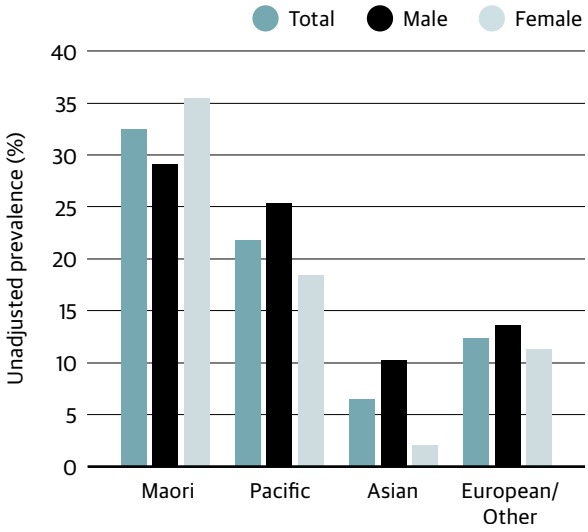
A major event not included in this timeline, but significant all the same, is the rise of publicly-funded campaigns to get people to quit smoking through denormalisation.[19] One such publicly-funded campaign, 'Smoking Not Our Future' aimed to encourage social disapproval of smoking/smokers by using the testimonies of many high-profile (at the time) New Zealand celebrities. Themes emphasised the unattractiveness of smokers, the unpleasant smell, how "uncool" it is, and how it negatively affects romantic relationships. While some public campaigns have since changed tack to be more compassionate and family/health focussed, these stigmatising themes persist.

When one considers the major events that have led up to the 'Smokefree by 2025' aspiration, the policies that have since been introduced to help New Zealand achieve that smoke-free aspiration have been overwhelmingly punitive.

But despite a range of measures being introduced, and population smoking rates dropping over time, there are obvious ethnic disparities (and to an extent, gender) between those who remain daily smokers (Figure 1).

It also appears that the number of ex-smokers (successful quitters) is increasing slowly, with only small gains made over the space of ten years. Figure 2, however, masks important differences in the age differences in smoking rates.

Figure 1: Daily smokers by ethnicity (2016)



Source: Ministry of Health, "New Zealand Health Survey 2016/17" (2017)

18. Studies that show plain packaging to be effective have been critiqued due to lack of methodological robustness. Sinclair Davidson and Ashton de Silva, "Stubbing out the evidence of tobacco plain packaging efficacy: an analysis of the Australian National Tobacco Plain Packaging Survey," (2016). When the authors extended the investigated time period to include pre-plain packaging incentives to quit smoking, they found there was no statistically significant difference in the effectiveness of graphic health warnings as a result of the plain packaging policy being introduced. Sinclair Davidson and Ashton de Silva, "What the government demanded as proof for plain packaging efficacy: an analysis the public health lobby did not perform," (2017).
19. The mass-media campaign ran from around 2006 until 2013. The official website now appears defunct, though an example of the content can be found here www.notourfuture.resn.co.nz/.

A timeline of major events contributing to the Smoke-free 2025 aspiration:

August 1990	Smoke-free Environments Act introduced, defining places where smoking is banned, and defines restrictions on smoking in public and private spaces. The marketing and promotion of tobacco products was also regulated. Subsequent amendments have been made, extending the scope of bans and tobacco advertising/visibility.
November 2000	Government subsidised Nicotine Replacement Therapy (NRT) such as nicotine patches and gum are made available through the national Quitline.
December 2004	All licensed premises (bars, restaurants, cafes, sports clubs, casinos) and other workplaces (including offices, factories, warehouses, work canteens and 'smoko' rooms) become smoke-free indoors.
February 2008	Tobacco packaging regulated to include graphic health warnings.
April 2010	Government introduces the first of a series of annual increases in tobacco excise. This was the first price increase above inflation in about a decade.
March 2011	Government sets the aspirational goal to have New Zealand 'Smokefree by 2025' in response to recommendations from the Māori Affairs select committee.
May 2012	The Customs and Excise (Tobacco Products—Budget Measures) Amendment Bill introduces four (cumulative) 10% annual increases (above inflation) to tobacco excise. These increases would have finished in 2016, but the regime was continued for another four years after 2016.[20]
March 2017	Government announces plans to legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products.[21]
May 2017	Charges laid against tobacco company Philip Morris NZ Ltd over the importation and sale of Heets, a non-combustible heated tobacco product. The court action is regarding the interpretation of Section 29 of the Smoke-free Environments Act 1990.[22]
August 2017	Government announces intention to establish a pre-market approval system for smokeless tobacco and nicotine-delivery products such as snus and HNB products. This would mean there would be a notification regime for e-cigarettes and a separate pre-market approval system for smokeless tobacco and nicotine-delivery products.
December 2017	Ministry of Health endorses vaping as a less harmful alternative to smoking as part of a Parliamentary briefing to the incoming associate health minister of the Labour-led Government.[23] The associate health minister Hon Jenny Salesa has not committed to continuing the e-cigarette and other nicotine delivery device legislation that was underway with the previous government.[24]
March 2018	Plain/standardised packaging of tobacco products introduced in New Zealand.
March 2018	A district court judgment rules in favour of Philip Morris NZ Ltd regarding the importation and sale of Heets.[25]

Source: Information gathered from a number of sources, including Quitline,[26] Hāpai Te Hauora,[27] and the Ministry of Health.[28]

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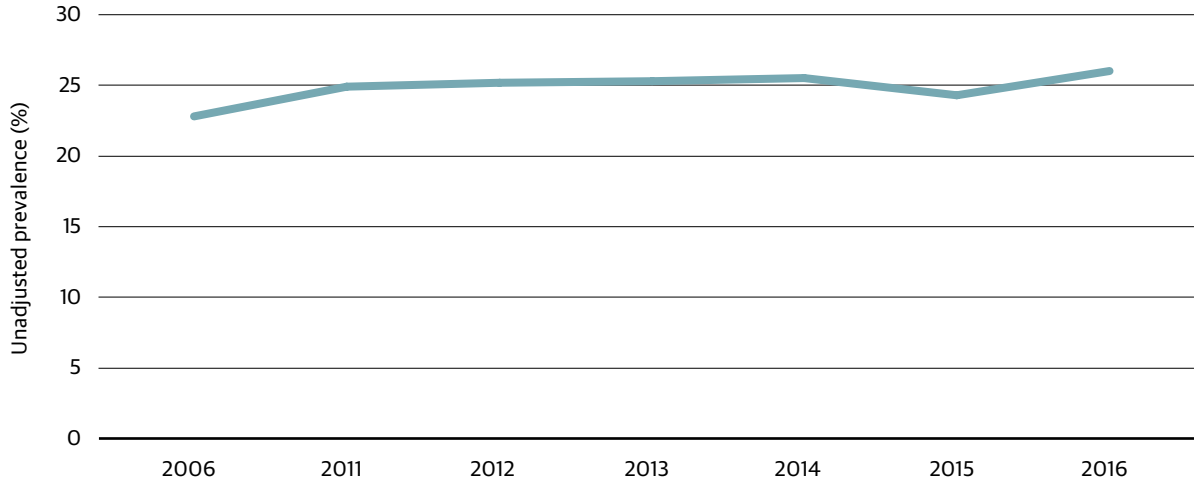
20. Office of Associate Health Minister Peseta Sam Lotu-Iiga, "Tobacco excise to rise 10 per cent per annum," New Zealand Government, Press Release (27 May 2016).
21. Specific changes to the law were anticipated to be made "from the middle of 2018 at the earliest". These would include regulations around advertising, R18 sales, retail display settings, compatibility with the Smoke-free Environments Act 1990, and product safety. New Zealand Ministry of Health, "Vaping (e-cigarettes)," (2017), www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes.
22. The Act prohibits the distribution/sale/advertising of " … any tobacco product labelled or otherwise described as suitable for chewing, or any other oral use (other than smoking)." New Zealand Ministry of Health, "Charges laid against Philip Morris," Press release (18 May 2017).
23. The Ministry of Health website includes the following endorsement: "The Ministry believes e-cigarettes could disrupt inequities and contribute to Smokefree 2025." New Zealand Ministry of Health, "Vaping (e-cigarettes)," op.cit.
24. Anna Bracewell-Worrall, "Vaping better than smoking, Ministry of Health tells MPs," Newhub (13 December 2017).
25. Judgment of Judge P J Butler, "Ministry of Health v Phillip Morris (New Zealand) Limited," op.cit.
26. The Quit Group Te Roopu Me Mutu, "Contributing to a Tobacco-Free Aotearoa: The Quit Group Annual Review 2009," (2009) https://quit.org.nz/-/media/Images/Quitline/PDFs-and-Docs/The-Quit-Group/Quit_Group_Annual_Report_2009.pdf?la=en
27. Hāpai Te Hauora, "Ko te whakapapa o te ao tupeka kore o Aotearoa: The History of Tobacco Control in New Zealand," www.hapai.co.nz/sites/default/files/history-of-tobacco-control.pdf
28. New Zealand Ministry of Health, www.health.govt.nz/

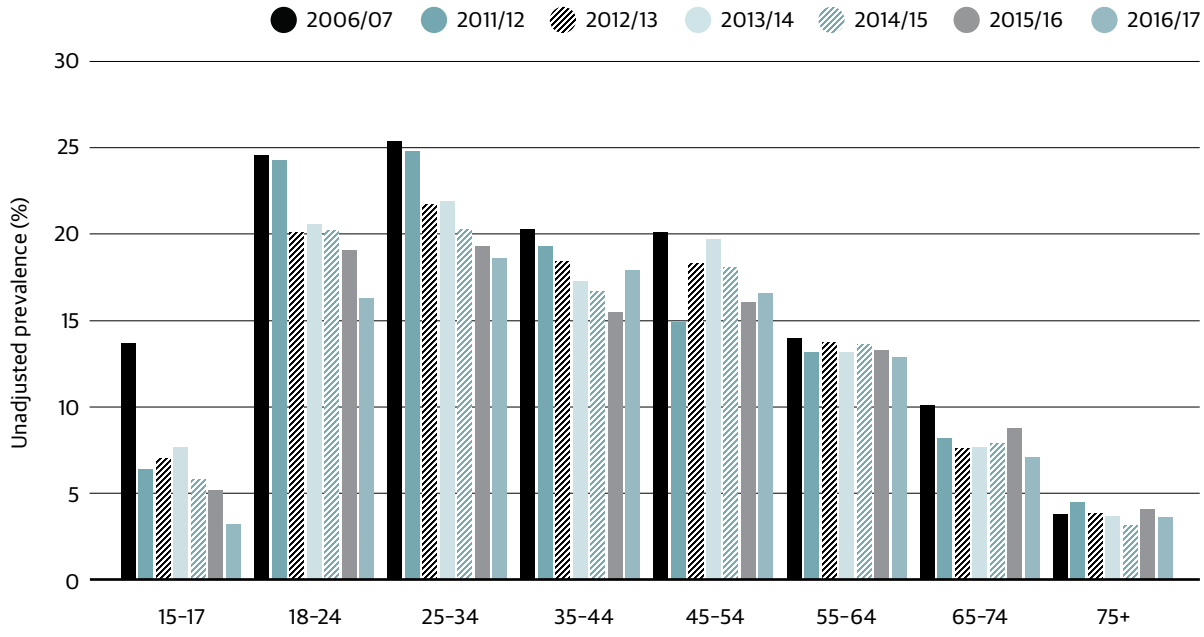
Figure 2: Total ex-smokers (2006–2016)



Source: Ministry of Health, "New Zealand Health Survey 2016/17" (2017)

While the ex-smokers rate might be disappointing, it is worth comparing that to daily smokers by age group over time (Figure 3). It appears that younger age groups identifying as daily smokers have dropped at a much greater rate than older age groups. One explanation for this is that younger cohorts are simply less likely to have ever smoked a cigarette. The good news story here is that youth uptake (which is a high predictor of future use) is declining. For public policy, this could mean that while policies have been successful in deterring youth uptake of smoking, more support is needed to help people quit.

Figure 3: Daily smokers by age group (2007–16)



Source: Ministry of Health, "New Zealand Health Survey 2016/17" (2017)

The continuing efficacy of tobacco excise has been a particular point of contention amongst experts.[29] The original reasoning behind the excise was to discourage smoking, rather than recuperate the costs to the health system that smokers might impose (a Pigouvian tax).[30] In 2012 it was acknowledged that "even aggressive increases in tobacco excise tax are unlikely to be sufficient on their own to achieve the smokefree goal in this timeline [2025]" however, the main aim of the excise tax is to deter new smokers.[31]

The table below shows that smoking prevalence is highly concentrated in the most deprived populations, therefore the proportion of excise paid would predominantly come from these groups. Further, the annual increases in tobacco excise has led to the scenario where smoking rates are decreasing while excise revenue increases.[32]

Neighbourhood deprivation (2017)	Prevalence (%)
Quintile 1 (least deprived)	8.2
Quintile 2	10.6
Quintile 3	14.5
Quintile 4	19.3
Quintile 5 (most deprived)	26.6

Source: Ministry of Health, "New Zealand Health Survey 2016/17" (2017)

The additional revenue the government expects to receive from the current excise regime is $705 million by 2020/21, while the difference in smoking prevalence by 2025 between the excise regime and doing nothing (no increases) is 1.7 percentage points (13.7% smoking prevalence in 2025 with no excise increases, and 12% smoking prevalence with the excise regime).[33]

Dr Eric Crampton has estimated the likely effects of the series of tobacco excise increases on low income households through 2020. He finds that the tax *increase*, by 2020, for a household with one current smoker would be about $1000, or about 4.3% of that household's annual income in 2020. But that is just the increase. The total burden of tobacco excise for a bottom quintile household if that household has one smoker who smokes half a pack of cigarettes per day is just under 14% of that household's annual income.[34]

Kathy Spencer, a former Deputy Director-General in the Ministry of Health (responsible for Sector Policy) and a former Manager of Personal and Indirect Tax in the Treasury has argued that "the reduction in smoking has been slow and has come at a very high cost to those who haven't been able to give up. This cost is given little attention in policy advice to ministers".[35]

Meanwhile, Massey University professor in public health, Marewa Glover, had originally supported rises in excise, but now believes that the policy is discriminatory. Professor Glover says "my support was contingent on a reduction in smoking, especially for Māori women, and that hasn't happened."[36]

29. A more in-depth discussion on the effectiveness of tax increases on smoking rates can also be found in The New Zealand Initiative's publication The Health of the State. Jenesa Jeram, "The Health of the State," The New Zealand Initiative (2016).
30. New Zealand Government, "Customs and Excise (Tobacco Products—Budget Measures) Amendment Bill," (2012) www.legislation.govt.nz/bill/government/2012/0022/3.0/whole.html.
31. Ruth Isaac, "Regulatory Impact Statement: Increase in tobacco excise and equivalent duties," New Zealand Treasury (2012), p5.
32. Ministry of Health, "Tobacco returns 2016," (2017) www.health.govt.nz/system/files/documents/pages/tobacco_returns_infographic.pdf
33. Matt Cowan, "Regulatory Impact Statement: Increases in Tobacco Excise," The New Zealand Treasury (2016).
34. Eric Crampton, "Tobacco excise: running the numbers," *Offsetting Behaviour* (2 June 2016).
35. Kathy Spencer, "Tax burden unfair on smokers," Op ed, *The Dominion Post* (28 December 2017).
36. Simon Collins, "Public health professor Marewa Glover claims tobacco tax rise racist towards Maoris," *New Zealand Herald* (30 May 2016).

2.1 Labour needs to clarify their position, but regulations should not hinder access to reduced risk products

There has been some (rightful) frustration with the pace of legislative change for e-cigarettes, smokeless tobacco and other nicotine delivery products. The effort to lift prohibitions and restrictions on these products has been hard-fought by experts, health advocacy groups and vapers. While some retailers have been operating as if e-cigarettes and the nicotine-containing e-liquids have already been legalised, they still operate at some risk.[37]

Retailers who are compliant with the law, or unwilling to take the risk of prosecution, such as service stations and supermarkets[38] are stuck in a bind where it is legal to sell cigarettes but illegal to sell much less harmful alternatives. As a result, it is possible that there is still unmet demand for nicotine e-liquids in New Zealand, as one online survey found that 46% of those who had difficulties with vaping were concerned with the availability of nicotine.[39]

Another downside of the current regulatory grey area is that information about these products is limited as legality around advertising nicotine e-liquids might deter retailers. As a result, some smokers might be unaware of the potential of these products as a less harmful alternative to smoking, and unaware of how to access them. Legalising the sale of e-cigarettes and nicotine e-liquids could also better protect consumers by encouraging better monitoring and expectations of product quality and consistency. At the moment, the onus is on New Zealand retailers acting in good faith, and manufacturers producing goods of a shared standard of quality (proper labelling of e-liquids, child-resistant packaging, accurate labelling of nicotine strength etc.)

> "As these products are not currently regulated in New Zealand, it is the responsibility of companies selling e-liquid to ensure customers receive products of a high standard and are given the necessary education at the point of sale to use these products safely and effectively."[40]

The regulatory grey area has only been exacerbated by a recent court judgment regarding section 29 of the Smoke-free Environments Act (SFEA) 1990. The section prohibits

> 'import for sale, sell, pack, or distribute any tobacco product labelled or otherwise described as suitable for chewing, or for any other oral use (other than smoking).'[41]

Charges were originally laid against tobacco company Philip Morris NZ Ltd by the Ministry of Health regarding the importation and sale of a HNB (non-combustible) tobacco product. The tobacco-containing product, *Heets,* were designed to be used in Philip Morris' HNB IQOS device. The Ministry of Health had argued that such products would be prohibited under section 29 of the SFEA.

37. My colleague Dr Eric Crampton argues that this legal limbo might be a good thing if there is already broad access to these products, because "whatever regulatory regime comes out of this will be more restrictive than the current de facto status quo." This is certainly true regarding the proposed advertising restrictions as currently, e-cigarette billboard and internet advertising is occurring in New Zealand. Eric Crampton, "Informative advertising," *Offsetting Behaviour* (8 February 2018).
38. However, one of New Zealand's major supermarket chains is trialling the sale of e-cigarette devices and non nicotine e-liquids. A New Zealand-based e-cigarette wholesale retailer has claimed a spike in sales through the supermarket channels. Matthew Theunissen, "Major supermarkets now selling e-cigarettes as tobacco price rises," *New Zealand Herald* (13 Jan 2018)
39. Penelope Truman, Marewa Glover and Trish Fraser, "An Online Survey of New Zealand Vapers," op.cit. (n=218)
40. Ben Pryor from New Zealand e-cigarette retailer Vapo, quoted in Lee Umbers, "Up in smoke: how vaping might save smokers," op.cit.
41. New Zealand Ministry of Health, "Charges laid against Philip Morris," op.cit.

In March 2018 Judge Patrick Butler ruled that section 29 of the SFEA was not intended to apply to a product such as *Heets*, and that banning the product would contradict what Parliament sought to achieve when passing the Act. Though the implications of this ruling are still being digested by experts, it is potentially significant that Judge Butler saw banning less harmful products (that could be used as an alternative to smoking) as contrary to the purposes of the Act.

A layman's interpretation of this judgment is that it is not only relevant to HNB products (and potentially snus unless it is wrongfully conflated with chewing tobacco[42]) but could have implications for e-cigarettes too. The Ministry of Health has applied the Medicines Act 1981, advising 'it is illegal to advertise, sell and distribute nicotine and non-nicotine e cigarettes *for a therapeutic purpose* [author's emphasis added] unless these products have been approved for that purpose by Medsafe'.[43] The Ministry of Health have applied the SFEA to nicotine-containing e-cigarettes, for products containing nicotine derived from tobacco.[44]

But if tobacco-containing reduced risk product like *Heets* are not intended to be included under section 29 of the SFEA, then nicotine e-liquids might be excluded too.[45]

In his judgment, Butler argued that while 'the use of *Heets* may have associated risks in itself, [it] is not as harmful or potentially harmful as ordinary cigarette use'. Butler pointed to particular parts of the SFEA which he found *Heets* to fit 'squarely with the purposes of the Act'[46] which includes the following clauses:

- 3A(1) (a) to reduce the exposure of people who do not themselves smoke to any detrimental effect on their health caused by smoking by others;
- 3A(1)(c) to monitor and regulate the presence of harmful constituents in tobacco products and tobacco smoke;
- 21(b)to reduce some of the harmful effects of tobacco products on the health of users by monitoring and regulating the presence of harmful substances in the products and in tobacco smoke.[47]

This suggests that not only were reduced risk products not intended to be banned under the SFEA, but some clauses in the SFEA would support their introduction as potential contributions to achieving the purposes of the Act of reducing the harms to health of

42. In this author's opinion.
43. New Zealand Ministry of Health, "Vaping (e-cigarettes) op.cit. There are differing interpretations of the Medicines Act, and some experts this author has corresponded with warn that the Medicines Act might still apply to nicotine e-liquids for the use of inhaling, even if the product is not making a health claim. For now, the only thing that is clear is that the legal status of e-cigarettes is not clear.
44. New Zealand Ministry of Health, "Vaping (e-cigarettes) op.cit
45. This was the view of Professor Marewa Glover, who stated in a press release "… His ruling could equally apply to nicotine vaping products, meaning they can be legally imported and sold in New Zealand. Of greater significance, he concluded that the Ministry of Health's prosecution, which sought to restrict smokers' access to an alternative less harmful product was the 'opposite of what Parliament sought to achieve when passing the SFEA'." Massey University, "Stop smoking services called upon to support vaping," Press Release (9 April 2018) www.scoop.co.nz/stories/GE1804/S00011/stop-smoking-services-called-upon-to-support-vaping.htm
46. Judgment of Judge P J Butler, "Ministry of Health v Phillip Morris (New Zealand) Limited," op.cit.
47. New Zealand Government, Smoke-free Environments Act (1990) www.legislation.govt.nz/act/public/1990/0108/54.0/DLM223984.html

smoking to non-smokers, regulating the harmful constituents in tobacco products and tobacco smoke, and reducing some of the health harms to smokers.

With this in mind, rather than simply applying tobacco-like regulations (including standardised packaging, advertising restrictions, excise) to these less harmful products, the Labour government should consider the purpose of the SFEA and how these products could contribute to (rather than hinder) the SFEA's smokefree aspirations. It is surely illogical to apply regulations designed to discourage usage and uptake of smoked tobacco, to products that can help achieve the government's goals of doing just that: decreasing usage of smoked tobacco.

The government will need to clarify its position on these products, and possibly introduce some additional monitoring systems to track what is available on the market and uptake (including tracking potential uptake from nonsmokers). Retailers need certainty that they will not be prosecuted for selling these products, and consumers will need reassurance that basic safety requirements[48] will be enforced.

In fact, there is a strong case to be made that beyond clarifying its position and giving the public certainty, few additional regulations would be needed. In most cases, New Zealand's e-cigarette market has set expectations of safety, restrictions on sales to minors, has established vape-friendly and vape-free spaces, and appears to be advertising responsibly, even in the absence of regulations.

But if the government wants to set regulations for e-cigarettes and other reduced risk products, it should be careful about disrupting the self-regulatory actions of the status quo. Of great concern would be the temptation to simply apply tobacco regulations, despite such regulations being counterproductive to the aims of the SFEA to reduce the harms of smoking and the exposure to harmful constituents in combustible tobacco products.

2.2 Who makes the decisions and when?

The new government will also need to put some thought into the regulatory vehicle for managing incoming reduced risk products. Under the previous government, the Ministry of Health had recommended a notification (self-certification) model for e-cigarettes but would establish a separate pre-market approval system for smokeless tobacco and nicotine-delivery products.

The Ministry also recognised some sound principles for regulating reduced risk products, namely: regulations should be proportionate to the risks associated with their use;[49] consumers should be informed of established risks; and that regulations should assist in preventing or reducing the impact of smoking for young people and populations with high smoking prevalence.

The differences between the pre-market approval system and self-certification model really depend on how the systems are implemented, and what regulations producers will have to meet. The pre-market approval system requires application

48. This report makes no strong calls on what constitutes "basic" safety requirements. However, the current Technical Expert Advisory Group reflects a good approach to determining requirements by seeking the input of health scientists, international experts, consumers, and manufacturers/retailers who advise on agreed standards. This should encourage standards that are both reasonable and practicable. New Zealand Ministry of Health, "Electronic Cigarette Technical Expert Advisory Group," (2018) www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes/electronic-cigarette-technical-expert-advisory-group

49. Though this author would add that proportionality ought to be based on existing products on the market. In this case, risks should be considered in proportion to the risks of smoked tobacco.

approval by the regulator before marketing, while the self-certification model requires manufacturers to submit required information and evidence, and self-certify on an online database that they meet regulations.

Hypothetically, there could be little real difference between a light-touch pre-market system that approves products swiftly, and an efficient self-certification system that removes non-compliant products.

There are costs and benefits to both systems.

A pre-market approval system includes more safe-guards than a self-certification model. Importantly, the pre-market approval system adds a layer of independent assessment and verification before products are put on the New Zealand market. While a self-certification model can require independent assessment of products, it cannot verify that products meet requirements *before they are made available on the market.* For new products, where a universal gold standard of methodology has yet to be determined, independent analysis is likely needed. Different product designs might also carry or mitigate different levels of risk, so independent analysis might be needed to negotiate nuances. Given some of these products contain tobacco, independent analysis might also be needed to confirm that the contents cannot be misused as smoking tobacco.

However, the pre-market approval system runs the risk of harming smokers by delaying or outright denying their access to reduced risk products. The costs to businesses of a premarket approval system (especially one that sought to recuperate costs by charging the industry) could be prohibitive to smaller players and could quash competition and innovation. While large companies and incumbents can easily face these cost burdens, the costs could be prohibitive for smaller companies or emerging companies who are unwilling to take that risk.

The time it takes to approve a product and take it to market might also harm consumers by delaying their access to potentially harm-reduced products.

Meanwhile a self-certification system sets a more consistent standard with the proposed e-cigarette legislation. After all, all products in the category are reduced risk products. Self-certification also has a degree of accountability built into it as competing companies and experts have a natural incentive to discredit unsafe products. In contrast, an individual arbitrator may have less knowledge, fewer resources and fewer incentives to actively test the credibility of producer's self-certification statements in a timely fashion.

In the absence of formal government regulations, a self-regulatory body has emerged in New Zealand (the Vape Trade Association of New Zealand) which is a voluntary body that sets out certain standards and manufacturing processes.[50] Other such bodies and certifications could easily emerge. Existing protections, such as the Consumer Guarantees Act 1993[51] and Fair Trading Act 1986[52] also already set far-reaching requirements to protect consumers from faulty products and false claims. Government-run agencies and regulatory bodies can be slow and overly cautious by nature. Though an efficient and light-touch pre-market approval system might sound good in theory, it might be difficult to pull off in practice.

The major risk of the self-certification model is that it potentially exposes consumers to harmful products if manufacturers do not comply with mandatory set standards. Given the nature of these products, where negative outcomes may not be immediately observable, there could potentially be a delay in removing

50. Vape Trade Association of New Zealand, http://vtanz.org.nz/
51. Regards the quality of the product.
52. Regards the accuracy of consumer information and product safety.

significantly risky or harmful products from the market. This risk, of course, needs to be considered proportionally with the likelihood that harm would occur, and the fiscal costs of overregulation given the opportunity costs within the government's health budget. The relevant counterfactual here is not a completely harm-free world, but rather one in which smokers continue to smoke.

Either system has the opportunity to start off as a liberal regime, then become tighter if risks are discovered. Likewise, either system could start out with tight regulations, then become more liberal if the benefits of the products become more apparent or if consumer demand rises (though this outcome is probably less likely).

In other words, an inefficient or overburdened pre-market approval system is risky, as is a slow-to-react self-certification model.

Another aspect of either approval process that could significantly slow down access to products is if regulations reached beyond basic safety requirements. The question is over whether producers must "prove" safety (a medicinal claim) or prove a lower level of risk compared to products already available on the market (a scientific claim).

Evidence of the product's effectiveness as a cessation tool, or its impact on certain populations, is also almost impossible to attain if the products are currently banned. Chapter 4 discusses snus, a product that could have been legalised ten years ago, but the Ministry of Health claimed it did not have enough evidence of long term risks or its effectiveness as a cessation product. It is also difficult to transpose definitive conclusions about uptake from overseas research as different populations may be drawn to different products and enjoy different rates of success.

For these reasons, whatever system is chosen should include basic product safety requirements and labelling, and evidence tobacco products are non-combustible. But evidence of product effectiveness is likely to be difficult in the short to medium term. The cost burden (both time and financial) on businesses should not be so exhaustive that they exclude smaller players, and the approval process should be timely and efficient. Likewise, the system should be timely and efficient in removing harmful products from the market. A comity agreement between countries with similar regulatory risk-management environments to New Zealand might also be appropriate, where products that have been legalised in other countries should be fast-tracked here.

All in all, the new government should consider a "light touch" to regulations and regulatory bodies. Regulations should not favour big companies or limit competition and innovation. The opportunity costs of the decision making process (both time and fiscal) should also be considered.

CHAPTER 3
Nicotine, tobacco and combustion

3.1 Understanding why people smoke is key to helping people quit

With the health warnings, rises in tobacco excise, and known adverse health effects, it can sometimes be a mystery why anyone would continue to smoke. Columnist Damien Grant describes the humiliating process of purchasing cigarettes in today's anti-smoking culture:

> "Asking for a packet of cigarettes today feels like asking the pharmacist for haemorrhoid cream or taking cling-wrapped girlie mags to the dairy counter. It's become a shameful thing; a sign of weakness rather than rebellion."[53]

The easy response, of course, is that people are addicted to nicotine and once they are weaned off it, they will have no interest in smoking. That is the reasoning behind administering Nicotine Replacement Therapy (NRT) where patches, lozenges or gum can deliver nicotine to the system to reduce physical cravings.

However, while NRT can satisfy physical cravings it does not satisfy the behavioural/sensory/social aspects related to both smoking and the consumption of nicotine. For some people, these behavioural/sensory/social aspects can matter a great deal. Therefore, the public health benefits of a product depend not only on the risk profile of alternative products, but the consumer acceptability and uptake of those products. NRT might pose little risk, but its contribution to tobacco harm reduction depends on smokers actually using these products to quit.

Further, as more people quit smoking, it is possible that the people who continue to smoke will require different kinds of support than those who have already quit.

A unique approach to understanding smokers' behaviour and motivations in New Zealand comes from a report from the Ministry of Health in collaboration with ThinkPlace. The report focuses on why young Māori women smoke. While the report only deals with one demographic in New Zealand, it is a demographic with high smoking rates, and gives a good snapshot of the complexity of backgrounds of smokers, and why abstinence will not be the most reasonable expectation for everyone.

The Ministry of Health and ThinkPlace find that the financial costs (rising excise) were not necessarily a reason for quitting, as the costs were prioritised in smokers' budgets. This insight is consistent with findings of various experts that raising excise is no longer a compelling mechanism for getting people to quit. Smokers are not substituting away from cigarettes because they are more expensive, they are reducing spending on other things. For smokers on low incomes, this could mean spending less on 'essentials' like food and electricity.

The report also argues that

> "packaging smoking cessation programmes as short-term 'medicalisable' treatments might not effectively support women making many

53. Damien Grant, "I know the risks of smoking – but I'm not bothered," Op ed, *Sunday Star Times* (25 February 2018)

attempts to quit over time and dealing with long-term inner conflict. There is need to creatively think about services which walk alongside these women as they work through their priorities.

…

It would help to think of tools and services that could help these women to eventually attain smoke-free status without compounding their sense of shame and stigma in the interim."[54]

The sense of shame or stigma attached with trying but failing to quit smoking is a cost that can act as an impediment to quitting. There are advantages, then, in emphasising the enjoyment or recreational aspects of vaping and other reduced risk products to shift the mindset away from a purely medical one. If the medicinal/health aspects add undue pressure on individuals who want to quit but face a lot of internal conflict, the smoke-free products have the advantage of helping people quit at a pace they are comfortable with.

The Ministry and ThinkPlace also acknowledge a sense of loss that might be felt when quitting smoking. For some, smoking is a coping mechanism that plays a functional part in their lives. For this reason, offering a feasible substitute could help ease some of those fears:

"Smoking offers some advantages as a coping mechanism in lieu of other supports. Smoking needs to be understood in that context and the real losses these women will incur if they stop smoking need to be acknowledged and addressed.

The Ministry needs to understand the 'returns' of smoking and address these in any interventions aimed at smoking cessation."[55]

Finally, the report argues that smoking cessation should not be forced on people, who might have more pressing priorities or challenges in their life. Policy-wise, this means that it is important to offer smokers a choice of less harmful nicotine delivery products, and to offer pathways to cutting down or reducing smoking, but compulsion is likely to be counterproductive:

"Smoking cessation may or may not be a priority issue when already dealing with problems and challenges in daily life. Forcing smoking cessation to the fore without addressing the wider conditions and circumstances is likely to be counterproductive and alienating."[56]

Innovations in methods to quit smoking are likely to address many of these concerns. So too is respecting situations where a smoker might prefer to cut down on their smoking by using reduced risk products, or might continue to smoke while using reduced risk products as a pathway to quitting smoking completely.

3.2 In pursuit of nicotine without the harm

Nicotine and tobacco

It is almost a cliché these days to quote the late tobacco researcher Dr Michael Russell whose insight that 'people smoke for the nicotine but they die from the tar' features in many reports and articles on e-cigarettes. Yet its pithiness and contribution to expert understanding on tobacco harm reduction makes this insight worth repeating, and often.

A majority of quality studies and systematic reviews on e-cigarettes share the conclusion that nicotine in and of itself is not a dangerous

54. New Zealand Ministry of Health and ThinkPlace, "Exploring why young Māori women smoke: Taking a new approach to understanding the experiences of people in our communities," (2017), p8.
55. Ibid. p10.
56. Ibid. p11.

substance.[57] Our own Ministry of Health makes the reasonable recommendation that "when used as intended, e-cigarettes pose no risk of nicotine poisoning to users, but e-liquids should be in child resistant packaging."[58]

Rather, it is the toxins released during combustion, as well as the chemicals added to tobacco to help it burn easier, that cause the harmful health effects associated with smoking. Inhaling the nicotine from tobacco smoke into the lungs is one of the most efficient ways of delivering nicotine to the brain. Unfortunately, early public health campaigns have tended to conflate the dangers of nicotine, tobacco and combustion. Though the scientific evidence for the dangers of nicotine are weak, the impressions of risk remain with both the public and some members of the health community.

The preoccupation with the so-called risks of nicotine has distracted from some of the perceived and evidenced benefits of the substance. Nicotine is perceived to be particularly beneficial for those with Alzheimer's, Parkinson's and schizophrenia. But because of nicotine's historically strong association with smoking, its benefits have been a neglected area of quality study.[59, 60]

Even today, some public health experts and policymakers see nicotine addiction as a risk of e-cigarette use, especially the risk that non-smokers, including young people, will experiment with nicotine e-cigarettes and become addicted.[61] But if nicotine is not a significantly toxic substance when used as intended, how much weight should the risk of addiction be given if it does not pose serious health consequences? In other words, how harmful – in and of itself – is addiction? And how should that harm be balanced against the benefits of switching from smoking to a reduced risk addictive product?

To complicate matters further, the very definition of 'addiction' is woefully lacking in clarity. In fact, there is no universally shared definition of the term. It has commonly been understood as compulsive behaviour that leads to harmful or debilitating outcomes (such as methamphetamine addiction), but in recent times the definition has been extended to nearly all activities from smartphone use, to sex, to junk-food. 'Addiction' often implies some level of risk or harm.

There is also a distinction between addiction and dependence, where dependence might cause discomfort, but addiction can cause disruptions to one's ability to function as a productive member of society. On the scale of addiction to risky substances, nicotine is probably less risky than methamphetamine, and probably on par with caffeine. Portraying addiction as a disease[62] is also problematic, as it has not only been scientifically challenged, but the disease perception also carries with it an unhelpful moral stigma.[63] The disease

57. Royal College of Physicians, "Nicotine without smoke: tobacco harm reduction," (2016), p57–59; and Ann McNeill, Leonie S Brose, Robert Calder, Linda Bauld, Debbie Robson, "Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England," Public Health England (2018), p53–62.
58. Note that many nicotine e-liquids sold in New Zealand are already self-regulating by ensuring child-resistant packaging. New Zealand Ministry of Health, "Vaping (e-cigarettes)," op.cit.
59. Jess López-Arrieta, Francisco José FJS Sanz, "Nicotine for Alzheimer's disease," *Cochrane Dementia and Cognitive Improvement Group* (2001, updated 2010).
60. Sumir Punnoose, Madhvi R Belgamwar, "Nicotine for schizophrenia," *Cochrane Schizophrenia Group* (2006).
61. New Zealand Ministry of Health, "Regulation of nicotine and non-nicotine e-cigarettes and e-liquids," Regulatory Impact Statement (2017).
62. That usage (such as drug use) changes the brain so that further use is beyond the voluntary control of the consumer.
63. Marc Lewis, a neuroscientist and professor emeritus in developmental psychology has summarised a wide variety of literature on the topic, and presents arguments from his own research experience. Marc Lewis, "Why the Disease Definition of Addiction Does Far More Harm Than Good", *Scientific American* (2018) https://blogs.scientificamerican.com/observations/why-the-disease-definition-of-addiction-does-far-more-harm-than-good/

model is particularly problematic if people do not see themselves as suffering from a 'disease'. A study collecting the reactions of smokers to the 'disease' portrayal of smoking addiction found that:

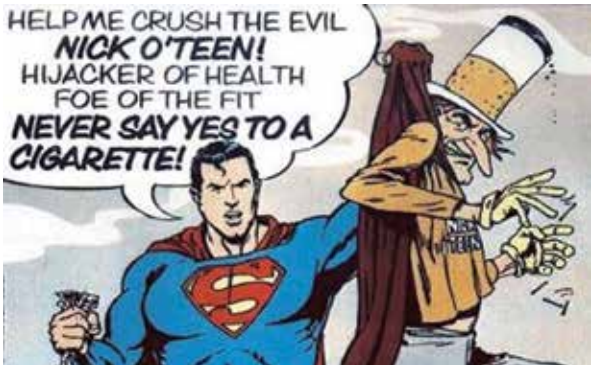
> "while most participants accepted that nicotine acts on the brain to influence their smoking, the majority rejected the label of smoking as a brain disease. The main reasons for this were: doubts about the scientific accuracy of the claim; concerns that such terminology would increase stigma and prejudice against smokers; and a belief that it would lead smokers to absolve themselves of personal responsibility for their smoking. Participants believed that most smokers would reject the label, even if it was scientifically accurate."[64]

So not only is the concept of 'addiction' poorly defined, but it is not obvious what action – if any – needs to be taken to address addictions that cause varying levels of harm.[65]

Tobacco too has had a chequered past in public health history. Synonymous with smoking, the tobacco leaf itself has traditionally been considered a dangerous substance. In fact, the World Health Organisation's current position is that "all forms of tobacco use are harmful, including HTPs [Heated Tobacco Products]. Tobacco is inherently toxic and contains carcinogens even in its natural form."[66]

While the leaf might be inherently toxic, it is also understood that the chemical composition of the substance can be affected by the genetic make-up of the leaf, existing environmental conditions, and processing methods.

Example of the demonisation of nicotine



In the late 1970's/early 1980's America's Health Education Council teamed up with DC Comics to produce a series of anti-smoking messages aimed at children, featuring the villain Nick O'Teen.

Source: Image from Retroist blog, www.retroist.com/2014/11/19/superman-loves-lungs/ (19 November 2014)

During the processing/manufacturing process tobacco is blended which changes the concentration and bioavailability of nicotine, and the levels of carcinogenic agents in the product.[67] In conventional cigarettes, the curing process and the addition of other chemicals during production is understood to contribute to the toxicity of cigarettes. Older forms of tobacco consumption, or methods of consumption specific to certain countries or cultures, have traditionally involved more dangerous methods of production by fire-curing the tobacco (dry snuff) or mixing the tobacco with harmful components (betel quid).

However, less harmful processes have been developed which significantly reduce the toxic components naturally found in

64. Kylie Morphett, Adrian Carter, Wayne Hall, Coral Gartner, "Framing Tobacco Dependence as a "Brain Disease": Implications for Policy and Practice," *Nicotine & Tobacco Research* (2017) 19:7.
65. Carl V. Phillips has suggested some sound criteria for a workable and consistent definition of "addiction". Of particular relevance is the requirement that "it must necessarily be a bad thing that someone is addicted" and "the definition cannot just be "uses a drug" or something similar." Carl V. Phillips, "Does ANYONE have a valid definition of "addiction"?" (7 October 2013) https://antithrlies.com/2013/10/07/does-anyone-have-a-valid-definition-of-addiction/
66. World Health Organisation, "Heated tobacco products (HTPs) information sheet," www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/
67. International Agency for Research on Cancer, "Smokeless tobacco," IARC Monographs – vol.100E (2012) http://monographs.iarc.fr/ENG/Monographs/vol100E/mono100E-8.pdf

tobacco. Swedish snus is composed of steam-pasteurised tobacco which has reduced the level of carcinogens. The risks or toxicity of tobacco, therefore, are related to the manufacturing processes and the means by which it is consumed.

A World Health Organisation study into the risks related to different forms of tobacco containing products found that:

> "Cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine is the least hazardous. Among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some [smokeless tobacco] products [traditionally] used in Africa and Asia approach those of smoking."[68]

The preparation of tobacco, then, can play a big role in lowering the hazardous components of the product, and although tobacco has been considered risky because of historical or traditional methods of consumption, new methods have been developed to decrease those risks.

The invention of the e-cigarette

Cigarettes have traditionally been the most effective nicotine delivery vehicle. As the understanding of the roles and relative risks of nicotine and combustion have evolved, so too has the technology for alternative nicotine delivery devices.

In 2001,[69] when Hon Lik developed the first commercially viable e-cigarette he was motivated to do so after watching his father die of lung cancer, and not wanting to suffer the same fate as a smoker.[70] The e-cigarette was borne out of demand for a less harmful means of delivering nicotine to the system, that would also satisfy nicotine cravings in ways that Nicotine Replacement Therapy (NRT) products failed to do.[71] Traditional NRT products release nicotine slowly and steadily into the system, rather than in high intensity bursts like in cigarette smoking. They are therefore poor substitutes for the sensory characteristics that smokers might prefer, nor the level of nicotine intake smokers are accustomed to.

Yet the first generation of vape products (the cigalike) are quite different from the vape products we see today, both in terms of look, consumer acceptability and nicotine delivery. While the cigalikes look the most like real cigarettes compared with other products, they do not deliver the same "feel" and satisfaction from nicotine delivery that other vape products have improved on. The creative destruction and displacement of the traditional cigarette might have started with Hon Lik's cigalike product, but it certainly did not end there.

68. World Health Organisation, "The Scientific Basis of Tobacco Product Regulation: Second report of a WHO study group," *WHO Technical Report Series: 951* (2008)

69. A number of attempts and activities occurred before 2001 that are noteworthy developments towards the invention of the e-cigarette. For a comprehensive timeline of events, see Consumer Advocates for Smoke Free Alternatives Association, "A Historical Timeline of Electronic Cigarettes," www.casaa.org/historical-timeline-of-electronic-cigarettes/

70. Martinne Geller, "E-cigs a 'consumer-driven' revolution born from a bad dream," *Reuters, London* (10 June 2015)

71. The weakness of NRT products as a substitute for smoking was reinforced by the Royal College of Physicians who pointed out "NRT products may not be effective in some smokers because they replicate few of the delivery, sensory or behavioural characteristics of cigarettes." Royal College of Physicians, "Nicotine without smoke: tobacco harm reduction," op.cit.

The images below show the evolution of vape products. The main difference between the generations are the refillable tank systems, battery size, power and efficiency of the products.

The evolution of vape products

1st generation (cigalikes)

2nd generation (vape pens)

3rd generation (mods)

In 2013, Goldman Sachs recognised the potential of e-cigarettes to transform the tobacco industry as one of eight industries where creative destruction will 'force established companies and business models to either adapt or die.'[72]

So what is driving this innovation? This continued innovation is undoubtedly consumer-driven. Ultimately, smokers want an effective nicotine delivery device. Creative destruction will get us closer to discovering a less harmful but more effective product.

The sensory experience of vaping has also developed over time and is catering to a variety of needs. There are differences in nicotine strength, e-liquid flavours, the size of 'vape clouds' that can be produced, and the strength of 'throat hit'.[73]

72. Robert D. Boroujerdi "The Search for Creative Destruction: An Excerpt from the August 7, 2013 report" Goldman Sachs Equity Research (2014)
73. Many e-cigarette/e-liquid retailers emphasise the importance of "throat hit" as one of the most important aspects of the vaping experience for those who want a similar sensation to smoking. The throat hit refers to the feeling of irritation felt in the back of the throat when consuming nicotine, ranging from smooth to harsh sensations.

The community aspect of vaping should also be appreciated in New Zealand. Because of the regulatory grey area, vapers helping vapers has been an important part of building a constituency for e-cigarettes.[74] Before retailers and producers began broad advertising of their products, word of mouth was an important means of communicating to smokers that this new alternative nicotine delivery device is available. There are various health groups and community organisations working hard to get e-cigarettes into communities under-served under the current regime, and vaper advocacy (in conjunction with public health support) has played a role in driving pressure on the government and policymakers for regulatory change.

3.3 E-cigarettes are working for some, but not others

While e-cigarettes are undoubtedly helping people to quit smoking, and seem to provide the satisfaction and sensory experience for some, this form of nicotine delivery will not be preferred by everyone. And any observer of technological progress would argue that it is a mistake to assume that improvements in nicotine delivery technology have already reached a pinnacle.

In Great Britain, a 2017 survey of smokers and e-cigarette users found that e-cigarette prevalence had plateaued from an 86% increase in 2013, to an 8% increase in 2016 and a 4% increase in 2017.[75] The same survey found that the main reason for stopping e-cigarette use among current smokers was that 'they didn't feel like smoking a cigarette'[76] (25%) and 'they didn't

74. An example of this is the Aotearoa Vape Community Advocacy's 'Vape it Forward' programme. www.avca.org.nz/vape-it-forward/
75. Action on Smoking and Health UK, "Use of e-cigarettes (vapourisers) among adults in Great Britain," Fact sheet (2017)
76. To avoid possible confusion in interpretation, the response here means that vaping e-cigarettes does not feel like smoking cigarettes.

help me deal with cravings for smoking' (20%). A follow up question, asking what would prompt current smokers to try e-cigarettes again, found that 'if it felt more like smoking' (28%) was the most popular response. A whopping 90% of respondents who were ex e-cigarette users and current smokers said that vaping was less satisfying than smoking.[77]

These insights from the United Kingdom are potentially useful, as the UK have a more developed market for e-cigarettes than New Zealand and could be indicative of future challenges here.

A small-scale study of 20 current e-cigarette users indicates similar sentiments might be shared in New Zealand.[78] One of the findings of the study was that "while ENDS [Electronic Nicotine Delivery Systems] controlled intense cravings, participants wanted more than a physiological distraction and hoped to continue experiencing other smoking attributes."[79] Importantly, the study also emphasised the psychological dissatisfaction as distinct from a physical dissatisfaction:

> "The absence of these physical sensations undermined the relationships participants developed with ENDS and the psychological benefits they received. While Angie described cigarettes as her 'best friend', Damian enjoyed tobacco's 'nostalgic feel' and Anthony felt smoking had a 'charm to it'; none viewed ENDS in these affectionate terms."[80]

This emotional attachment to smoking over vaping includes using smoking as a coping strategy, that it does not replicate "smoking rituals" like providing a socially sanctioned reason for being alone, and that it was not a substitute for complementary behaviours like drinking alcohol or coffee. It also indicates a potential role for marketing to emphasise the emotional appeals of a product in order to convince people to shift their existing loyalties and positive sentiments away from smoking.

Some respondents were also concerned about the lack of social acceptability of vaping in some social peer groups:

> "I didn't find myself bringing it out to town … It was almost embarrassing, for some reason … I didn't want to be associated with that culture …. when I went out to town, I'd smoke a cigarette." [Kelvin, a study participant][81]

While this study was only small-scale, it does indicate that the effectiveness of quit smoking methods will vary across groups, and that the psychological and social elements should be considered alongside physical satisfaction.

What people need is a range of alternative nicotine delivery products and methods to choose from. These products need to be affordable, and people need access to the most effective products. In policy-terms, this means that if New Zealand is to introduce a regulatory system, it needs to be one that is flexible enough to encourage innovation and one that encourages competition between retailers and producers so that there are improvements in price, quality and consumer acceptability.

77. Action on Smoking and Health UK, "Use of e-cigarettes (vapourisers) among adults in Great Britain," op.cit.
78. Lindsay Robertson, Janet Hoek, Mei-Ling Blank, Rosalina Richards, Pamela Ling, Lucy Popova, "Dual use of electronic nicotine delivery systems (ENDS) and smoked tobacco: a qualitative analysis," *Tobacco Control* (published online ahead of print: February 2018).
79. Ibid, p.2. Though some of the people quoted to support this argument sounded like the dissatisfaction they experienced was lack of "throat hit" that might be satisfied with the right vape device and e-liquid.
80. Ibid. p.4.
81. Ibid. p.5.

CHAPTER 4

The changing face of tobacco harm reduction

While the market for e-cigarettes and e-liquids has been well-established in New Zealand, there are other nicotine delivery devices that have established markets overseas. As companies invest more in research and development,[82] other products will make it through the pipeline. Though these products will have differing risk profiles,[83] consumers seeking less harmful products will reward innovators able to reduce harm further. This report looks at two products, Swedish snus and heat-not-burn, to illustrate the kinds of products New Zealand should consider.

4.1 Swedish snus

In 2007, New Zealand's Ministry of Health commissioned a review into the health effect of Swedish snus and whether it could have a role in reducing tobacco related harm. The review "confirms that snus carries a considerably lower risk of harm than smoked tobacco, but that there are still many unanswered questions about its long-term safety and the role it might play – if any – in reducing smoking."[84]

In other words, the Ministry of Health was satisfied from the research at hand that snus is a reduced risk product, but considered they did not have 'enough' evidence of the role of snus in reducing smoking. Over ten years on, and with a body of literature behind the product and its usage, New Zealand policymakers might want to reconsider.

Snus

Snus use: prevalence and habits

Sweden presents a useful case study for the role of snus as an aid to quitting smoking because Sweden is the only EU-member country where snus is legal. An exemption from the EU's blanket ban was reportedly an important factor for the Swedes joining the EU and continues to be a point of contention as the Swedes fight to have the EU ban on snus lifted.[85]

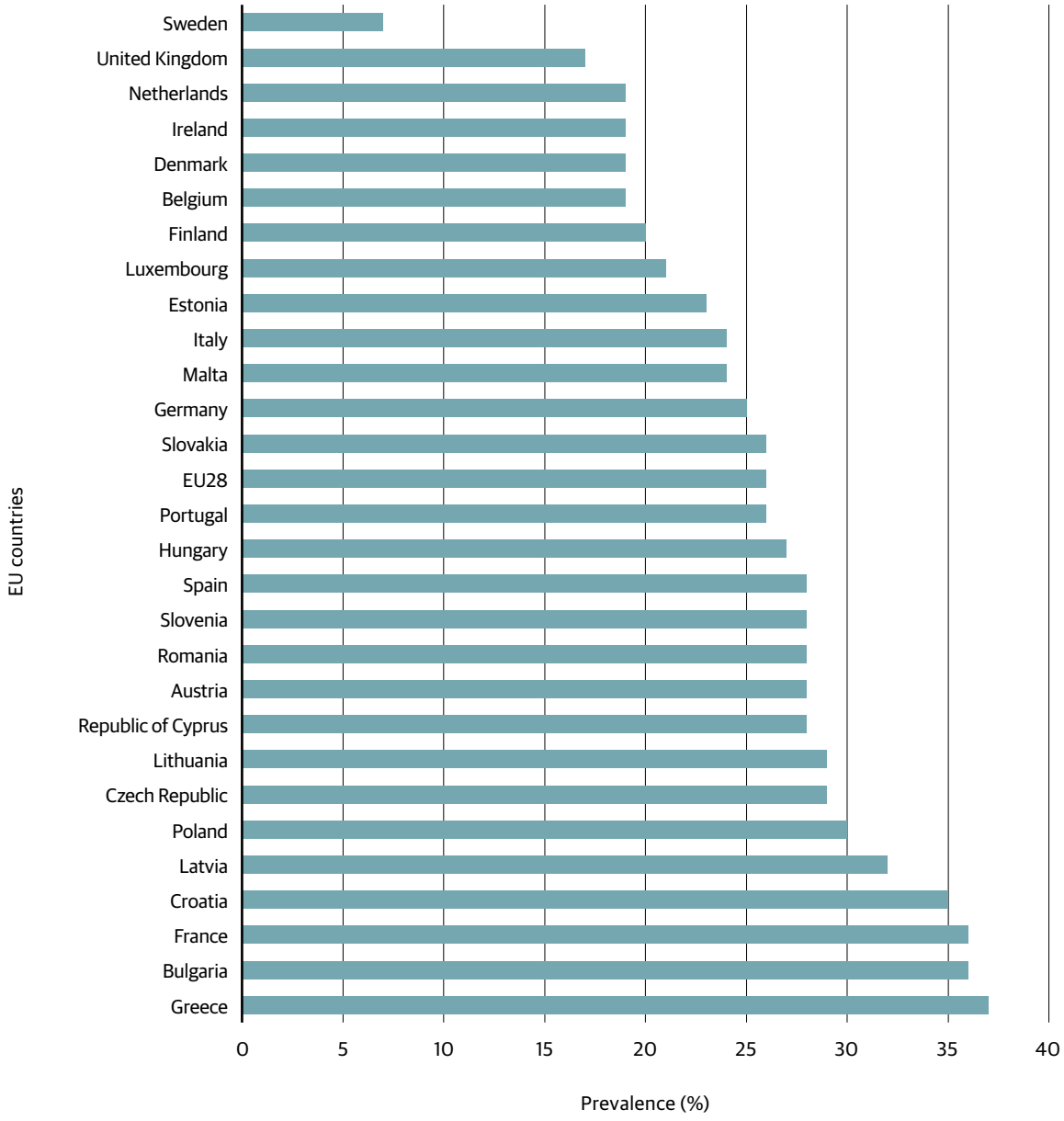
As a side note, the Eurobarometer reports that people living in Sweden's neighbours, Denmark and Finland, both report having tried snus in

82. Business journalists have paid particular attention to the increase in R&D investment by tobacco companies, and the part tobacco companies are playing in the creative destruction of the cigarette. Paul McClean, "Big Tobacco's technology battle heats up," *Financial Times* (January 10 2017); Felix Gillette, Jennifer Kaplan, and Sam Chambers, "Big Tobacco Has Caught Startup Fever," *Bloomberg* (8 March 2017)
83. Disclaimer: This report makes no definitive claims about the relative riskiness of these products, but discusses their potential as reduced risk products. The relative risks of these products would still need to be independently adjudicated in accordance with whatever policy framework is developed.
84. New Zealand Ministry of Health, "Review of the Health Effects of Swedish Snus," Press Release (29 March 2007), www.scoop.co.nz
85. Niclas Rolander, "Sweden to EU: Hands off our snus," *The Wall Street Journal* (13 June 2013)

significant shares (16%). In 2015, Denmark lost a case with the European Commission to sell snus after a long legal battle.[86] Meanwhile, it appears that Finland might have developed a lucrative black market for snus.[87]

Sweden's smoking rate of 7% is significantly lower than other EU-member countries (see figure 4). Sweden is also unusual in that the smoking rates for females are greater than males. Many experts and commentators attribute

Figure 4: Current tobacco smoking (cigarettes, cigars, cigarillos, pipe) in the European Union 2017



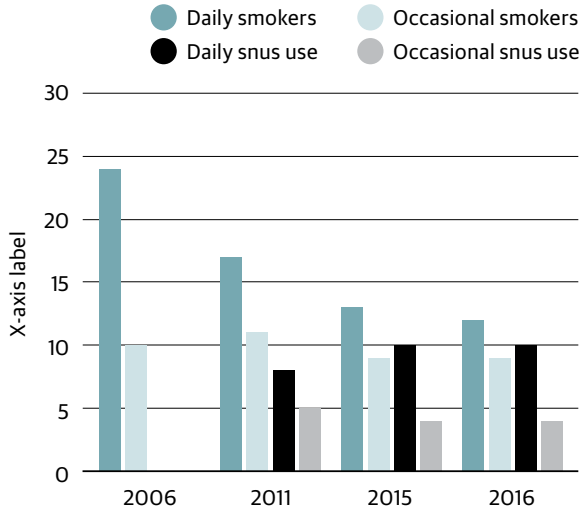
Source: Data from European Commission, "Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes," (2017)

86. The Local Denmark, "Denmark loses snus case in European court," *The Local Denmark* (17 July 2015)
87. Sara Silvennoinen, "Meet the 17-year-old getting rich dealing snus illegally," *VICE Scandanavia* (18 June 2017)

this idiosyncrasy to the rates of snus use amongst males relative to females. In 2016, eight percent of men and eleven percent of women were daily smokers. Meanwhile, snus use for males aged 16–84 was 18 percent, compared with approximately 3–4 percent among women.[88]

Perhaps most compelling is that in Sweden, snus is the predominant form of nicotine consumption. The Swedes have not quit nicotine consumption, but have switched to a less harmful alternative.

Figure 5: Norway's falling daily smoking rate (2006–2016)



Source: Statistics Norway, "Smoking habits, 2016," (2017) www.ssb.no/en/helse/statistikker/royk/aar/2017-01-18#content

Norway – which is not an EU member country – is also closing the gap between smoking rates and snus use (see figure 5). In 2017, 11% were daily smokers compared with daily snus users at 12%.[89] Within a decade, the daily smoking rate in Norway has almost halved, while snus users have grown to close the gap. While the statistics between smoking and snus are still marginal, there appears to be a generational shift in Norway where older people are more likely to smoke, whereas younger people are more likely to use snus.[90]

Though snus could be considered in the 'new wave' of nicotine delivery products, it is actually a very old product, with the first brand of snus registered in 1822. The origins of snus can be traced back to moist snuff (dipping tobacco), which in turn developed from dry snuff (nasal tobacco).

Like moist snuff, snus is placed under the top lip and nicotine is absorbed through the gum. But unlike moist snuff, snus does not require spitting, making it a more convenient and more discrete option. And just to add to the confusion, sometimes Swedish snus is called snuff or moist snuff, but it is not the same as the traditional moist snuff.

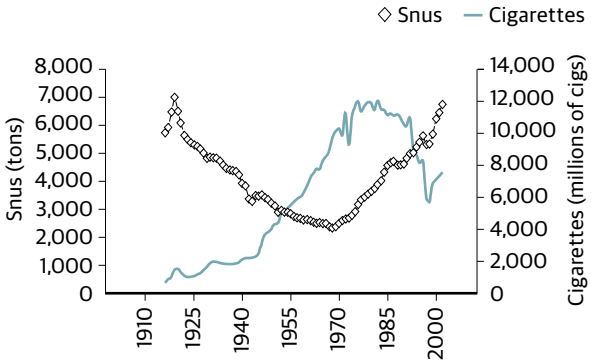
Despite being a very old product, for a long time, snus lost popularity compared with the conventional cigarette (see figure 6). The popularity of snus began to rise again around the late 1960s when the health risks of smoking became apparent.[91]

Today, snus consists of moist tobacco that is portioned in teabag-like pouches. In contrast to dry snuff, snus tobacco is steam-pasteurised, rather than fire-cured.[92] The difference in curing process affects the level of tobacco-specific

88. Public Health Agency of Sweden, "Tobacco," (2017) www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/alcohol-narcotics-doping-tobacco-and-gambling/tobacco/
89. Statistics Norway, "Smoking habits," (2018) www.ssb.no/en/royk
90. Statistics Norway, "Snus more used than cigarettes," (2018) www.ssb.no/en/helse/artikler-og-publikasjoner/snus-more-used-than-cigarettes
91. Swedish Match, "History of snus," (2016) www.swedishmatch.com/Our-business/Snus-and-moist-snuff/History-of-snuff/
92. This report only discusses Swedish snus. The United States also manufacture snus but there is evidence to suggest that the different manufacturing process might affect the risk profile of the product (with Swedish snus being less risky). J. Foulds, L. Ramstrom, M. Burke, K. Fagerström, "Effect of smokeless tobacco (snus) on smoking and public health in Sweden," *Tobacco Control*, 12:349–359 (2003)

nitrosamines (one of the primary carcinogens found in tobacco), with the snus process producing a much less carcinogenic product than other tobacco curing processes.[93] In terms of nicotine delivery, snus appears to offer similar levels of nicotine to cigarette smoking, and is absorbed rapidly.[94]

Figure 6: Sales of snus and cigarettes in Sweden 1916–2002



Source: J. Foulds, L. Ramstrom, M. Burke, K. Fagerström, "Effect of smokeless tobacco (snus) on smoking and public health in Sweden, op.cit.

A Swedish study of 60,675 respondents[95] found that snus also improves a smoker's chances of quitting smoking completely (see the quit ratios in the table below).[96] For men, snus was reported as the most common method for quitting smoking. In the study period from 2003 to 2011, among those who had started the study as smokers, those who had subsequently started using snus saw significant quit rates for smoking. 76.3% of men and 71.6% of women had stopped smoking completely after starting using snus, including 31.5% of the men and 28.6% of the women who had quit all forms of tobacco (smoking and snus).[97]

The study also gives an interesting take on dual use, finding that

> "more than eight out of ten secondary [dual] snus users had quit daily smoking [during the study period] and that almost one-third of them had become completely free of daily tobacco use. Consequently, there are strong reasons to assume that "dual use" is usually a transient rather than permanent state or an endpoint."[98]

This insight is important for those concerned about dual use as a means of maintaining smoking habits or nicotine habits, or as a barrier to quitting smoking completely. Tracking the dual use of individuals over time is an important means of ascertaining whether dual use is a pathway to quitting smoking. As the Sweden case shows, a good proportion of dual users not only quit smoking over time but quit using snus as well.

While the proportion of primary snus users who become smokers might be of some concern for people who believe snus should only be used by smokers/ex-smokers, the occurrence appears to be generational and is dwarfed by the proportion of non-snus users who take up smoking.

93. "The major group of carcinogens in STP [Smokeless Tobacco Products] includes non-volatile tobacco-specific nitrosamines (TSNA) and *N*-nitroamino acids. During the last two decades the levels of TSNA in snus have been considerably lowered. One recent study documented total TSNA levels in one brand of Swedish snus to be 2.0 microgram/gram product wet weight, whereas total TNSA levels in 6 American brands varied from 1.3 to 9.2 microgram/gram." Scientific Committee on Emerging and Newly-Identified Health Risks, "Health Effects of Smokeless Tobacco Products," European Commission (2008), p.33
94. Herman Holm, Martin J. Jarvis, Michael A. H. Russell, Colin Feyerabend, "Nicotine intake and dependence in Swedish snuff takers," *Psychopharmacology* (1992) 108:4, pp 507–511
95. There are many studies on this subject, but this study was chosen because it looks at daily use of both smoking and snus (so results are not confused with ever-users or more casual users), and defines dual use in the same way (daily use of both kinds). This clarity is an improvement on other studies that may feature vastly different levels of use. The study also uses a decent time frame (2003 to 2011) to track usage over time.
96. Lars Ramström, Ron Borland, and Tom Wikmans, "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health," *International Journal of Environmental Research and Public Health* (2016) 13:11, p.1110, www.ncbi.nlm.nih.gov/pmc/articles/PMC5129320/
97. Ibid.
98. Ibid.

Occurrence and effects of secondary snus use in different birth cohorts of men in Sweden

Born in	Proportion of non-primary snus users becoming smokers	Proportion of primary snus users becoming smokers	Proportion of primary smokers who take up secondary daily snus use	Quit ratios (ratio of ex-smokers as function of ever-smokers)	
				Primary smokers without daily snus use	Primary smokers with daily snus use
1940s	60.4%	19.6%	34%	0.60	0.83
1950s	53.8%	22.8%	40%	0.48	0.77
1960s	36.6%	18.6%	41%	0.40	0.72
1970s	28.7%	13.5%	45%	0.31	0.66
1980s	21.8%	14.3%	46%	0.19	0.47

Source: Lars Ramström, Ron Borland, and Tom Wikmans, "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health,"op.cit.

The table above shows that the "gateway" hypothesis, that snus use amongst young people might be a gateway to smoking, is largely unfounded. The proportion of those that ever started daily smoking was significantly lower among primary snus users[99] (17.6% among boys, 8.2% among girls) than among those without previous snus use (45.9% among boys, 40.2% among girls)."[100] Again, while some may be concerned that young people are using snus at all, this needs to be compared with smoking as a counterfactual.

Literature on snus harms historically overstated

As with e-cigarettes, the health risks of snus have been the centre of many public health studies and public commentary. And like e-cigarettes, poor quality studies have emerged that undermine the message that snus is a reduced risk product compared with smoking.

One thing to watch in the literature is the lack of sorting in early studies between types of smokeless tobacco (Swedish snus, US snus and moist snuff). Some study findings have been applied to snus despite the substances having different risk profiles. Potential confounders also affect the difficulties in measuring risk, including alcohol use, smoking and other lifestyle factors. When comparing snus users to smokers or non-smokers, snus use and levels of smoking can both vary widely.

An epidemiological review of 21 published studies (20 of which were case-controlled) that controlled for the type of tobacco product found that "the use of moist snuff and chewing tobacco imposes minimal risks for cancers of the oral cavity and other upper respiratory sites, with relative risks ranging from 0.6 to 1.7. The use of dry snuff imposes higher risks, ranging from 4 to 13."[101]

99. Lars Ramström, Ron Borland, and Tom Wikmans, "Patterns of Smoking and Snus Use in Sweden: Implications for Public Health,"op.cit.
100. Ibid.
101. While many of the studies reviewed have the limitation that they did not adjust for confounders (particularly alcohol use and smoking status), it is likely that adjusting would have reduced these estimates further. Brad Rodu and Philip Cole, "Smokeless tobacco use and cancer of the upper respiratory tract," *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics* (2002) 93:5, pp511–515

A systematic review by Peter Lee and Jan Hamling looked at the relation between smokeless tobacco and cancer in both US and Scandinavian studies. Though the US studies showed some possible effects for oesophagus, pancreas, larynx and kidney cancer, the Scandinavian studies showed no such risk. Even for the US, the risks are small, with the authors concluding that even if the whole US never-smoked population used smokeless tobacco, the increase in smokeless tobacco-attributed deaths would represent only 2% of the 104,737 deaths attributed to cigarette smoking [102]

Of course, coming up with risk estimates is difficult. One study sought to collate the opinions of health experts and to measure their confidence in those estimates. In comparison with smoking, experts perceive at least a 90% reduction in relative risk by switching to low-nitrosamine smokeless tobacco[103] use. The study gathered the panel members' estimates on a range of diseases, but found experts "tended to be more confident for estimates pertaining to total premature mortality and lung cancer risks than for estimates for heart disease and oral cancer. Panel members submitting the higher estimates tended to be less confident."[104] Though this estimate might be challenged, it does reflect the differences in confidence scientists can have when talking about different risks. Diseases with a lower overall risk are harder to accurately estimate.

A different study assessed the potential population health effects of snus, by focusing on snus uptake by current smokers, ex-smokers and never-smokers. The study found "little difference in health-adjusted life expectancy between smokers who quit all tobacco and smokers who switch to snus" meaning that abstinence from all tobacco did not have to be the only choice to improve life expectancy.[105] The study also considered the costs and benefits of legalising snus in Australia and describes the circumstances under which net harm to the population would occur: "14–25 people who have never smoked would need to start using snus to offset the health gain from every new tobacco user who used snus rather than smoking."[106]

Another way of looking at the risks of snus is to compare public information to scientific evidence. One study reviewed the information in health education brochures on smokeless tobacco use, compared with the scientific literature. The study recognised that although the brochures linked usage with a range of cancers and conditions, no cancers[107] were substantiated by evidence of persuasive causation except oral cancer. Even for oral cancer, the evidence was suggestive and not definitive.[108]

102. Peter N Lee and Jan Hamling, "Systematic review of the relation between smokeless tobacco and cancer in Europe and North America" BMC Medicine (2009) 7:36, https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-7-36
103. The products in the study were Swedish snus and Ariva (a dissolvable tobacco tablet placed between the upper gum and cheek).
104. David T. Levy, Elizabeth A. Mumford, K. Michael Cummings, Elizabeth A. Gilpin, Gary Giovino, Andrew Hyland, David Sweanor and Kenneth E. Warner, "The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts" *Cancer Epidemiology, Biomarkers and Prevention* (2004) 13:12, http://cebp.aacrjournals.org/content/13/12/2035
105. Coral E Gartner, Wayne D Hall, Theo Vos, Melanie Y Bertram, Angela L Wallace, Stephen S Lim, "Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study," *Lancet* (2007) 369: 2010–14
106. Ibid.
107. No cancers except oral cancer were substantiated, but there was evidence to support some other (largely reversible) oral conditions. The authors recommend that rather than exaggerate risks, these health brochures would do better to recommend regular oral examinations to prevent or detect these conditions early.
108. Also keep in mind that the study looked at all forms of smokeless tobacco, not just Swedish snus. J.W. Waterbor, R.M. Adams, J.M. Robinson, F.G. Crabtree, N.A. Accortt, J. Gilliland, "Disparities between public health educational materials and evidence that smokeless tobacco use" *Journal of Cancer Education* (2004) 19(1):17–28.

The study concluded that

> "broadening the [health education] message to include additional diseases for which the evidence is inadequate could cause the message about true risks, as well as the messenger, to be discounted."[109]

A similar study looked at the health education provided by popular websites on smokeless tobacco, paying particular attention to whether the relative risk of smoking compared with smokeless tobacco use was accurately communicated. An examination of 316 relevant websites found that "accurate comparative risk information was quite rare, provided by only a handful of websites, all appearing low in our search results (i.e. of low popularity and thus unlikely to be found by someone searching for information)."[110]

The study found that even prominent sources that released tobacco harm reduction statements supporting the use of smokeless tobacco like Action on Smoking and Health (ASH) UK and the American Council on Science and Health ranked low in internet search engine results. The spread of misinformation (based on poor quality or outdated studies) regarding snus and smokeless tobacco is therefore likely to be quite high. Given the modern day reliance on websites to provide accurate information on health risks, the researchers conclude "the negative health implications of preventing people from realizing that ST [smokeless tobacco] is relatively safe should not be underestimated."[111]

An analysis of The Global Burden of Disease Study published in The Lancet found that there was no sufficient evidence that the relative risk ratio for snus was greater than one for any health outcome.[112] In other words, the relative risk of snus use for any adverse health outcome was not significantly different from that of the control group.

Meanwhile, the Royal College of Physicians has also claimed that the availability of snus in Sweden "demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product."[113]

Though this report does not claim to adjudicate on all the relevant scientific evidence, a number of meta-analyses and systematic reviews indicate that snus is significantly less harmful than conventional smoking and can increase one's chances of quitting.

4.2 Heat-not-burn products

Heat-not-burn (HNB) products contain tobacco but do not involve combustion like conventional cigarettes. Instead, tobacco is heated to a level where nicotine is released, but not the same toxins or level of toxins associated with combustion. While heating will cause some chemical reactions in the tobacco, as mentioned in this report previously, combustion is understood to be attributed to the greatest risks involved with cigarette smoking.

109. J.W. Waterbor, R.M. Adams, J.M. Robinson, F.G. Crabtree, N.A. Accortt, J. Gilliland, "Disparities between public health educational materials and evidence that smokeless tobacco use, op.cit.
110. Carl V Phillips, Constance Wang and Brian Guenzel, "You might as well smoke; the misleading and harmful public message about smokeless tobacco," *BMC Public Health* (2005) 5:31, https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-5-31
111. Ibid.
112. Global Burden of Disease 2016 Risk Factors Collaborators, "Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016," *Lancet* (2017) 390: 1345–422, p1364.
113. Royal College of Physicians, "Nicotine without smoke: tobacco harm reduction," op.cit. p.6.

Although currently considered two distinct products, some manufacturers are developing hybrids between HNB and e-cigarettes.[114]

What these technologies have in common is the use of specially prepared tobacco[115] (in contrast to e-cigarettes using only e-liquids), and the fact they do not involve combustion. Like e-cigarettes, most of these devices provide a sensory experience that could provide a substitute for smokers wanting to switch to a less harmful alternative. However, unlike e-cigarettes, HNB products contain tobacco and therefore potentially provide a more authentic tobacco taste that might appeal to some of those smokers. While most products on the market involve prepared tobacco compatible with only that company's device, it is possible that future products might allow cross-compatibility.[116]

As of September 2017, the World Health Organisation estimates that HNB products are marketed or plan to be marketed in nearly forty countries.[117]

These products are being developed by only a handful of companies so far, most of them tobacco companies. A reasonable explanation for this is that it is currently a high-risk market that might face regulatory challenges in many jurisdictions (not to mention all the normal market risks like customer acceptability and technological safety and efficacy). That does not necessarily mean that once risks have been tested, smaller players could not provide real market competition against large companies. In fact, it might be the smaller players who bring about real disruption and innovation to the field. As an article in *Bloomberg* argues, mature industries like tobacco companies do not necessarily have an advantage:

> "Mature industries typically have a hard time disrupting themselves, but, flush with cigarette profits, the big competitors have decided to try. Since the rise of e-cigarettes, it's no longer such a stretch to imagine a messianic engineer in a garage somewhere inventing a nicotine-delivery gadget capable of doing to cigarettes what Uber did to taxicabs or Napster did to the compact disc."[118]

Once the regulatory status of these products is clearer, and there is market demand for such products, smaller players can have more confidence entering the game. It is likely that these companies will compete on patented technologies based on the relative riskiness of their devices; their effectiveness and attractiveness to consumers; and the ability of the technology to meet the requirements of existing regulatory regimes. This report will explain later how regulatory systems can encourage or limit market competition.

114. Loose-leaf vaporisers (vaporisers that use real tobacco) might also be considered in the heat-not-burn category, but the distinction between the two is that vaporisers use tobacco prepared for smoking.
115. Though the preparation of tobacco may differ, the tobacco should not be used for smoking or provide a pleasant smoking experience.
116. This will pose a regulatory challenge in determining the risks of products. For example, a low quality electronic device might pose more risks than a high quality one using the same prepared tobacco. On the other hand, it could be the case that the electronic devices pose similar risks (or lack thereof) but compete on price. Manufacturers might also use cross-compatibility to compete on safety and verifiable claims of relative risks.
117. World Health Organisation, "Heated tobacco products (HTPs) information sheet," op.cit.
118. Felix Gillette, Jennifer Kaplan, and Sam Chambers, "Big Tobacco Has Caught Startup Fever," op.cit.

HNB products have been developed since the 80s and 90s but early models were commercially unsuccessful. Only recently has the technology developed to a stage where they can attract a notable customer base. An article published on Euromonitor describes the risks involved in trying to develop such products, but argues that unlike previous attempts by companies to develop and market HNB products, the timing might be more favourable this time around.[119] After all, tobacco companies are no longer denying the serious harms that smoking causes. This puts them in a better position of marketing reduced risk products, without having to worry about self-censorship.[120] The article also points out that HNB products can fill a gap in the market that e-cigarettes have not yet been able to meet:

> "HnB technology in theory also has the potential to reach the markets, in which for taste or cultural reasons, combustible tobacco smoking is more entrenched and which e-cigarettes cannot currently penetrate … "[121]

Prevalence and use

There are reports that Chinese tobacco companies are also investing in research and development to produce their own HNB products.[122] Meanwhile, the locally produced Lil HNB device launched in South Korea is reportedly a viable price competitor in the market after the launch of other HNB products. In fact, having multiple producers in the market can benefit consumers by keeping the products affordable, even in the face of rising taxes,[123] as the Lil producer signals: "KT&G will go through discussions and watch the market if the government decides to raise taxes on the sticks. But the company could just keep the current price as a measure to become more aggressive in the market."[124]

The product that has had the most publicity and reportedly has the most developed market is Philip Morris' IQOS product. The product was introduced to Japan and Italy as test markets in 2014. Of the countries IQOS has been launched in (see table on p. 40), uptake in Japan has been strongest. Though keep in mind that Japan's market might not be as informative for New Zealand as countries that offer a range of products because nicotine e-liquids/e-cigarettes are banned in Japan.[125]

119. Note this article was written in 2014, before markets for these products were properly developed. Shane MacGuill, "Has Philip Morris Learned From the Mistakes of Heat-not-Burn Tobacco's Past?," *Euromonitor International* (23 January 2014)
120. Ibid.
121. Ibid.
122. TobaccoChina Online, "China Warms Up to Heat-Not-Burn," (2017) www.tobaccoasia.com/features/china-warms-up-to-heat-not-burn/
123. Larger companies with an established consumer base will be in a better position to absorb these rising costs. However, the pressure to absorb rising excise might discourage new competitors or smaller players from entering the market.
124. Tobacco Reporter, "KT&G launches HNB device," (8 November 2017) www.tobaccoreporter.com/2017/11/ktg-launches-hnb-device/
125. E-cigarettes are regulated as medical products and therefore subject to more rigorous regulatory requirements. Thomas Schmid, "Asia's E-Cig Regulations: Confusion & Uncertainty," (2016) www.tobaccoasia.com/features/asia-e-cig-regulations-confusion-uncertainty/

Examples of HNB products

Device	Company	How it works	Where it is available
glo[126]	British American Tobacco	"A battery-powered device that heats specially-designed tobacco sticks to approximately 240 degrees Celsius. This process produces a nicotine containing aerosol with a tobacco taste which the user inhales."	Japan, Switzerland, Canada, South Korea, Russia, Romania and Italy
glo iFuse[127]	British American Tobacco	Hybrid e-cigarette and HNB device. "glo iFuse heats cartridges which contain not only tobacco, but also a pharmaceutical-grade, flavoured nicotine liquid solution which is heated. The nicotine-containing aerosol produced by this heating process is channelled over the tobacco to deliver a tobacco taste."	Romania
IQOS[128]	Philip Morris International	"IQOS uses sophisticated technology to heat specifically prepared and blended tobacco to temperatures below 350°, generating a nicotine-containing vapour without combustion, fire, ash or smoke. The lower temperature heating releases the true taste of heated tobacco."	Available in more than 35 countries including Canada, Germany, Japan, and the United Kingdom.
IUOC (I Use Ordinary Cigarette)	Shenzhen Yukan Technology Co.	"When using IUOC, we just need to put the whole cigarette into it without any additive and then start heating. The temperature of tobacco will be at around 350°. It will produce extremely mellow taste of nicotine and tobacco without tar and solid harmful substance."[129] [This is the only product to use a conventional cigarette[130]]	Shenzhen, China
Lil (A little is a lot)	Korea Tobacco & Ginseng Corporation (KT&G)	The devices uses specially designed tobacco sticks and is an integrated device (the charger and holder are not separate). Though scientific evidence of risks were not released at the time of launch, the managing director of KT&G's innovative product department has said "What we know now is that lil produces less substances conventionally emitted by ordinary cigarettes to a level similar to competing products." He added that relevant experiments take time and promised to "open more information after we receive confirmation from a credible institute." [131]	South Korea
Ploom Tech[132]	Japan Tobacco International	"Uses a hybrid technology to create a tobacco-enriched vapor, by heating a non-nicotine liquid, which passes through a capsule containing granulated tobacco. In doing so, the tobacco is heated at around 30 degrees Celsius."	Japan and Switzerland

Source: descriptions of these products use the claims provided on the respective company websites, but in some places have been edited for brevity.

126. British American Tobacco, "Tobacco heating products," www.bat.com/group/sites/uk__9d9kcy.nsf/vwPagesWebLive/DOAWUGNJ
127. Ibid.
128. Philip Morris International, "Our Tobacco Heating System: IQOS," www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system
129. Shenzhen Yukan Technology Co., "What is IUOC," www.iuoctech.com/en#wqd1460982942538serial
130. For regulatory purposes, this product would not be regulated as a combustible tobacco product because it does not use specially prepared non-combustible tobacco.
131. Second-hand descriptions of the product, and its likeness to IQOS and glo (also available in South Korea) can be found here: Lee Min-hyung, "KT&G's heat-not-burn cigar overcomes downsides of competitors," The Korea Times (22 December 2017); and Song Kyoungson, "KT&G introduces the first Korean heat-not-burn cigarette," Korea JoongAng Daily (November 8 2017)
132. Japan Tobacco International, "Reduced-Risk Products – our next generation products," www.jti.com/about-us/what-we-do/our-reduced-risk-products

A survey of 8240 people in Japan found that between 2015 and 2017, IQOS use in the past 30 days had increased ten-fold from 1.3% in 2015 to 3.6% in 2017.[133] Using Google Trend data and feedback from the survey respondents, the study found that interest in, and subsequent use of, IQOS skyrocketed following a popular entertainment television show that discussed IQOS. IQOS use among those who saw the show was over three times higher than use among those who had not seen it (confirmed by multivariable[134] regression analyses) resulted in IQOS use being nearly four times higher than people who did not watch the television show (10.3% vs 2.7%). The dual use of HNB products and conventional cigarette smoking remains high though, with 72% of HNB or e-cigarette users also smoking combustible cigarettes (unfortunately HNB and e-cigarette use are not separated out).[135]

Meanwhile, claims from Philip Morris are more optimistic, and possibly indicate the importance of clearly defining 'dual use'.[136] In a public presentation to shareholders for the second quarter of 2016, Philip Morris reported that in Japan, of the people who buy IQOS 70% were converted either predominantly[137] or fully.[138] Conversion rates for Italy and Switzerland were reported to be 68% and 70% respectively.[139]

Risk-reduced status

Public Health England have recently updated their highly influential work on e-cigarettes (2015)[140] to include heated tobacco products (HNB). The authors acknowledge the lack of independent literature on the products, with 12 of the 20 studies reviewed funded by manufacturing companies. But as the market develops, so too should the pool of independent research.

Nevertheless, Public Health England finds that "compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds. The extent of the reduction found varies between studies."[141]

Public Health England come to the conclusion that "the available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes."[142]

The authors also make some recommendations to improve the evidence base overall, while acknowledging that different HNB products might have different characteristics and effects

133. Takahiro Tabuchi, Silvano Gallus, Tomohiro Shinozaki, Tomoki Nakaya, Naoki Kunugita, Brian Colwell, "Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol," *Tobacco Control*, Published Online (2017) http://tobaccocontrol.bmj.com/content/early/2017/12/15/tobaccocontrol-2017-053947
134. The researchers tested for the theory that 'people who often watch TV may be more curious and therefore more likely to use new products'.
135. Though keep in mind that the definition of 'dual use' is very loose: "Current combustible cigarette smokers who had concurrently used any HNB tobacco or e-cigarette in the previous 30 days were defined as dual users." Takahiro Tabuchi, Silvano Gallus, Tomohiro Shinozaki, Tomoki Nakaya, Naoki Kunugita, Brian Colwell, "Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol," op.cit.
136. Philip Morris International, "2016 Second-Quarter Results," Slides (2017) www.pmi.com/investor-relations/press-releases-and-events/2017-annual-meeting
137. 8% were predominantly converted, meaning they use IQOS 70–95% of the time compared with smoking.
138. 62% were fully converted, using IQOS over 95% of the time.
139. Philip Morris International, "2016 Second-Quarter Results," op.cit.
140. A .McNeill, L.S. Brose, R. Calder, S.C. Hitchman, "E-cigarettes: an evidence update: A report commissioned by Public Health England," op.cit.
141. Ann McNeill, Leonie S Brose, Robert Calder, Linda Bauld, Debbie Robson, "Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England," op.cit., section 12.
142. Ibid. Public Health England also voice some scepticism about whether these products are needed in the UK which already has a highly developed e-cigarette market, but that appears to be a qualitative observation.

which presents a challenge for research. Their recommendations include comparing the relative risks of HNB products, conventional cigarettes, and e-cigarettes; monitoring HNB behaviour as it relates to smoking; conduct studies according to established guidelines[143]; and developing a gold standard for methods of measuring emissions and how those emissions affect health outcomes.

This last point would be particularly useful given the current back-and-forth between experts on which method is more accurate and reliable, and how best to replicate human behaviour.[144] Independent analysis and scrutiny means that manufacturers will be answerable to the riskiness and/or any health claims of these products, and regulations will be developed accordingly.[145]

Meanwhile the UK Committees on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment investigated two different HNB products to assess the toxicological risks compared with conventional smoking.[146] The Committees compared the harmful and potentially harmful (HPHCs) in cigarette smoke with the aerosol generated by HNB products. They found that for both products, "there were some HPHCs where the reduction was approximately 50%, but the reduction in a number of other HPHCs was greater than 90%, with many of the compounds being below the limits of detection or quantification for the assays used."[147]

The Committees concluded:

> "It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products.
>
> While the Committees conclude there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, a risk remains and it would be more beneficial for smokers to quit smoking entirely."[148]

These findings suggest that HNB products ought to be understood as a 'reduced risk' product (alongside e-cigarettes and snus). The US FDA, however, has concluded differently.

In December 2016, Philip Morris International applied to the US FDA to register IQOS as a Modified Risk Tobacco Product and receive approval to market the products with a reduced risk health claim, submitting over a million pages of evidence. This year, a panel advising the FDA recommended that the FDA reject approval to market IQOS as a reduced risk product. The decision is not binding, but it shows the difficulties manufacturers face in claiming a reduced risk status. While the panellists were near unanimous in agreeing that "scientific studies have shown that switching completely from cigarettes to the IQOS system *significantly* [author's emphasis added] reduces your body's

143. Ibid. These include shared definitions of abstinence from smoking, using intention-to-treat analysis and registering trial protocols prior to the start of participant recruitment.
144. To illustrate the importance of setting gold standards for methodology and sharing universal definitions, consider the criticism and reply to criticism between Auer et al. and Philip Morris International. R. Auer, N. Concha-Lozano, I. Jacot-Sadowski, J. Cornuz, A. Berthet, "Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name," *JAMA Internal Medicine* (2017) 177(7):1050–1052; Serge Maeder and Manuel C. Peitsch, "Comments on the article entitled "Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name"," Philip Morris International (2017) www.pmiscience.com/news/comments-on-the-article-entitled-heat-not-burn-tobacco-cigarettes-smoke-by-any-other-name
145. For example, studies are currently being conducted in Japan to determine the health risks of the second-hand vapour emitted from IQOS as the government is trying to establish smokefree laws for the 2020 Olympic games. Kanae Bekki, Yohei Inaba, Shigehisa Uchiyama and Naoki Kunugita, "Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes," *Journal of University of Occupational and Environmental Health* (2017) 39(3):201–207
146. UK Committee on Toxicity, "Statement on the toxicological evaluation of novel heat-not-burn tobacco products," (2017) https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf
147. Ibid.
148. Ibid.

exposure to harmful or potentially harmful chemicals", the application had not convinced panellists that the reduced exposure to these harmful chemicals translates to less harm than continuing to smoke.[149]

In other words the application did not convincingly prove that "lowering exposure to those chemicals is reasonably likely to translate into a measurable reduction in disease or death." The latter takes a much longer study period to prove than the former, but it is reasonable to assume that significantly reducing exposure to disease-related toxins should in turn reduce disease risk.

However, as the science develops, some New Zealand public health professionals are reiterating the principles of tobacco harm reduction, rather than harm elimination. Given a recent New Zealand court decision that concludes these products are legal in New Zealand,[150] there might be more of an incentive to understand and engage with the evidence on these products.

In response to a recent study,[151] some New Zealand public health experts believe there is still a role these products can play in our 'Smokefree 2025' future. The paper, by Davis et al. claims there are risks associated with the HNB product.

University of Auckland's Dr Natalie Walker says that those wanting to quit smoking should use traditional cessation methods or e-cigarettes as their first port-of-call as they are less risky options. However, Walker acknowledges that these existing methods are not working for everyone, so sees a role for HNB products in a tobacco harm reduction framework:

> "…what do we offer people who've tried everything (repeatedly) to quit smoking – even e-cigarettes? We have no other tools in our toolbox to offer. Do reduced harm products like 'heat-not-burn' devices, have a role then? I would argue yes – but in order for this to happen the New Zealand Government would need to consider proportional regulation around tobacco harm."[152]

Massey University's Professor Marewa Glover also criticises the Davis et al. paper for over-emphasising the harms of the product, without considering its benefits in reducing the harm of smoking:

> "It's a war of words that obfuscates the real question. Would switching from smoking tobacco to using an iQOS reduce a person's risk of developing diseases causing suffering and potentially a shorter life?
>
> …
>
> No one has claimed that heat-not-burn products providing an alternative to smoking tobacco are harm-free or harmless. The correct word they should have been focused on was 'harm-reduced'. On this point the paper has added nothing."[153]

These views emphasise the point that a range of products are needed to help New Zealanders quit or reduce smoking, even if those products represent a sliding scale of risk.

149. Julia Belluz, "Philip Morris wanted to market a new tobacco device as safer than cigarettes. An FDA panel said no," *Vox.com* (26 January 2018)
150. Judgment of Judge P J Butler, "Ministry of Health v Phillip Morris (New Zealand) Limited," op.cit.
151. Barbara Davis, Monique Williams, Prue Talbot, "iQOS: evidence of pyrolysis and release of a toxicant from plastic," *Tobacco Control* (2018) Published Online.
152. Science Media Centre, "Tobacco stick health claims challenged – Expert reaction," (2018) www.sciencemediacentre.co.nz/2018/03/14/tobacco-stick-health-claims-challenged-expert-reaction/
153. Ibid.

CHAPTER 5
Raising net social welfare

Any public policy, including policies in public health, require a calculation of the costs and benefits, and a judgement of how to weigh them. In drug harm reduction policies, cost-benefit analyses are an important means of considering how the possible risks of a policy should be considered alongside the health and social benefits. Or on the flipside, how the harms of a policy can come to outweigh the benefits. The resulting balance of the costs and benefits to society is 'net social welfare'.

A common and current example is New Zealand's drug prohibition policy, where experts and politicians from across the ideological spectrum have joined voices in agreement that drug prohibition as a policy is not working.[154] Though introduced to "protect" the public from the harms of drug use, it is now clear that the policy has caused a host of adverse consequences by exacerbating inequalities and acting as a barrier to people seeking the healthcare they need. There appears to be a contrast between drug harm reduction and tobacco control, where:

> "the drugs harm reduction model of "enabling" and "engaging" populations, of facilitating behavioural change, and de-stigmatisation and on the other the tobacco control model of repression, sanctions and stigmatisation. One embraces people, the other is predominantly hostile to consumers."[155]

In the quest to have New Zealand smoke-free by 2025, it is important that policymakers do not replicate the same punitive mistakes trying to protect New Zealanders from the known harms of smoking, and the possible risks of alternative nicotine delivery products. Raising social welfare will require mitigating risks and allowing benefits to be realised so that the overall social gain is positive.

5.1 Recognising consumer surplus

As was argued in the first chapter, smoking is not just a means to satisfy a physical addiction, but has important psychological, behavioural and social aspects that will influence the desire to quit and effectiveness in quitting methods. Individuals make trade-offs between pleasure and risk every day, from the choice to drive to work, to what they eat, and what recreational activities they pursue.

Preferences matter in public policy. Consumer surplus focusses on decision making, and how individuals weigh their willingness to take on costs (financial, health or otherwise) against the perceived benefits (including enjoyment). Consumer surplus is realised when the benefits outweigh the risks or costs the individual is willing to take on.

154. Representatives from six different political parties in New Zealand, including Labour and National, agree that the prohibition on cannabis isn't working and drug law reform is needed. Simon Day, "Who's going to fix our drug laws?," *The Spinoff* (6 July 2017)

155. Gerry V. Stimson, "A tale of two epidemics: drugs harm reduction and tobacco harm reduction in the United Kingdom," op.cit.

One of the difficulties/disagreements in public health has been how to, and whether to, count the pleasure from risky activities like smoking in cost-benefit analysis.[156] In 2010, the FDA's regulatory impact analysis on requiring graphic warnings on cigarette packages included a consideration of foregone consumer surplus – a somewhat watershed moment in tobacco control policy. The foregone consumer surplus in this case was the lost enjoyment of the activity, which would offset some of the predicted health benefits.[157] While the move was criticised by opposing parties for both overstating[158] and understating these benefits, it is still important for consumer surplus to be considered in policy decision making.

So how does a consideration of consumer surplus affect access to reduced risk products?

To improve consumer surplus, individuals who want to quit smoking need access to nicotine delivery products that fit with their own personal trade-offs of risk and pleasure. While total abstinence from smoking, and to a lesser degree abstinence from other nicotine delivery devices, is the only way to reduce potential risks and harms completely, abstinence might have a negative effect on consumer surplus.[159] On a more practical note coerced abstinence is likely to lead to adverse unintended consequences.

In fact, the only world where greater availability of reduced risk products would not increase consumer surplus would be if people prefer their enjoyment of smoking over any health benefits experienced from reducing/quitting smoking; and they prefer smoking over the physical/behavioural/psychological satisfaction from reduced risk products.

Policymakers need to realise that smokers will be at different stages of their quitting journey, and some might not want to quit at all.

There will be those who prefer the sensations of reduced risk products over smoking. These people will enjoy obvious benefits, then, if there were greater availability of these products. The enjoyment and pleasure derived from the product should not be taken for granted, nor seen as a bad thing. Some proposed regulations, like banning flavoured e-liquids,[160] would almost

156. Levy et al. discuss a number of different possible methods for accurately calculating the pleasure derived from risky and addictive activities like smoking. Helen Levy, Edward C. Norton, Jeffrey A. Smith, "Tobacco regulation and cost-benefit analysis: how should we value foregone consumer surplus?" *National Bureau of Economics Working Paper Series*, Working Paper 22471 (2016).

157. A counter argument is that consumers already consider the trade-off between pleasure and health risks/benefits when making their decision, so the two should not be equally weighted.

158. There are some who believe that 'pleasure' should not be counted at all because tobacco is not like other consumer goods. Frank J Chaloupka, Kenneth E Warner, Daron Acemoğlu, Jonathan Gruber, Fritz Laux, Wendy Max, Joseph Newhouse, Thomas Schelling, Jody Sindelar, "An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation," *Tobacco Control* (2014) Published Online.

159. A prominent group of New Zealand public health experts insist that they are not aiming for total nicotine abstinence, but this contradicts their belief that the 'social, economic and cultural costs of maintaining nicotine addiction' should be considered for policies that would increase the availability of e-cigarettes. Richard Edwards, Tony Blakely, Chris Cunningham, Frederieke Sanne van der Deen, Stephanie Erick, Zoe Hawke, Janet Hoek, George Thomson, Louise Thornley, Anaru Waa, Nick Wilson, "Achieving Smokefree Aotearoa by 2025": a response to critiques," *Public Health Expert* (2017).

160. The US FDA has requested information on proposals to regulate e-liquid flavours that could be appealing to children. Ex Director of Action on Smoking and Health (ASH) UK, Clive Bates, has set out some good criteria for assessing the adequacy of the proposal to ban such flavours: "It is unclear how FDA could design interventions that only address (minor) harms without compromising the likely (substantial) benefits. It would first need to know the disposition of harms and benefits attributable to flavors" Clive Bates, "Regulating e-liquid flavors – is the U.S. regulator more likely to do harm than good and how would it know?" *The Counterfactual* (28 December 2017) www.clivebates.com/regulating-e-liquid-flavors-could-the-u-s-regulator-do-more-harm-than-good-and-how-would-it-know/

surely cause harm by taking away the aspects that drew people to switch to reduced risk products in the first place.[161]

For those who no longer 'enjoy' smoking but have tried and failed to quit using current methods available, access to reduced risk products could help these people realise the health gains of quitting and help them attain their preference of identifying as a non-smoker (or as a vaper, or however else a person wants to characterise their use of reduced risk products).

For those who enjoy smoking but want to/need to cut down, dual use is actually welfare enhancing. If the alternative is fully abstaining, that person might realise health benefits, but might be miserable. Conversely, the fear of a sense of 'loss' has been recognised earlier in this report as a barrier to quitting. The other counterfactual to dual use is continuing to smoke, which would not be welfare-enhancing if a person *wants* to cut down. Keep in mind that, as the Swedish experience shows, for many dual use is simply a transitional phase to stopping smoking completely and should be seen as a positive step.

Finally, there will be those who are open to using reduced risk products and might have even tried to quit smoking in the past, but found these alternatives unsatisfactory. It is conceivable that a significant number of people fall into this category, as variants of the theme 'vaping isn't as satisfying as smoking' is one of the most common reasons for going back to smoking. Even these people will be better off as a permissive regulatory regime will encourage improvements in the technology and consumer acceptability of products that exist today.

There are obvious financial costs and costs to individuals in being unhealthy and suffering the health consequences of smoking. But there are costs too in giving up an activity that could give one pleasure or can act as a coping mechanism. Public health policy should empower them to take the steps to enhance their own physical and psychological wellbeing. For too long, anti-smoking policy has focussed on doing things *to* smokers, rather than respecting smokers' agency and preferences. Public health policy should recognise that smokers will make the choices that are right for them.

5.2 Transparency around risks – overcoming asymmetrical information

An important principle of economics is that governments should only intervene in private markets if there is evidence of a market failure. One such market failure occurs when there is an instance of asymmetric information. In this context, asymmetric information would occur if the real risks (or lack thereof) of reduced risk products are not communicated to consumers.

Because many people will use these products to improve their health and life expectancy, people should be fully aware of any disproportionate risks that might be established. Knowing the risks and pursuing the activity anyway is very different from taking on an activity because it is assumed to be (relatively) safe. In other words, different contexts require different levels of acceptable risk. The acceptable level of risk for partaking in an activity that is presumed safe (like eating food bought domestically) will be different from partaking in a known high-risk activity like smoking. Those who already smoke might accept a higher level of risk or uncertainty

161. Recently released results from an online survey of New Zealand vapers found that most vapers use a range of flavours of e-liquid. The results also indicate that while vapers might start with tobacco or menthol flavours, they switch to other flavours over time. This suggests that transitioning to non-tobacco flavours might be a part of the vaper's journey as their preferences and tastes change. Penelope Truman, Marewa Glover and Trish Fraser, "An Online Survey of New Zealand Vapers," op.cit.

about absolute risk when they seek out reduced risk alternatives.

Consumers should be made aware of the risks (established and potential) of the product so that they can make an informed decision. Additionally, consumers should be made aware of any benefits (established and potential) of the product: even if the product involves some risk, it might also improve health outcomes compared with continuing to smoke. Ensuring smokers are aware of the potential health benefits of use or the reduced risk status of these products ought to be equally as important as communicating potential risks when the policy objective is to encourage smokers to switch.

But some information is not asymmetric. It would be difficult – not to mention commercially reckless – for a manufacturer to conceal known risks of their product. A large body of independent literature has developed to scrutinise the risks of e-cigarettes and snus, and independent analysis for HNB products is attracting similar attention.

A larger problem is the unknown: the potential risks that may yet to be discovered or scientifically substantiated.

From a public policy perspective, this, of course can pose a quandary. For new technologies, the evidence base is still developing to determine the long-term risks of the product. Studies on the subject also face a limitation in that their accuracy for determining health outcomes depends on their ability to replicate human consumption and behaviour. Further, observational studies must establish the inherent risks of the product while adjusting for the smoking status of users given these products are primarily for current or ex-smokers whose smoking history presents a difficult confounder for scientific research.

The accuracy of the studies matter. If studies underestimate the risks, then people may unknowingly partake in harmful activities. But if studies overestimate or overstate the risk, then smokers will delay or abstain from switching to a less harmful alternative. In this context, a previous report by The New Zealand Initiative has found that the risks of dual use have historically been overstated in the literature, sending the damaging message that 'you might as well smoke'.[162]

Waiting years or decades for a full body of evidence before legalising or easing regulations on reduced risk products also causes harm. Again, because it stops people switching, but also because regulation could not possibly keep up with new technologies as they arise. Delaying access could have very real adverse health consequences. On the other hand, there is always the opportunity to monitor the uptake and consequences of products once that knowledge is available.

The public policy question, then, is whether there is sufficient evidence to determine whether these products are significantly less harmful than smoking. While some would disagree and argue that the relevant counterfactual ought to be how usage compares with abstaining completely, as the above section argues, smokers will be at different stages of their quitting journey and quitting smoking is not the preference of everyone.

Of course, the wellbeing of non-smokers and youth uptake of reduced risk products must also be considered. Here, the accurate and effective communication that these are reduced risk products, and might not be risk-free products matters a great deal.

162. A discussion of the common mistakes found in such studies or claims can be found in Jenesa Jeram, "The Health of the State," op.cit.

However, from a public policy perspective, a consideration of non smokers does not automatically justify limiting access to these products for smokers, nor would it justify overly burdensome regulations. Of course, restrictions around sales to under 18s are reasonable,[163] especially when balanced with allowances to ensure access for young people who would benefit from e-cigarettes to stop smoking.[164]

Studies on youth uptake need to be read with care. The counterfactual needs to be whether these same individuals would have otherwise taken up smoking. Even if there were evidence that youth using these reduced risk products would have otherwise abstained from nicotine or tobacco products completely, the harms of youth uptake need to be considered against the population health benefits of helping smokers quit.

Further, the harms need to be considered as proportionate to the associated health consequences. 'Youth uptake' of an addictive substance is not necessarily a harm in and of itself if the health consequences are minimal (for example, youth uptake of coffee would not trigger stricter coffee regulations or an outright ban).

As long as consenting adults are making an informed decision based on accurate information, it is hard to identify what additional market failure would justify government intervention.

5.3 Encouraging innovation/competition – the risks of overregulation

Though highly regulated markets might be designed to protect the health of the population, they can also protect large companies and limit market competition. Market competition is important for reasons cited earlier in this report: it can bring prices down, can encourage a diversity of products on the market to meet a diversity of needs, and incentivises greater investment and innovation in the sector.

Meanwhile, regimes with expensive and overly cumbersome regulations favour the incumbent. In this case, a highly regulated regime for nicotine delivery products favours existing products and manufacturers.

An overly regulated market for reduced risk products is a sure-fire way to delay or inhibit the creative destruction of cigarettes.

New Zealand has an opportunity to be leaders in this field by embracing market competition and innovation. Importantly, New Zealand should be wary of creating a regulatory behemoth like the US FDA. Once regulations are put in place, they can be costly and burdensome to lift.

The Economist makes the case that FDA regulations in the US favour 'Big Tobacco'. They argue that only Big Tobacco companies might have the resources to go through the e-cigarette application process and requirements, which the FDA estimates might take up to 5,000 hours, though the average is estimated to be closer to

163. The restrictions are reasonable for the time being, though youth uptake of smoking relative to vaping should be monitored to ensure that restricting vaping access isn't adversely affecting teen quit smoking rates. For example, a US based study found minimum age-restricted e-cigarette laws increased underage pregnant teenagers' smoking by 2.1 percentage points, compared with having no such laws. Though pregnant teenagers would be a highly motivated group to quit smoking, it has been suggested that they do not have access to the cessation products that would help them. Michael F. Pesko and Janet M. Currie, "The Effect of E-Cigarette Minimum Legal Sale Age Laws on Traditional Cigarette Use and Birth Outcomes among Pregnant Teenagers," *National Bureau of Economics Working Paper Series*, Working Paper 22792 (2016)

164. The Cabinet paper for e-cigarettes released under the previous government recommended no restrictions to prevent whanau from providing young smokers with an e-cigarette "if they consider that they would benefit from one". A legal route through the Medicines Act 1981 also exists for the approval of e-cigarettes as a medicine which, if successful, would be available as a cessation device for people aged 12 and over. New Zealand Ministry of Health, "Vaping (e-cigarettes)," op.cit.

1,700.[165] As well as proving general product safety, the FDA's regime requires a risk and benefit assessment of the effectiveness of the product in helping people quit smoking, and its likely impact on third parties. Such applications to the FDA can span millions of pages. Keep in mind that for new products, obtaining such data can take a long time, and is excessive compared to testing on other consumer products. The rigorous application process could very easily become a prohibitive cost that smaller players in the market would not be able to bear.

Legal commentator Jonathan Adler also recognises the ability of overly-burdensome regulations to lock out smaller players, arguing that:

> "Even if smaller manufacturers can satisfy the relevant regulatory deadlines, the rules will increase the cost of e-cigs, limiting their cost advantage vis-a-vis traditional cigarettes and inhibit continued product innovation (thereby inhibiting the ability of e-cig manufacturers to make their products even more attractive to current tobacco users). So, as a consequence of the FDA rule, the e-cig market will shrink, and Big Tobacco will be in a better position to dominate what's left."[166]

It is no secret that the FDA application process requires a high burden of proof for new products before products can be marketed legally, and there is a separate process for marketing products with a reduced risk claim. Writing on the economics of pharmaceutical regulation, Charles L. Hooper recognises that the FDA – or any government agency – will have a bias towards conservatism. They will face greater repercussions and scrutiny for approving a bad drug than they will for failing to approve or delaying approval for a good drug.[167]

Hooper talks about the way the FDA curtails people's freedom:

> "The available medicines are what the FDA experts think we should have, not what we think we should have. It is common to picture uneducated patients blindly stumbling about the complexities of medical technology … Of course, not all patients make competent decisions at all times, but FDA regulation treats all patients as incompetent."[168]

Peter Huber, a Supreme Court law clerk, explains how such a risk-averse approach is "not only a major obstacle to technological transformation and innovation but also often aggravates the hazards it is supposed to avoid."[169] A risk regulator like the FDA must balance two often contradictory goals: reducing 'old risks' (like smoking) and ensuring 'new' hazards are not introduced (approving new nicotine delivery products). The former sets standards to protect against known and established risks, while the latter protects against the 'ominous unknown'. A standard-setting system excludes only the "unacceptably hazardous."

In recognising that most new products and processes do not 'add to' the existing environment but are 'substitutes for' or 'improvements to' an existing product or process, Huber recommends a comparative approach to the risk regulation of 'new hazards'.[170] Rather than regulate according to absolute risks, new

165. The Economist, "Snuffed out: how not to regulate e-cigarettes," *The Economist* (12 May 2016)
166. Jonathan H. Adler, "Why the FDA's new e-cigarette regulations are a gift to Big Tobacco (and could actually harm public health)" *The Washington Post*, Op ed, (5 May 2016)
167. Charles L. Hooper, Pharmaceuticals: Economics and Regulation, *The Concise Encyclopedia of Economics* (2008) www.econlib.org/library/Enc/PharmaceuticalsEconomicsandRegulation.html
168. Ibid.
169. Peter Huber, "Exorcists vs. Gatekeepers in Risk Regulation," *The American* (1 November 1983) www.aei.org/publication/exorcists-vs-gatekeepers-in-risk-regulation/
170. Ibid.

products should be regulated on the basis of risks relative to what is already legal.

Such an approach would be favourable towards tobacco harm reduction and reduced risk products. Policymakers should keep this in mind when deciding the regulatory approvals process for reduced risk products. Regulations matter (such as basic safety requirements, accurate risk warnings etc.), but the regulatory body matters too. Applications to the regulatory body ought to be efficient, proportionate (based on relative risks), and reasonable (do not ask for evidence that is impossible to collect).

5.4 Making less harmful alternatives readily available – allowing substitution

Legalising nicotine delivery products is important, but it does not automatically guarantee access. Of equal importance are the regulations affecting access to and information about reduced risk products. Smokers wanting to quit need to know what products are out there that could help them, and must have ease of access to these products. In an environment where cigarettes are readily available,[171] and considering the addictive nature of nicotine, convenience matters.

Newer reduced risk products, after all, must compete with the incumbent product – cigarettes – for customer recognition and loyalty.

Advertising

The importance of advertising in encouraging uptake of a new product is obvious from a commercial and consumer perspective. Advertising is an important means of informing consumers of new products and changes to those products; it can encourage market competition between brands; it can encourage improvements and innovation[172]; and it can act as a reputation mechanism.[173]

However, from a public health perspective, the advertising of nicotine delivery products also risks uptake from people for whom the product is not designed (non-smokers and young people who would not otherwise smoke).

These concerns ought to be less of a regulatory issue in New Zealand where people can make complaints to the Advertising Standards Authority to assess whether advertisements are socially responsible.[174] Like alcohol and junk food, it would not be too difficult to apply similar standards to ensure the products are not aimed at children, and are marketed as adult-only products. It would also not be unreasonable to expect advertisements to include clear and transparent information about potential risks, and that the products are not recommended for non-smokers.

Standardised packaging (colloquially known as plain packaging) regulations in New Zealand prohibit advertising on both the inside and outside of cigarette packets,[175] which would limit

171. Some have tried to argue that the legalisation of e-cigarettes could justify policies to limit the supply of cigarettes. They argue that this could help incentivise smokers to switch to e-cigarettes. But given the policies already in place to discourage smoking, restricting supply would only add tension to an already punitive environment. Janet Hoek, Mei-Ling Blank, Nick Wilson, Lindsay Robertson and Louise Marsh, "Will liberalising nicotine availability increase quitting?," *Public Health Expert* (2017)

172. As this report has mentioned earlier, it is likely producers in this field will compete to improve their products. There are fewer incentives to make changes to the product if there is no way of communicating those changes to the consumer.

173. False advertising hurts the credibility and profits of producers, so those producers who do invest in advertising are signalling the quality of their product.

174. Lauren Baker, "Concerns e-cig ads attract non-smokers," *Radio New Zealand* (14 May 2015)

175. Office of the Associate Minister of Health, "Smoke-free Environments Regulations 2017," Cabinet Paper (2017)

even communication targeted directly to smokers informing them of less harmful alternatives. In Canada, Philip Morris International have included IQOS communications on some of their cigarette packets.[176]

Example of IQOS advertising direct to smokers on cigarette packets

Source: Crawford Moodie, David Hammond and Linda Bauld, "Philip Morris International: a New Year's resolution," Tobacco Control (2018) Published Online.

Meanwhile, some of the risks of advertising are overstated. There are some poorly conceived studies out there claiming that e-cigarettes are advertised to children. Yet many of the aspects that are purportedly attractive or exciting for children and young people were intended to appeal to adults too.[177] These aspects could play an important role in the individual and social acceptability of these products. For example, one study considered 'social status, appearance and celebrities' as advertising features applying to youth.[178] It urges advertisements to instead focus on aspects that appeal to adults like 'health claims, instructional demonstrations of how to use e-cigarettes, and anti-tobacco cigarette comparisons'. This ignores the behavioural and psychological attachments to smoking that advertisements need to convince smokers to substitute or overcome.

Emotional appeals in advertising matter, especially given the widespread denormalisation campaigns that have stigmatised smoking and smokers. Remember, the Ministry of Health and other government agencies have spent a lot of time telling the public how "uncool" smoking is.

Those wanting to quit smoking might be more receptive to advertising messages that portray these risk-reduced products as a positive change in their lives, and something they can be proud to use. As was described earlier in the report, some have described a sense of shame associated with smoking, while others have concerns that e-cigarettes do not yet have the status of social acceptability in their peer groups. Advertising could help empower both of these groups to make the decision to switch.

Advertising might also play an important part in health-enhancing campaigns. In England, an annual quit smoking campaign called Stoptober (New Zealand runs a similar campaign) has recognised the role of e-cigarettes as a possible aid in quitting smoking.[179] Large scale public health campaigns like Stoptober that promote the use of e-cigarettes might be restricted if advertising bans are too far-reaching.

176. Crawford Moodie, David Hammond and Linda Bauld, "Philip Morris International: a New Year's resolution," *Tobacco Control* (2018) Published Online.
177. For what it is worth, the same argument applies to flavourings of e-liquids: children are not the only ones who enjoy fun branding and sweet/fruity flavours. There is no scientific or even qualitative delineation between what appeals to adults and what appeals to children.
178. Alisa A. Padon, Erin K. Maloney and Joseph N. Cappella, "Youth-Targeted E-cigarette Marketing in the US," *Tobacco Regulatory Science* (2017) 3(1): 95–101.
179. Public Health England (2018) www.nhs.uk/oneyou/stoptober/home#bC2w9xtigAGwRBF0.97

As was mentioned in section 5.2, television advertising played a notable role in encouraging IQOS uptake in Japan.[180]

The importance of advertising is not just a theoretical assumption. A recent study has been released which is the first of its kind[181] to establish a causal relationship between advertisements and e-cigarette uptake to quit smoking.[182] Keep in mind that the study took place during a period of FDA deliberation on the regulation of e-cigarettes (2013–2015), which the authors believe discouraged many e-cigarette producers from investing in advertising as their future was uncertain. The authors found a causal link between television advertising of e-cigarettes as an encouragement for people to quit, while no causal link was found for magazines.

Additionally, the authors found that if a policy to ban television advertising of e-cigarettes were in place during the study period, the number of smokers who quit would have reduced by 3%.[183] And if the FDA had not encouraged e-cigarette producer uncertainty, the reach of advertising might by similar to the number of nicotine replacement therapy advertisements, increasing the number of smokers who quit by 10%.

180. Takahiro Tabuchi, Silvano Gallus, Tomohiro Shinozaki, Tomoki Nakaya, Naoki Kunugita, Brian Colwell, "Heat-not-burn tobacco product use in Japan: its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol," op.cit.
181. Previous studies have looked at whether e-cigarettes help people quit, and whether e-cigarette advertisements increase sales or consumption, but not whether advertisements caused people to use e-cigarettes to quit smoking.
182. Dhaval M. Dave, Daniel Dench, Michael Grossman, Donald S. Kenkel, Henry Saffer, "Does E-Cigarette Advertising Encourage Adult Smokers to Quit?," *National Bureau of Economics Working Paper Series*, Working Paper 24277 (2018)
183. The authors point out that the magnitude of this effect is based on a small amount of advertisements being aired because of e-cigarette producer uncertainty. The magnitude could be even greater if the regulatory environment were different.

Retail access

Another important means of raising awareness of less risky alternatives to smoking is through the degree of retail access. These alternatives, after all, must at least be as accessible and convenient as combustible cigarettes in order to encourage smokers to make the switch.

One way of severely restricting smokers' access to less harmful alternatives would be by only allowing sales from pharmacies or specialist vape/nicotine product stores, as has been recommended by some.[184] The reason given is that smokers will need expert advice in order to find the right nicotine delivery device to meet their needs, and how to maximise their likelihood of quitting smoking. Specialist stores might also allow greater sampling of products, which might be inappropriate in other retail outlets like supermarkets and petrol stations. The argument is that these products are not like other fast-moving-consumer-goods and they should not be sold alongside low involvement consumer products.[185]

But this in itself is not a strong case for retail restrictions. Though it would be beneficial for smokers to receive expert advice when they are choosing a reduced risk product, there are also subsequent purchases that consumers will make that will not require such attentive ongoing advice. Once consumers know what product works for them and what their preferences are, they need to access these products as conveniently as they would cigarettes, otherwise there is a risk people could switch back to smoking. Consumers do not require medical advice or attentive customer service for every subsequent purchase.

Communities outside of urban centres or areas not considered lucrative markets by retailers will

184. Janet Hoek, Mei-Ling Blank, Nick Wilson, Lindsay Robertson and Louise Marsh, "Will liberalising nicotine availability increase quitting?," op. cit.
185. Ibid.

be poorly served if access is restricted. Access would also be restricted by the limited trading times of pharmacies/specialist stores compared with dairies, supermarkets and service stations. Retail outlets like dairies can often play an important role in smaller communities, and can be a main point of purchase for smokers.

Both restrictive advertising and retail restrictions can risk over-medicalising these nicotine delivery consumer products, or can make smokers feel like health patients. While it is important to emphasise the product's purpose as a risk-reducing device, these devices can also be intimidating for some potential quitters. As the report previously pointed out, there will be some smokers who have tried – perhaps many times – to quit and have been disappointed. Applying unnecessary formality to the product or process can discourage people from trying to quit again and risking a sense of shame if they fail.

5.5 Doing what is legislatively simple vs. doing what is best

One of the difficulties policymakers will face when regulating these new products is deciding how these products fit in with existing legislation. To avoid legislative complexity and public confusion, policymakers may wish to simply overlay existing tobacco regulations on the new reduced risk products. But doing so would be counterproductive if policymakers wish to encourage people to switch to less harmful alternatives to smoking.

Smoke-free areas

Another policy that has been recommended in Hon Nicky Wagner's members' bill[186] and by some members of the public health community is extending tobacco smoke-free zones to vaping and reduced risk products. This policy had been advocated by some experts as a means of protecting public health.[187] The reasons given are in the table opposite, as well as this author's response. Of these reasons, none are particularly compelling.

Meanwhile, there is a good case for letting people use risk reducing products where cigarette smoking is banned. Applying smoke-free bans sends the damaging message that vaping is just as harmful or undesirable as smoking. One of the attractive features of vaping over smoking is that vaping is more convenient than smoking in public. In a society where smoking has been socially marginalised, no doubt exacerbated by rigorous public health campaigns, vaping should be incentivised as a more attractive option.

Tobacco excise

It has also been proposed that current tobacco excise rates should be applied to reduced risk products. While most public health experts, both domestically[188] and internationally,[189] have rejected applying excise to e-cigarettes or e-liquids, there has yet to be a public conversation in the context of tobacco harm reduction about whether the tobacco contained in reduced risk products ought to be subject to excise.

186. "Smoke-free Environments (Regulation of Electronic Cigarettes) Amendment Bill," Proposed members' bill, 52nd Parliament (22 Mar 2018)

187. Nick Wilson, Janet Hoek, George Thomson, Richard Edwards, "Should Smokefree Indoor Areas = Vapefree Areas?," *Public Health Expert* (2016)

188. Richard Edwards, Chris Bullen, Natalie Walker, Janet Hoek, Robert Beaglehole, "E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal: Prepared for the National Smokefree Working Group," Background Paper (2016) "To be reviewed if there is evidence of substantial uptake of nicotine-containing EC by non-smoking children and young people."

189. British anti-smoking campaigner Clive Bates, and Canadian health and ethics academic David Sweanor told a New Zealand audience that it would be unethical to impose excise tax on e-cigarettes. Rob Stock, "Please don't make e-cigarettes too expensive, international anti-smoking experts tell New Zealand," *Stuff.co.nz* (9 October 2016)

Public health justifications for extending smokefree zones

Public health claim[190]	This author's response
There are risks to third parties	There might be justification for extending smoke-free laws to reduced risk products if these products are found to pose a significant risk to others. But where studies have found a risk in second-hand vaping, many have greatly exaggerated those findings.[191] Scientific evidence to date identifies negligible harm from second-hand vaping exposure.[192] Although the same independent body of literature is still developing for HNB products, it would make little sense to extend the smoke-free ban on these products if the emissions released are significantly less risky than smoking (as one might reasonably expect). Meanwhile, snus can be consumed without any third party detecting it, let alone that third party experiencing harm, so it would be pointless trying to ban that.
The simplicity of the law matters	It is hard to see how applying smoke-free laws to reduced risk products is simpler from a legal perspective than making a clear distinction between smoke from combustible cigarettes and emissions from non-combustible products. It is also difficult to understand how the law can be confusing for the public when the emissions from combustible tobacco and non combustible products cause quite different levels of nuisance and risk.
There are risks of normalising smoking	There is no evidence to date that vaping normalises smoking. The argument makes little logical sense too. Risk reduced products are mainly used and widely understood as products to help people quit or cut down on their smoking. If anything, greater prominence of vaping could normalise quitting smoking.
There are risks of vaping triggering smoking	While vaping replicates many of the physical and behavioural aspects of smoking, the two actions deliver quite different sensations. People making the switch to reduced risk products need opportunities to get used to the sensation, and derive satisfaction from smoking, in order to make it harder for them to switch back to smoking.
There are nuisance aspects	Nuisance aspects do not need to be covered by law, and it ought to be up to individual business to decide whether they will allow vaping inside their premises. There might be some businesses who wish to differentiate themselves as vape-friendly venues (cafes, bars, mental health facilities), where the clientele are mainly vapers or those who do not consider it a nuisance. Similarly, there may be work environments where indoor vaping would be inappropriate (public transport, schools). Blanket public policies are inappropriate for decisions that businesses can make themselves in the best interests of their staff and customers.[193] Vapers too can exercise common courtesy by not causing undue discomfort in public spaces.

The legislatively simple solution would be to treat tobacco as tobacco, and therefore subject to excise. However, if it is in fact combustion that causes the most harm from tobacco-containing products, then a case should be made that smoking tobacco ought to be regulated differently. The tobacco in reduced risk products, after all, is not designed for smoking and does not cause the same harm as smoking.[194]

190. Ibid.
191. Beware that some studies exaggerate second-hand vaping risks. In fact, one oft-cited systematic review that apparently "proves" these dangers had acknowledged that of the 16 papers reviewed, all papers had a number of limitations. The study: I.M. Hess, K. Lachireddy, A. Capon, "A systematic review of the health risks from passive exposure to electronic cigarette vapour," *Public Health Research and Practice* (2016) 26:2.
192. Public Health England, "Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making," (2016). Health experts have even been recommended that hospitals set up vaping zones. Alex Matthews-King, "NHS hospitals should sell e-cigarettes, says Government agency," *Independent.co.uk*
193. Action on Smoking and Health UK "Will you permit or prohibit electronic cigarette use on your premises?," Briefing document (2015)
194. It is not impossible to smoke tobacco in heat-not-burn products but because the tobacco has been prepared in a different way, the experience would not be comparable or pleasant.

The justification for the current tobacco excise regime also needs to be considered. The annual rises in tobacco excise were never designed (explicitly) to be a revenue raising tool. Contrary to some popular understanding, the purpose of tobacco excise is not to cover the fiscal burden that smokers may place on the public health system. In fact, it has been known for years now that smokers pay more than their fair share of the tax burden when it comes to covering their own costs.[195] The only reason for the continuing rises in excise is to actively discourage consumers from purchasing the product:

> "Social policy arguments for tobacco excise rest on judgements about the extent to which the government should seek to discourage an addictive, destructive and harmful habit (especially amongst young people and relatively disadvantaged communities) to improve the health and wellbeing of all New Zealanders and to address inequalities in health and economic outcomes."[196]

As this report argued at the start, it is clear that though the initial rises in excise on combustible tobacco products were successful in this respect, the diminishing returns on the policy today are marginal at best, while causing real harm. Applying excise to reduced risk products – even tobacco containing ones – assumes that quitting or reducing smoking is an undesirable activity.

Another popular understanding of tobacco excise is that it is applied to convey the riskiness of the product. Given that some reduced risk products like HNB are less harmful than smoking, but could be more risky than vaping, there could be a case for applying excise to this category. But in order to make that case, policymakers would need to agree on what degree of risk would justify excise in relation to the risk of continuing to smoke. There are, after all, many products on the market that do not attract excise but pose some risk.[197] A lack of sugar tax is an obvious example. The main reason why we don't have a sugar tax is not because experts and policymakers disagree that over-consumption of sugar results in poorer health outcomes.[198] Policymakers would also need to consider a possible trade-off between the riskiness of a product, and consumer acceptability. Setting a safety threshold too high might limit access to and the development of products that are slightly more risky but meet the needs of people who would otherwise continue to smoke.

Our current regulatory environment is not based on applying excise to any product that poses some degree of risk, it is applied to products that are significantly risky. And excise is not generally used as a signalling tool to communicate risks to consumers. Besides, as Carl V. Phillips argues, excise as a means of risk signalling is based on poor economic reasoning:

> "The naïve claim that taxes should be proportional to the risk seems to be motivated by a rudimentary understanding of the economics, with the assumption being that consumers completely ignore health costs when making a decision, and thus consumption would be [zero] in the absence of taxes."[199]

195. Ruth Isaac, "Regulatory Impact Statement: Increase in tobacco excise and equivalent duties," op.cit.
196. Ibid. p.5.
197. I would give more examples here, but I'd hate to give policymakers any ideas on what to tax next.
198. The sugar tax debate is, of course, for another time and place. But for those curious, The New Zealand Initiative agrees with the Ministry of Health's findings that there is not yet any real world evidence that a sugar tax would improve health outcomes. The New Zealand Initiative, "Sugar tax: documents released under the OIA," (2018) https://nzinitiative.org.nz/reports-and-media/reports/sugar-tax-oia-summary-and-background/
199. Carl V. Phillips, "Understanding the basic economics of tobacco harm reduction," op.cit., p30.

Although there are risks that non smokers[200] or young people[201] who would not otherwise smoke might begin using these products in significant numbers, for now that is only a hypothetical. There is no strong evidence to date to support this hypothesis.[202] Even if this were to eventuate, applying excise is a very blunt tool and there might be more targeted interventions that would be more appropriate. Excise, after all, would still harm smokers who are using these reduced risk products to cut down or quit. Curtailing uptake by one group, while harming another group, does not sound like a socially just policy when there are other mechanisms available.[203]

The application of excise to reduced risk products could also act as a barrier to entry for smaller players in the market. Established companies (most obviously tobacco companies) or larger players in the market are in a better position to absorb the costs of excise, while smaller companies who lack an existing customer base or who face high up-front costs would be more likely to pass on excise costs to consumers.

Any established health costs of these products must also be balanced with the benefits they bring. From a public health perspective, it makes little sense to apply excise to a product that on a net basis, is improving the health outcomes of smokers and ex-smokers. In fact, then Māori Party co-leader Marama Fox went so far as to suggest the government should subsidise e-cigarettes.[204] However, subsidies might not be necessary if there is a clear price differential between cigarettes and reduced harm products. Keep in mind that some nicotine delivery devices require higher upfront costs for the technology, and lower costs of day-to-day use (nicotine e-liquids or tobacco capsules). Therefore, it may take some time for quitters or potential quitters to experience the real financial "savings" of quitting. They also face a risk of not realising those "savings" at all if the product does not meet their needs. Facing higher day-to-day costs will simply act as a further deterrent.

Perhaps most importantly, policymakers should question whether they should extend an existing policy if that existing policy has resulted in unintended adverse consequences. Associate Health Minister Hon Jenny Salesa has recently announced a review on tobacco taxes to investigate these consequences.[205] Rather than

200. Results from a recent online survey of New Zealand vapers found that of 218 vapers who participated, 3 were non-smokers but had not gone on to smoking. They are aged between 20 and 40 years old, with one respondent citing "to support my friend to stop smoking" as the reason to begin vaping. Of those three, all used nicotine e-liquid strengths between zero and 1–6 mg/mL (the lowest concentration of nicotine normally available). Penelope Truman, Marewa Glover and Trish Fraser, "An Online Survey of New Zealand Vapers," op.cit.

201. Amongst young people, it is also important to consider whether their e-cigarettes contain nicotine (which is arguably more concerning than those that do not). Currently, young people (15–24) who use e-cigarettes are significantly less likely to use nicotine-containing e-cigarettes. Health Promotion Agency, "Data Release: updated preliminary analysis on 2016 Health and Lifestyle Survey electronic cigarette questions," op.cit.

202. A large-scale UK study condensing the results from five surveys collecting data from 60,000 youth found that "surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low [around 1% or less]." L. Bauld, A.M MacKintosh, B. Eastwood, A. Ford, G. Moore, M. Dockrell, D. Arnott, H. Cheeseman, A. McNeill, "Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017," *International Journal of Environmental Research and Public Health* (2017) 14(9).

203. Better targeted policies could include greater communication that these products are not recommended for never-smokers, that there are still some risks involved, and greater monitoring and penalties for retailers who sell to children.

204. If e-cigarettes and other nicotine delivery products were to meet the regulatory standards to be approved as a medicine (like Nicotine Replacement Therapy) through the Medicines Act, then this report would support this recommendation. But only for products that have met the higher regulatory burden of being approved as a therapeutic device. Nicholas Jones, "Subsidise e-cigarettes to help smokers quit: Maori Party co-leader Marama Fox," *New Zealand Herald* (2 March 2017)

205. Radio New Zealand, "Review to weigh up tobacco tax," (15 March 2018) www.radionz.co.nz/news/political/352612/review-to-weigh-up-tobacco-tax

hasten to apply excise to products designed to reduce the harms of smoking, policymakers should first better understand how excise can cause harm in and of itself.

Of course, it might also be the case that the government has become reliant on the government revenue gained from tobacco excise. If people are quitting smoking, then the lucrative revenue the government was gaining from tobacco excise might diminish.[206] But that is no excuse for applying excise to reduced risk products. The tax is regressive, disproportionately affecting poorer households, and could increase health inequities. If gaining government revenue is the only concern, the government should be looking to raise a broad-based tax like GST.

Applying existing laws to risk reduced products sends the wrong message about the relative harms of these products and their social acceptability. Those who have made the decision to quit or cut down their smoking with the support of these products should not feel like they are being punished by punitive policies.

206. In 2016 the tax revenue from both domestic and imported tobacco was $1.8 billion (up from $1.6 billion in 2015). Ministry of Health, "Tobacco returns 2016," op.cit.

Conclusion

In a public policy environment designed to stop people smoking, the needs and preferences of the smoker are often overlooked. Though the harms caused by smoking are well known in public health and by most smokers, current public policies are not giving smokers the support they need to quit or reduce smoking. Over recent years though there has been a rise in public health voices who acknowledge that alternative products are needed to help people quit smoking.

Dr Lance O'Sullivan, national advisor for Hāpai Te Hauora and a GP in Kaitaia argues:

> "If it was really as simple as just telling people to quit, a smokefree Aotearoa would have been achieved years ago … But the reality is that it's bloody hard to quit, and we have seen little change in Māori smoking rates. We need to open our minds to new approaches to eliminating tobacco harm, and the fact is e-cigarettes are less harmful than tobacco."[207]

Professor Marewa Glover from Massey University's College of Health also argues that smokers wanting to quit need to be given a choice, and while vaping will work for some, it won't work for everyone:

> "And people are people, they need a choice, and these heat-not-burn products might work for some people who don't like vaping, they don't want to blow a cloud or they think it looks dicky or something so we need to provide them with a choice."[208]

As we head closer and closer to the 'Smokefree by 2025' deadline, new methods are needed to help people give up smoking. But the radical shift in tobacco harm reduction is not just about finding new methods of quitting smoking. The lessons learned from anti-smoking policies so far is that punitive measures (such as regular excise increases) can have negative adverse consequences for the people they are trying to help. Rather than continuing to punish often already marginalised groups, it is time to empower them.

That means respecting that people have a lot going on in their lives, and physical health is just one priority contributing to overall wellbeing. While eliminating harm might be a virtuous end goal for public health, policies in pursuit only of harm elimination will not yield the benefits of harm reduction. The ability for smokers to make improvements to their health and livelihoods is surely a worthwhile goal, even if greater improvements are always possible.

It also means encouraging a regulatory environment where manufacturers and retailers compete to deliver the least harmful, most acceptable to consumers, and cost-competitive products to consumers. Regulators can be great protectors of the status quo, and can quash innovation.

Though legalising these products would be a good start, equal thought needs to be put into how to ensure smokers have access to these

207. Healthcentral.co.nz, "Health lobbyists clash over push to regulate e-cigarettes as quit smoking aid," *Healthcentral.co.nz* (16 December 2017) While the New Zealand Initiative might disagree with Hāpai Te Hauora that tobacco cigarette supply needs to be reduced by regulation, we think it's important to celebrate the things we do agree on.

208. Waatea News, "Tobacco stick prosecution counterproductive," *Waateanews.com* (23 May 2017)

products and accurate information about them. Applying tobacco-style regulations would be counterproductive to New Zealand's wider smokefree policies and aspirations. Regulations around advertising, where products can be publicly consumed, retail access and whether excise is applied all affect the motivation and ease for smokers to switch to less harmful alternatives.

The most damaging message public health experts can give potential quitters is that they 'might as well smoke'. Communication of the risks involved need to be proportionate and should be equally balanced with messages of potential benefits. Likewise, if the risks of attracting non-smokers, or the risks of maintaining the smoking habits of those who would have otherwise quit are realised, then the policy response ought to be equally proportionate.

The perfect (harm elimination) must not be the enemy of the good (harm reduction). This report calls on policymakers and political parties across the spectrum to give smokers the choice of switching to a range of less harmful products. As tobacco control policies have traditionally restricted the freedoms of smokers, the changing face of tobacco harm reduction is one of opening up choices to smokers.

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The adverse health outcomes associated with smoking are well known.

But for those who struggle to quit smoking, or do not want to quit, what support can be offered to minimise smoking related harms?

Some people are poorly served by abstinence-only policies.

Meanwhile, a range of alternative nicotine delivery products have been developed that are significantly less harmful than smoking, including e-cigarettes, snus and heat-not-burn tobacco products. And they can change the way tobacco harm reduction has traditionally been approached. Quitting or reducing smoking need not be treated as a medical intervention, but as a process that can be enjoyed.

Ensuring smokers have access and encouragement to switch to less harmful substitutes for cigarettes can improve the lives of these people. In fact, less harmful alternatives to smoking might even help save those lives.

Smoke and Vapour: the changing world of tobacco harm reduction finds that there is a role for alternative nicotine delivery products to play in tobacco harm reduction policy. Smokers need access to a range of products to meet a range of needs.

Not only should these products be legalised, but regulations should enable rather than inhibit smokers' access to these products.

As New Zealand approaches the government's 'Smokefree by 2025' aspiration, it is clear that new kinds of support are needed to meet that goal. Given tobacco control policies are overwhelmingly punitive, surely it is time to try a more compassionate approach where the needs and preferences of smokers are taken into account.

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