Regulating E-Cigarettes & Heated Tobacco Products: Democratic Lessons for Asia?

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EXECUTIVE SUMMARY

In the area of tobacco harm reduction and reduced-risk products, could Western democracies hold valuable lessons for Asian regulators and stakeholders? The overriding lesson is that it is possible to advance public health through the regulation of such products, which this report terms "Electronic Exits from Injurious Tobacco" (EXITs).

How will Asian governments regulate EXITs? Based upon the global experience to date, broadly stated there are three approaches available to most Asian governments. The first approach, taken by some (mostly un- or semi-democratic) nations, is to prohibit e-cigarettes and "heat not burn" products.

But bans on EXITs that result from insular, top-down decision-making are inconsistent with democratic ideals. How should such public health policymaking be conducted? In a democracy, the policymaking *process* is more important than the actual policy outcome. Policymaking must not only be inclusive and debate-driven; it needs to be seen to be these things, too.

Opposition to EXITs is usually driven by threatened domestic economic interests seeking to protect the combustible (usually domestic) tobacco industry, as well as pharmaceutical interests. Such rent seeking behavior has had a deleterious influence upon liberal democracies. One of the challenges for Asian governments is to ensure that their policymaking is not influenced by such self-interested economic actors.

For politicians seeking to reduce the harm associated with tobacco consumption, the decision to outlaw EXITs would be an unintentional signal that the health, even lives, of smokers is a low priority item. Prohibition of EXITs guarantees three albeit unintended

consequences: first, a thriving illicit trade in these devices; second, EXITs become 'cool' "forbidden fruit" to underage users; and, third, more smokers die prematurely.

While prohibition may not be the answer, for Asian governments there is no generic, cookie-cutter import that may serve as the regulatory silver bullet. The second approach, taken by some Western democracies, is to legalize EXITs, but stringently regulate e-cigarettes and heat not burn devices as tobacco or medicinal products.

As outright bans benefit domestic tobacco companies, too strong a regulatory framework – for example, by allowing these products to be sold only if they are approved as medicines – also will benefit these same companies, as draconian regulations will ward off smaller competitors in a tightly controlled domestic market.

A third approach, adopted by other Western governments, is to legalize EXITs and regulate the respective devices as consumer products.

The regulatory roadmap recommended in this report recognizes the following:

- **EXITs are an effective harm reduction tool.**
- **EXITs are contributors to dynamic, technology-driven, competitive economies.**
- **The pitfalls of the prohibition, or the over-regulation of, these new technologies.**
- **Western democracies have chosen to regulate, rather than to prohibit, EXITs.**
- **Consumer protection measures are integral to new regulatory frameworks. EXITs are no exception to this rule.**
- **Restrictions on truthful health information and comparative risk claims further inhibits potentially life-saving innovation by threatening to keep smokers and other consumers in the dark about the harm-reducing potential of e-cigarettes and heat not burn products.**
- **Evidence-based policies on EXITs should be developed in consultation with policy experts, stakeholders, and consumers.**

The policymaking sweet spot, therefore, is Goldilocks-style regulation, that is, a level of regulation that provides the necessary balance between too little and too much regulation. Should they concur, Asian stakeholders will encourage sensible, science-based regulations for EXITs as an alternative to smoking.

INTRODUCTION

Overview

In the area of tobacco harm reduction and EXITs, could Western democracies have lessons for Asian regulators and stakeholders? That is the central question posed in this report.

Joshua Newman identifies the fundamental dilemma facing these policymakers: "Increasingly, the regulation of public health hazards is subject to an appraisal of the risk of harm to various target populations. However, an expanding body of evidence suggests that when faced with a deficit of information concerning a particular public health risk, governments and regulators do very little to address the risk directly."[1]

One of this report's goals is to erase that information deficit to enable policymakers to address the risk directly. To aid in that effort, questions posed in this report include the following:

- **What are prohibition's predictable consequences?**
- **Do EXITs contribute to dynamic, technology-driven, competitive economies?**
- **How do EXITs benefit public health?**
- **Are consumer protection measures integral to new regulatory frameworks?**
- **Is the opposition to EXITs driven by threatened economic interests?**
- **Are bans on EXITs consistent with democratic ideals?**
- **How should policymaking be conducted in a healthy democracy?**
- **How best to facilitate informed public debate as the basis for democratic policymaking?**
- **In a democracy, how important is the policymaking process, itself?**

An attempt is also made to classify and describe the regulatory approaches employed by Western nations so that the report may recommend an actionable regulatory roadmap for Asian governments.

Reducing tobacco-related harm

Public health expert Kristin Voigt points out that, "Regulatory choices must…be informed by the relevant facts."[2] The most pertinent fact is that smoking is one of the leading causes of avoidable death and disease in the world.[3] Since the publication of the US Surgeon General's 1964 report, *Smoking and Health*, which clearly identified smoking as a cause of lung cancer, anti-smoking advocates were on solid scientific footing.[4]

Fast forward four decades and one finds the World Health Organization (WHO), a strong supporter of harm reduction in other contexts, calling for the tight regulation of EXITs, including prohibition; regulation as medicines; or, at a minimum, regulating in line with requirements for conventional combustible cigarettes.[5] In an open letter[6] to the WHO Director General, 53 specialists in nicotine science and public health policy advised the WHO to recognize the "harm reduction" potential of e-cigarettes and, subsequently, reverse recommendations that reflected the WHO's precautionary stance on e-cigarette regulation, which would suppress the availability of EXITs. In fact, "the WHO stance is underpinned by a review they commissioned that has been criticised for an unorthodox use of evidence."[7]

Public health experts Zachary Cahn and Michael Siegel define harm reduction as "a framework for public health policy that focuses on reducing the harmful consequences of recreational…use without necessarily reducing or eliminating the use itself."[8] As one team of addiction researchers explain, "Harm reduction can be described as a pragmatic approach acknowledging that people will inevitably use drugs, and viewing risk minimization as a worthy public health goal," whereas "precautionary approaches focus

on the complete elimination of harmful habits, arguing that simply reducing harm is undesirable and cautioning against serving the interests of [transnational tobacco companies].”[9]

Jonathan Adler describes the win-win scenario that a harm reduction approach offers both public and private stakeholders:

> **“Product innovations that help smokers quit, whether by satisfying nicotine addiction in a less harmful manner or by helping wean smokers from current habits, could reduce the death toll of tobacco and prove profitable for innovative firms. In the case of tobacco harm reduction, entrepreneurs have the opportunity to do well by doing good. Yet, as in many areas, government regulation threatens to hamper welfare-enhancing innovation and discourage the use of life-saving technologies.”[10]**

Twelve years ago, the UK Royal College of Physicians published a prescient report that made “the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.”[11] Nine years on, one finds the UK Royal College of Physicians declaring that:

> **“The rapid growth in use of e-cigarettes by smokers since 2007 demonstrates that many smokers want reduced-harm products…This [2016] report…concludes that, for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society. With careful management and proportionate regulation, harm reduction provides an opportunity to improve the lives of millions of people. It is an opportunity that, with care, we should take.”[12]**

In America, a year later, then-Commissioner Scott Gottlieb said that the FDA must be attentive to “the potential for innovation to lead to less harmful products.” Gottlieb’s July 2017 remarks suggest that he was aware of the significant harm reduction potential

of e-cigarettes and other reduced-risk products.[13] According to Cahn and Siegel, "By dramatically expanding the potential for harm reduction strategies to achieve substantial health gains, they [e-cigarettes] may fundamentally alter the tobacco harm reduction debate."[14]

What are EXITs?

Initiatives to reduce the risks associated with smoking are not a new, or even a recent, phenomenon.[15] The University of Ottawa's David Sweanor, a leading harm reduction proponent and public health expert, explains that, "We've known for decades that if we can deliver the nicotine without the process of combustion, we could essentially end the epidemic."[16]

There are currently two main types of EXITs that provide demonstrable net gains to public health.[17] The first type are "vaping" devices, commonly known as electronic cigarettes ("e-cigarettes"), and other electronic nicotine delivery systems (ENDS)[18] and alternative nicotine delivery systems (ANDS). These devices do not contain tobacco and instead heat a flavored liquid containing nicotine salts to produce a steam-like vapor.[19] For the user, "e-cigarettes mimic the sensation of smoking very closely—in the physical movement, the inhalation of a vapor, and so on,"[20] giving users "the tactile feel and familiarity of a combustible cigarette."[21]

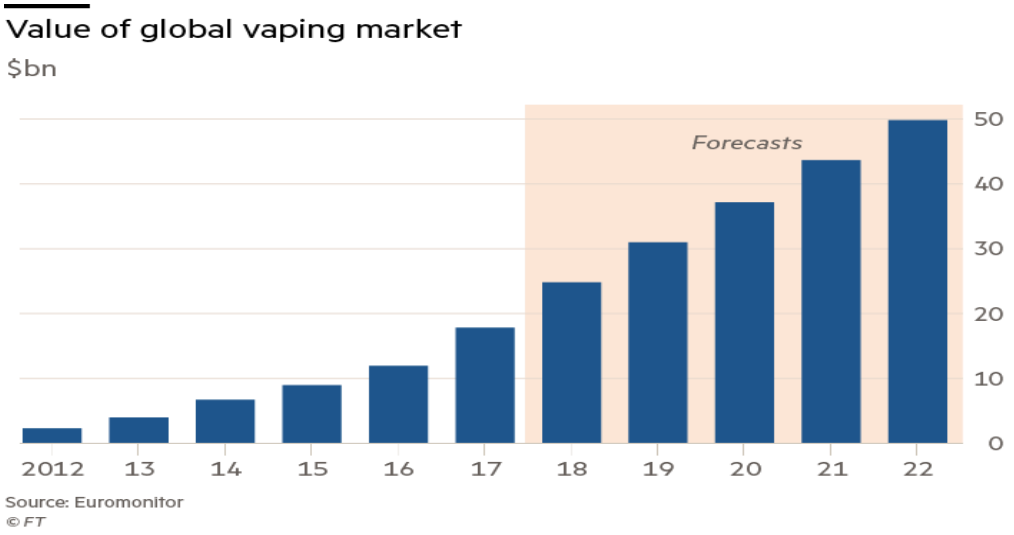
The e-cigarette is credited to the Chinese pharmacist Hon Lik, who invented the product in 2003; three years later, e-cigarettes became commercially available in Europe and the United States.[22] Initially manufactured by small companies, e-cigarettes are now manufactured by a range of businesses, including transnational tobacco companies.

As e-cigarettes became increasingly popular in recent years,[23] it also became clear that EXITs are net contributors to dynamic, technology-driven, competitive economies. A 2014 study documented over 450 brands of e-cigarettes.[24] Unquestionably, "electronic

cigarettes have emerged as one of the most popular and controversial products of the 21st century...from single-proprietor vaping shops in suburban malls to multinational companies with global tobacco holdings, e-cigarettes have taken root as an important new consumer product."[25]

Some experts think e-cigarette sales could overtake those of combustible cigarettes within a decade or two.[26] E-cigarette sales in the United States have been increasing rapidly, from just $20 million in 2008 to $5.5 billion in 2018. The global market for e-cigarettes has also exploded. By 2015, the market for e-cigarettes topped $8 billion worldwide;[27] it is projected to grow at least 20 percent annually from the current $25 billion, reaching $48 billion by 2023 (see Figure 1 below).[28]

Figure 1.



The second type are "heat not burn" (HnB) electronic devices that heat tobacco into a vapor, producing an aerosol that tastes like tobacco and delivers nicotine in a similar way to a cigarette, but without reaching the temperature of combustion (in a cigarette, around 600 degrees Celsius); instead, they are heated to 350 degrees Celsius, which significantly reduces the levels of harmful chemicals compared to cigarette smoke.[29]

All major international tobacco companies are moving into e-cigarettes, heated tobacco products, or both. Philip Morris International (PMI) manufactures the industry-leading HnB device, IQOS. Created in 2014, it is a pen-like tobacco-heating device that is halfway between a vape pen and a cigarette, and provides nicotine and gives off some smoke-like vapor without combustion. There are now 11 million IQOS users worldwide.[30] Eight million people have already stopped smoking cigarettes and switched to the device.[31]

Shipments of the sticks of tobacco used in IQOS are expected to more than double to 100 billion by 2021.[32] IQOS is sold in 47 countries and already accounts for $10 billion of the $18 billion EXIT market. PMI launched IQOS in Britain in 2016; recent sales figures confirm that more than 100,000 units have been sold in the UK.[33]

Also prominently involved and influential in the development and commercial success of HnB products are British American Tobacco (BAT)[34], Japan Tobacco / Japan Tobacco International[35], Imperial Tobacco[36], Korea's KT&G[37], and China's CNTC[38].

PUBLIC HEALTH BENEFITS

This section provides a summary of the most relevant scientific research on the epidemiological impact of e-cigarettes and HnB products. Eric Feldman points out that, "Public health policy rarely rests on a bed of scientific certainty."[39] Yet, most recently, Ken Warner, a professor emeritus at the University of Michigan and an expert on tobacco harm, informs us that there is now a wide consensus among public health experts that e-cigarettes, for example, are less harmful than conventional cigarettes.[40]

Perhaps, therefore, one should not be surprised that the 30 countries that have prohibited e-cigarettes have experienced disappointing smoking reduction outcomes. The Eastern Mediterranean region, which is the WHO-designated region with the highest concentration of e-cigarette bans, forecasts *increased* smoking

prevalence in member countries such as Bahrain, Egypt, Oman, Qatar, Saudi Arabia, and the United Arab Emirates, and no significant declines in Iran and Kuwait. Meanwhile, in Australia the 2017 *National Household Survey* shows that the proportion of Australians who smoke daily nearly halved from 24 percent in 1991 to 12.8 percent in 2013, but showed little change from 2013 to 2016 (12.2 percent).[41] Furthermore, smoking prevalence did not decline in either Singapore or Thailand.

Reducing harm to users

> **"Combustible tobacco has approximately eighty carcinogens and the scientific evidence of their negative impact on health is overwhelming. Most (but not all) e-cigarettes vaporize a nicotine-containing liquid, which makes them potentially addictive. But nicotine is not what kills smokers and is not likely to be the key vector of whatever harm may be caused by e-cigarettes. Although it is possible that e-cigarettes contain certain carcinogens in concentrations that will affect vapers, such harms are, at least at this point, hypothetical. tobacco dependence, then smokers can add e-cigarettes to the menu of options they can use to end their combusted cigarette habit and extend their lives."[42]**
>
> **Thomas J Glynn**

Many researchers are optimistic that a strategy of replacing cigarette smoking with vaping will yield substantial life year gains. They project that, if most current American smokers switched to vaping e-cigarettes over the next 10 years, there could be as many as 6.6 million fewer premature deaths and 86.7 million fewer life years would be lost.[43]

E-cigarettes are an alternative way for smokers (and others) to consume nicotine at lower risk and (in many jurisdictions) lower cost.[44] The primary reason for this is that e-cigarettes do not involve combustion and therefore do not expose the user (or others) to the thousands of contaminants that are found in tobacco smoke. As the FDA acknowledged, "the inhalation of nicotine (i.e., nicotine without the products of

combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."[45] As one recent review of the available scientific literature concluded, e-cigarettes "contain some toxicants in concentrations much lower than in tobacco smoke and negligible concentrations of carcinogens."[46]

A January 2018 congressionally mandated report by the US National Academies of Sciences, Engineering, and Medicine stresses the evidence that e-cigarettes "reduce users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes" and that "e-cigarettes result in reduced short-term adverse health outcomes in several organ systems."[47] A letter to the WHO Director General from 53 prominent public health experts and leading scientists from 18 countries stated that, "There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks."[48] When proposing to deem e-cigarettes as tobacco products subject to regulation by the American government's Food & Drug Administration (FDA),[49] the FDA stated that "several studies support the notion that the quantity of toxicants [in e-cigarette vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine replacement therapies."[50]

The scientific-cum-political tipping point among Western nations may have been Public Health England's full-throated endorsement of e-cigarettes. Public Health England serves as the research arm of the UK government's Department of Health. The agency stated that "vaping is at least 95 percent less harmful than smoking," emphasizing "the large difference in relative risk" between smoking and vaping, declaring that "vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking."[51]

In 2014, Public Health England produced a comprehensive report surveying the available medical literature on e-cigarettes. The report concluded that e-cigarettes are

significantly less harmful than other tobacco products, cigarettes in particular.[52] A follow-up report published in 2015 was even more emphatic about this conclusion.[53] Subsequently, the UK's Royal College of Physicians has encouraged the promotion of e-cigarettes as an aid in smoking cessation.[54]

Recent research indicates a potential for relatively significant and rapid health gains for smokers who switch to e-cigarettes.[55] Hence, the UK government's pronouncement that "the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco." Consequently, "The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products."[56] In this vein, Gerry Stimson, Emeritus Professor at Imperial College London, and programme director of the Global Forum on Nicotine, states, "It's essential that people around the world have access to and are positively encouraged to switch away from cigarettes to safer nicotine products."[57]

The FDA recently produced research that concluded HnB products are "appropriate for the protection of the public health because, among several key considerations, the products contain fewer or lower levels of some toxins than combustible cigarettes." In fact, "HnB exposed users and bystanders to toxicants, although at substantially lower levels than cigarettes…Peer-reviewed evidence on heated tobacco products indicates that HnB are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes."[58]

Less smoking

Deborah Arnott, the chief executive of Action on Smoking and Health UK and a leading tobacco control campaigner, maintains, "[T]here's good evidence they [e-cigarettes] help smokers quit."[59] She is correct; clearly, e-cigarettes are effective tobacco reduction tools.[60]

According to the US Centers for Disease Control, e-cigarettes are not safe for children and teens, but, "E-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products."[61] A study by British researchers published early this year in the *New England Journal of Medicine* found e-cigarettes worked almost twice as well as conventional nicotine replacement therapies (NRT), such as patches and gum, at helping smokers quit regular cigarettes. This is the first large, randomized study to test whether modern e-cigarettes can help people quit smoking.

Why are e-cigarettes such effective public health instruments? Stimson offers the essential insight that it is easier to persuade people to do something if that thing is enjoyable rather than a painful chore: "For those trying to stop smoking, e-cigarettes have profoundly changed the experience. For the first time, quitting cigarettes is no longer associated with being a 'patient' and personal struggle."[62]

According to PMI's own survey research, 70 percent people who bought IQOS switched completely from cigarettes to IQOS.[63] In England, meanwhile, half of e-cigarette users no longer smoke.[64] In Japan, the introduction of IQOS and other EXITs (introduced by BAT, Japan Tobacco Inc, and Imperial Brands, respectively) led to a 20 percent reduction in cigarette consumption in only three years. In Japan, "[e]vidence there shows that 70 percent of heated tobacco users give up smoking altogether. That is a better conversion rate than for any other alternative nicotine-containing product on the market."[65]

As e-cigarette use has increased, smoking rates have declined. For example, the number of British adults using e-cigarettes has risen 70 percent in the past two years, from 3.7 per cent of adults in 2014 to 6.3 per cent in 2018, while smoking rates have reached a record low.[66]

More significantly, perhaps, is the increase in e-cigarette use appears associated with an increase in smokers quitting combustible cigarettes.[67] Impressively, "More than six million smokers in the European Union have quit smoking and more than 9 million have reduced smoking consumption with the use of electronic cigarettes…These are probably the highest rates of smoking cessation and reduction ever observed in such a large population study."[68] Preliminary research suggests that, at least for some smokers, e-cigarettes may be a more effective stop-smoking aid than existing NRT.[69]

DEMOCRATIC POLICYMAKING

How should public health policymaking be conducted in a healthy democracy? What are the principles of democratic government that have greatest relevance for Asian stakeholders in the EXIT space? Under a system of democratic norms and values, governance, that is, the establishment off policies and the monitoring of their proper implementation, requires political trust, transparency, notice and consultation, and consideration of all available evidence, among other characteristics.

University of Maryland sociologist Kurt Finsterbusch's seminal work on policymaking in democratic societies focuses upon a fundamental question: how should policy decisions be made?[70] In a democracy, policymaking emphasizes the process, itself. The *process* is as, arguably more, important than the actual outcome. Policymaking cannot simply be inclusive and debate-driven; it needs to be seen to be these things, too. Hence, the overriding principle for determining how policy decisions should be made is to make the democratic *process* the supreme value.

Democratic decisions may produce – often will have – unsatisfactory outcomes; however, it is up to the citizens themselves to learn from their mistakes and democratically correct them. In the medium to long run, most other worthy values will be addressed by democratic decision-making.

In a democratic political system, there is a clear, identifiable process for the formation of new regulations. The democratic process does not countenance decree-based policymaking; it does not discourage, let alone prohibit, research work into and study about EXITs, specifically, and tobacco harm reduction generally. Such actions on the part of government tangibly demonstrate how democratic policymaking is *not* conducted. In striking contrast, the democratic process prioritizes transparency among decisionmakers and consultation with stakeholders.

Without question, the denial of nicotine-related health information is a breach of the freedom of information and freedom of speech precepts inherent in a democratic political system. One's access to accurate and all available health information about nicotine and other related products that contain it is, in fact, a human right.[71]

A tobacco harm reduction approach centers this principle, in the same way that the United Nations justifies harm reduction for so-called "hard" drugs, such as heroin and cocaine. Unfortunately, UN institutions such as the WHO fail to recognize that international human rights treaties and conventions mandate governments to permit full access to information about *every* form of nicotine use. Any such human rights violations necessarily weaken political trust.

Successful government institutions and regulatory agencies are building blocks for political trust.[72] That is important because support for democracy is even more dependent upon political trust among the electorate than the latter's economic expectations.[73]

More tangibly, product marketing research shows that consumers benefit from allowing product manufacturers to make truthful and non-misleading health-related claims because "[i]n modern economies, sellers routinely supply helpful information about their products."[74] Where companies can position their products as either

healthier or less dangerous than their competitors, they have an incentive to both educate consumers about the relative health benefits of their products as well as to develop products about which truthful positive health claims can be made.[75]

Correspondingly, consumers draw negative inferences when a company fails to make positive health claims about their product vis-à-vis competing products. Therefore, limiting reduced risk and stop-smoking claims by EXIT manufacturers and retailers advantages non-EXIT tobacco companies and limits the market positioning of EXITs as an alternative to tobacco. It also risks misleading consumers, and current smokers in particular, into believing there are no meaningful health differences between EXIT use and smoking.

Overcoming "democratic deficit"[76]

Most longstanding democracies have experienced a growth in "the undemocratic power of government technocrats."[77] In most Western nations, therefore, there is an appreciation that the policy decision-making process should be democratized further.

Intense interest group pressures may make it difficult for policymakers to implement the most efficient policies since such policies often impose costs on parts of the public. Ultimately, if some groups constantly win, interest group politics may undermine the legitimacy of electorally accountable decision making in a democracy.[78]

The University of Maryland's Clarence Stone demonstrates, for instance, that, in practice, agency heads and most government staff exhibit a pronounced bias in favor of powerful interest groups even when they do not think they have.[79] Groups representing the most powerful business interests tend to dominate agency lobbying at least as much as they do legislative lobbying, which has important implications for the ultimate content of policies chosen by democratic governments, broadly construed.[80] Political scientist Andrew Roberts finds that health policies, for example,

"can be better explained by differences in access to the policymaking arm of the state…[therefore] scholars of health policy should focus more attention on the actors seeking change and their access to policy makers."[81]

Even when they are not bending to direct influences, agency heads and government staff are unconsciously biasing their actions to those groups who control resources.[82] Furthermore, George Krause's insightful research demonstrates that one cannot assume that the benefits that may accrue from government agency-directed policymaking will exceed those from the political decision-making empowered by a democratic mandate.[83]

Special mechanisms, therefore, must be employed to democratize the decision-making process and to reduce the natural bias of officials against less powerful interest groups.[84] For at least 20 years, John Durant observes, "the general public…is demanding greater participation in important decisions as to their application in everyday life. Ideals of equality between scientists and non-scientists and of informed public debate as the preconditions for forging socially sustainable public policies need to be translated into new processes of deliberative democracy."[85]

Consequently, the recent trend has been toward more public participation and more effective participation mechanisms.

Evidence-based policymaking

> **"The increasing emphasis on the need for evidence-based policy indicates the continuing influence of the 'modernist' faith in progress informed by reason… the attempt to ground policy making in more reliable knowledge of 'what works' retains its relevance and importance. Indeed…it is argued that 'reflexive social learning' informed by policy and programme evaluation constitutes an increasingly important basis for 'interactive governance'…More emphasis should be placed on developing a sound evidence base for policy through long-term impact evaluations of policies and programmes."[86]**
>
> **Ian Sanderson**

A successful, central governance reform across the Western democracies has been the adoption of "evidence-based policymaking" (EBPM). Ross Brownson, Jamie Chriqui, and Katherine Stamatakis describe EBPM's three key elements:[87]

- **"Process" – approaches that will enhance likelihood of policy adoption**
- **"Content" – identifying specific policy elements that are likely to be effective**
- **"Outcomes" – documenting the potential impact of policy**

Given these essential elements, political and bureaucratic instruments to further evidence-based policy include preparing and communicating data effectively, using existing analytic tools effectively,[88] conducting policy surveillance, and tracking outcomes with different types of evidence.

Conventional wisdom holds that bureaucrats are expert technocrats well-equipped to not simply execute policy decisions, but to originate and to initiate them, too. Yet, recent research challenges the conventional view of the bureaucracy role in policymaking. This research confirms that the bureaucracy is not a primary source of issue expertise.[89]

In a nutshell, "Evidence-based policymaking represents a contemporary effort to reform or restructure policy processes in order to prioritize evidentiary or data-based decision-making…[I[ts aim is to avoid or minimize policy failures caused by a mismatch between government expectations and actual, on-the-ground conditions through the provision of greater amounts of policy-relevant information."[90]

In the British experience, EBPM was first formally advanced during the late 1990s Labour government's modernization agenda under Prime Minister Tony Blair.[91] In that context, the importance of EBPM in the EXITs field was most tangibly demonstrated two years ago with the publication of the UK Department of Health's latest tobacco control plan.

***Towards a smokefree generation: A tobacco control plan for England*[92] features four "ambitions." Ambition number four is, "Backing evidence-based innovations to support quitting." The UK Department of Health is unequivocal in its support for an evidence-driven harm reduction approach to EXITs: "We are committed to evidence-based policy making, so we aim to: Help people quit smoking by permitting innovative technologies that minimise the risk of harm. [And,] [m]aximise the availability of safer alternatives to smoking."[93]**

Rent seeking's unhealthy influence

Economists refer to "rent seeking" when an individual, business, or institution seeks to increase their own wealth without creating any benefits for society. In practice, rent-seeking activities aim to obtain financial gains and benefits through the manipulation of regulations to influence the distribution of economic resources. Economists view such activities as detrimental to the economy in particular and to society as a whole. The practice reduces economic efficiency through the inefficient allocation of resources. Such rent seeking behavior has had deleterious influences upon the Western democracies.

In reality, vested interests in the public and private sectors present a formidable obstacle to more dynamic economies.[94] As a result, rent-seeking activities discourage innovation. Instead of developing new innovative methods for revenue generation, companies may rely on rent seeking to increase their own wealth. In addition, it commonly leads to other damaging consequences, including lost government revenues, and a decrease in competition. Examples of rent-seeking activities include special interest lobbying, government subsidies, and protectionist tariffs.

When rent seeking is successful, policymakers do not base their policy choices on the available evidence; rather, they base their policy choices on other factors, such as political pressure, as well as financial opportunities and constraints. Often, political pressures, financial interests, and institutional arrangements play an important role in determining how policies are shaped, which policies are adopted, and how vigorously policies are enforced. When the stakes are high, the influence of such factors can be particularly acute.

Rent seeking & EXITs

Rent-seeking, commercially entrenched tobacco companies in the Western democracies often benefitted from the anticompetitive effects of domestic advertising restrictions.[95] It is one illustration of how increased regulation may help established cigarette manufacturers establish a dominant position in a less dynamic and less innovative market, which may explain why some large tobacco companies have supported some elements of e-cigarette regulation.

Opposition to EXITs is usually a product of rent seeking activities and it is usually driven by threatened domestic economic interests. One of the challenges for Asian governments is to ensure that their policymaking is influenced as little as possible by such self-interested economic actors.

It is therefore unsurprising that the political and economic forces that historically shaped tobacco policy in Western nations are a crucial part of the explanation for the evolution of those nations' respective EXITs regulatory policies.[96] Government stakeholders, non-governmental organizations (NGOs), transnational tobacco companies, and large agricultural interests have strong interests in these new regulatory outcomes.

In four of these nations (Australia, Canada, New Zealand, and the US), these actors exhibited an out-sized influence upon early decision-making in favor of either outright bans on EXITs or a draconian regulatory framework. However, the relatively open, transparent, inclusive, and accountable nature of political debate in these nations ensured that, ultimately, EBPM was the decisive factor in the overall regulatory process in three of the four nations.[97]

The array of economic and political interests that shaped American tobacco regulation is partly defining American e-cigarette regulation and could shape e-cigarette regulation in a host of other countries where currently e-cigarettes are largely imported into these countries, while combustible cigarettes are produced locally. "Under an ENDS ban, the former will be accorded less-favourable treatment, while its domestic counterpart will be available," argues Carrie Wade, director of harm reduction policy for the R Street Institute.[98]

E-cigarettes and HnB products have proven to be a commercially disruptive technology, threatening the market for traditional tobacco products.[99] It is often rent seeking that leads to proposals to ban EXITs. For example, if there is an economically important domestic tobacco industry, a ban on EXITs prevents multinational companies from establishing a monopoly, or at least dominance, in the domestic EXIT market. In this way, the domestic tobacco industry is not required to compete for customers and market share with foreign competitors.[100]

As Jonathan Adler and his fellow business regulation experts explain:

> **"Electronic cigarettes pose a competitive threat to the makers of cigarettes and other tobacco products, as well as to nicotine replacement therapies such as nicotine gum and patches. A common response to such a threat is support for government regulation to suppress competition. Predictably, cigarette manufacturers and other threatened producers, as well as the governments that earn revenue from tobacco taxes, are supporting greater regulation of electronic cigarettes that would replicate the cartel-supporting rules of the [US] Master Settlement Agreement."[101]**

Given that, globally, the stop-smoking marketplace was worth €14 billion in 2018, it is unsurprising that rent seeking in the EXIT space is not restricted to tobacco companies. Large pharmaceutical companies object to e-cigarettes and HnB products on the basis that they perpetuate former smokers' addiction to nicotine, discouraging them from cutting down their nicotine consumption or quitting altogether.

This is a commercial problem for pharmaceutical companies because they manufacture most commercial stop-smoking products, such as gum and patches.[102] As Carmen Paun reports, clearly:

> **"Big Pharma has Big Tobacco in its sights. The drugs industry is objecting to the marketing of e-cigarettes and vape pens as a way to quit cancer-causing cigarettes. Pharmaceutical companies…want e-cigarettes to be regulated as medical products….At stake: Who will take the larger share of the Europe's market for smoking cessation…If tobacco companies can convince regulators that e-cigarettes don't merit the scrutiny patches and gum receive, the competitive advantage could be decisive."[103]**

In such circumstances, as exist in some marketplaces, there may be a "perfect storm" of institutional actors weighting the political equation in favor of the traditional combustible

tobacco industry, especially local tobacco companies. In this way, the unintentional, yet direct, consequence of a ban is the protection of the domestic cigarette industry.

Respective governments' appreciation of the economic contribution, and sensitivity to the financial influence, of these tobacco companies is to be expected and is perfectly rational. In 2019, however, it is not necessarily conducive to the optimal public health outcome.

HOW TO REGULATE EXITS?

> **"Many governments are seeking the most effective measures to address social and economic challenges and minimize the negative impact…human activity has on…health. The effectiveness of the measures often depends on their combination and balance. These include product regulation, licensing, prevention, taxation, preferences as well as non-restrictive and non-prohibitive measures. Solutions should be effective at reducing consumer risks… and, at the same time, they should stimulate the development of manufacturing and production without killing off certain traditional industries but, rather, creating competitive economic and regulatory conditions and incentives for the radical improvement and enhancement of production technologies and product quality."**
>
> **St Petersburg International Economic Forum[104]**

Attitudes to e-cigarettes vary widely from one country to another.[105] Consequently, regulations regarding the use of EXITs vary widely around the world.[106] According to the WHO's *Report on the Global Tobacco Epidemic 2017*, the vast majority of countries have not banned e-cigarettes.[107] Most leading democracies have chosen to regulate, rather than prohibit, EXITs. Australia, Turkey and Mexico are the only three OECD countries that have not legalized e-cigarettes containing nicotine.[108]

How will Asian governments approach EXITs? Based upon the global experience to date, broadly stated there are three approaches available to most Asian governments.[109]

The first approach, taken by some (many of them un- or semi-democratic) nations, is to protect the combustible (usually domestic) tobacco industry by prohibiting e-cigarettes and HnB devices. The second approach, taken by some Western democracies, is to legalize EXITs, but stringently regulate e-cigarettes and HnB devices as tobacco or medicinal products. A third approach, adopted by other Western governments, is to legalize EXITs and regulate the respective devices as consumer products.

What specifically are the regulators in Western nations doing to control the manufacture, sale, and use of EXITs?[110] This section provides answers to that question. Mitch Zeller, director of the FDA's Center for Tobacco Products,[111] arguably speaks for his peers across the West when he offers that, "The challenge for us as regulators is really to strike the appropriate balance between smart regulation that encourages innovation of those satisfying, less harmful products for people who need them, all the while being guided by the best possible regulatory and scientific foundation for our actions."[112]

United States

E-cigarettes are regulated, not banned, in America. The FDA has moved haltingly toward e-cigarette regulation; after an initial effort to regulate e-cigarettes as pharmaceutical products was challenged in court, the agency decided to allow sales of e-cigarettes and to treat them as tobacco products, but has so far failed to issue specific regulations. Various municipalities, cities, and states have developed their own e-cigarette policies, most of which fold e-cigarettes into existing tobacco control law.

In 2009, Congress granted the FDA authority to regulate cigarettes and other tobacco products, including those "made or derived from" tobacco, under the *Family Smoking Prevention and Tobacco Control Act*. The FDA uses this law to assert regulatory authority over e-cigarettes, but that law only allows the FDA to regulate certain

enumerated tobacco products, not including e-cigarettes. So, the FDA is engaged in a lengthy effort to 'deem' e-cigarettes as tobacco products under the Act.[113]

With the so-called "deeming" rule, the FDA effectively extended the Act's regulatory framework to e-cigarettes.[114] Under the deeming rule, the FDA also prohibited sales to minors, mandated health warnings on product packaging, and severely limited vending machine sales. It also prevents e-cigarettes from being marketed as safer alternatives to traditional cigarettes or as a way to help smokers quit.

In March 2019, the FDA announced planned restrictions on retail sales of cartridge-based e-cigarettes in fruity and sweet flavors, which the agency says teenagers favor. According to the recent FDA Commissioner, Scott Gottlieb, the FDA's "plans recognized that products for delivering nicotine exist on a continuum of risk, with cigarettes being the deadliest form. Medicinal products such as gum and patches are so safe, they can be bought over the counter without a doctor's prescription. E-cigs are somewhere in the middle."[115]

Significantly for product development and innovation, the *Family Smoking Prevention and Tobacco Control Act* requires manufacturers to undergo an extensive and expensive approval process for new tobacco products, a process that was designed specifically for combustible cigarettes. At the time of writing, e-cigarette manufacturers may have less than a year's time to submit applications to the FDA to have their devices approved for sale. The agency then has a year to decide whether to permit them to stay on the market.[116]

This requirement does not apply to all EXITs, however. Those EXITs that have been on the market for more than a decade are exempt from the premarket approval requirement. Specifically, the *Family Smoking Prevention and Tobacco Control Act* grandfathers those products marketed prior to 15 February 2007.

This rule is likely to produce significant consolidation within the e-cigarette industry, largely to the benefit of major tobacco companies, while simultaneously reducing innovation and the harm reduction potential of e-cigarettes.[117] Jonathan Adler informs us, "With continued innovation, the ability of e-cigarettes to help wean smokers from tobacco could further improve. On the other hand, insofar as regulation hampers continued innovation in this market and reduces the availability of e-cigarette products, the harm reduction potential of e-cigarettes is constrained."[118] As David Abrams warned:

> **"Applying overly burdensome, expensive regulatory hurdles to e-cigarettes could stifle innovation and favor the market domination of tobacco companies, which potentially promote dual use of cigarettes and e-cigarettes to minimize losing market share for their primary cigarette products. Independent e-cigarette companies are more likely to have the goal of eliminating combusted cigarettes."[119]**

In January 2018, the FDA pronounced that, "With appropriate product regulation, new technology, and product innovation – including new medicinal nicotine products and electronic nicotine delivery systems (ENDS) – could present an opportunity for more smokers to quit and stay quit."[120] In that vein, this spring the FDA gave PMI the go-ahead to sell its HnB device, IQOS, after the company convinced the American regulator that IQOS "products produce fewer or lower levels of some toxins [carbon monoxide, formaldehyde, and acrolein] than combustible cigarettes," thereby meeting the FDA's rigorous standards, which includes being "appropriate for the protection of public health." It took the FDA over two years to decide whether IQOS could be sold.

Going forward, "IQOS will probably not be as popular [as e-cigarettes] among teens, the FDA says, since it does not come in fruity or sweet flavors and will have a relatively high price point. Data out of Italy and Japan…suggests that it's not

popular among youth and non-smokers...But to be safe, the FDA will require that IQOS advertisements are targeted toward adults, and will prohibit television and radio advertising."[121] Last month, 500 tobacco stores in Atlanta, Georgia, became the first in the United States to start selling IQOS.[122]

An application by Philip Morris to market the IQOS as a reduced-risk product is still pending a decision. As the FDA has yet to allow IQOS to be marketed as safer than traditional cigarettes, for now the product must adhere to the same strict regulatory standards as cigarettes. Nonetheless, Zeller said the FDA recognized the potential for the new technology to "completely move adult smokers away from use of combustible cigarettes."[123]

More recently, the FDA has confirmed plans to continue to create a regulatory pathway for less harmful products while also cracking down on manufacturers that market products to youths and retailers who sell to minors.[124] For example, the FDA emphasizes the differences between the two types of e-cigarette devices characterized as "closed system" and "open system," respectively. Open system refers to refillable liquid vaping devices typically sold in 15,000 vape stores nationwide and primarily used by adults.[125] Closed system describes disposable, cartridge-based devices available in convenience stores and favored by minors.

Gottlieb states that, "Both types are currently subject to similar regulations. Yet their different potential benefits and patterns of use mean they could be treated differently." Therefore, in a regulatory sense, he argues, "Not all e-cigs are equal. Policies that account for the different risks and patterns of use are our best chance to help adults quit smoking while keeping kids from picking up a deadly addiction."[126] As a result, the FDA is considering an increase to the minimum age for purchases of vaping products, as well as other measures to limit the exposure of vaping to young people.[127]

Along similar lines, new state and local laws restrict who can buy e-cigarettes. This summer, the minimum age to purchase tobacco, nicotine, and vaping products rose to 21 years old from 18 in Virginia and Illinois.[128] Public vaping bans and restrictions are now quite common across America. For example, in Colorado vaping is now banned either in indoor public areas or near them, while Florida prohibits vaping in indoor workplaces, and New Mexico restricts vaping to indoor areas.[129]

For the past two months, stakeholders were consumed by the Trump administration's apparent desire to ban the vast majority of, even perhaps all, flavored e-cigarettes. This policy preference reflected the counsel President Trump received during the summer from the FDA as well as a significant segment of the public health establishment, including a number of influential tobacco control groups.

In an unhealthy democratic system, President Trump's stated preference could have become law without further debate or reflection. However, those potentially negatively affected by this policy prescription, that is, tens of millions of e-cigarette consumers and e-cigarette store owners found common political ground with many non-smokers and non-vapers who nonetheless objected to the federal government's heavy-handed intrusion into this area.

Despite her well-documented failings, the American system nevertheless heard and responded to the grassroots opposition to Trump's proposed ban on flavors. Consequently, a lively, comprehensive public and private debate ensued among government officials, public health experts, journalists, elected officials, campaign strategists, and organizations representing both e-cigarette consumers e-cigarette store owners. The de facto conclusion of this vigorous, inclusive debate occurred on 22 November when President Trump invited the leading pro-vaping organizations to meet with him at the White House.[130] In the days leading up to that meeting, he announced that he was reconsidering his earlier call for a flavor ban.

Ultimately, what is important is not that President Trump supported or opposed a flavor ban. What is important is that the policymaking process was transparent, consultative, and open. All sides of the issue have been heard and are therefore willing to accept the outcome, however disagreeable it may be to some.

United Kingdom

E-cigarette consumption is legal in the UK, and sales22 are allowed as tobacco products, medicinal products, and as consumer goods. There are minimum age restrictions on sales and health warnings on packaging.

Since May 2016, e-cigarette products containing less than 20 mg of nicotine have been subject to various restrictions under the revised European Union *Tobacco Products Directive*,[131] while those containing more than 20 mg, or making medical claims, must be licensed as medicines by the Medicines and Healthcare Products Regulatory Agency.

The British government also allows the sale of HnB products, which are regulated as novel tobacco under the *Tobacco and Related Products Regulations 2016*, in accordance with the EU's *Tobacco Products Directive*. On 1 July 2019, the UK government's tax system recognized HnB products.

No public advertising of EXITs is allowed; however, advertising is allowed at the point of sale, although no health claims are permitted. Those advertisements must contain nothing which promotes any design, imagery, or logo that might be associated with a tobacco brand. Equally, advertisements for e-cigarettes must contain nothing which promotes the use of a tobacco product or shows the use of a tobacco product in a positive light.

Crucially, and revealingly, the British government has adopted numerous policies to explicitly encourage smokers to switch to e-cigarettes.[132] For example, indoor vaping is

legal. Most recently, the state-run and state-funded National Health Service opened vape shops in two NHS hospitals where both patients and visitors may purchase e-cigarettes.[133]

Canada

E-cigarettes use is now legal, with sales allowed as tobacco and medicinal products, and as consumer goods. There are minimum age restrictions on sales along with significant public vaping restrictions.

Despite the longstanding popularity of e-cigarettes,[134] until fairly recently Canada prohibited the sale of EXITs unless they were approved as medicines. Convinced by the large, growing body of evidence in favor of EXITs, the Canadian government recently reversed its earlier position.

***The Tobacco and Vaping Products Act* became law on 23 May 2018. E-cigarettes are now allowed to be legally sold to the public and are regulated as consumer products "according to provincial or territorial legislation," states Health Canada.[135]**

Adults can now legally purchase vaping products with nicotine "as a less harmful option than smoking."[136] The legislation prohibits the sale of vaping products to minors and restricts certain forms of advertising for these products. According to the Canadian government, "*The Tobacco and Vaping Products Act* provides a balanced framework for vaping products by protecting youth and non-users of tobacco products from nicotine addiction and inducements to use tobacco, while allowing adults to legally access vaping products as a less harmful alternative to tobacco."

In early 2018, the tobacco industry launched the first wave of EXITs onto the Canadian market. Unlike the United States, Canada does not require any kind of pre-market authorization prior to the introduction of new tobacco products. PMI's Canadian

subsidiary, Rothmans, Benson & Hedges, launched IQOS. BAT's Canadian subsidiary, Imperial Tobacco, followed suit in the Greater Vancouver Area with its version of heated tobacco, a product called IGLO.[137]

Health Canada has advised that nationally HnB products are regulated as tobacco products under the *Tobacco and Vaping Products Act*, so they feature restrictions on flavors, packaging and labelling, and advertising and promotion, including the possibility of being able to make promotional relative risk statements.

Meanwhile, eight Canadian provinces have passed or are in the process of passing vapor product legislation. Although these laws regulate HnB products as tobacco products, the definition of an e-cigarette product in all these provinces also captures HnB products. This means that HnB products may be legally displayed at the point of sale in specialty vape shops where minors are not permitted access. In the provinces of British Columbia and Manitoba, customers may actually test HnB products prior to purchase. However, municipal smoke-free and vape-free bylaws can override provincial legislation, which is the case in the major city of Vancouver, where the use of e-cigarettes is prohibited everywhere smoking is prohibited.[138]

New Zealand

Like Canada, New Zealand previously banned the sale of e-cigarettes unless they were approved on an individual basis as medicines.[139] However, the New Zealand government recently reversed its position. Two years ago, the New Zealand Ministry of Health released a position statement on e-cigarettes that concluded, "Expert opinion is that vaping products are significantly less harmful than smoking tobacco but not completely harmless…Smokers switching to vaping products are highly likely to reduce their health risks and for those around them."[140]

In October 2017, the Ministry of Health officially declared that the evidence was persuasive "that e-cigarettes could help people to quit smoking, and they could be a valuable tool to achieving the ministry's Smokefree 2025 goal."[141] Subsequently, in 2018 New Zealand legalized the various reduced-risk alternatives to cigarettes.

Hence, despite being increasingly banned in public places, the use of e-cigarettes will be promoted as a safer alternative to smoking by the Ministry of Health. On 9 June 2019, Associate Minister of Health Jenny Salesa launched a new website to provide New Zealanders with a source of clear and credible information about vaping as a way to stop smoking. The website was developed by the Ministry of Health and the Health Promotion Agency with input from a New Zealand expert advisory group. Each of those stakeholders agreed to the following statement:

> **"The best thing you can do for your health is to be smokefree and vape free. Vaping is not for children or young people. Vaping can help some people quit smoking. Vaping is not harmless but is much less harmful than smoking. Vaping is not for non-smokers."[142]**

A campaign encouraging smokers, and particularly young Māori women, to make the switch was launched in August 2019.[143] Later this year, the New Zealand government will propose new draft legislation to improve the regulation of EXITs.

Australia

Both the Canadian and New Zealand experiences demonstrate how democratic governments presented with the best available evidence can and will move in the tobacco harm reduction direction in policymaking terms. Critically, the evolving situation in Australia also provides tobacco harm reduction proponents with reason for

optimism, as the Australian government appears to be in the (albeit slow) process of catching up to her policymaking peers across the West.

Conventional e-cigarette sales and HnB products are currently banned in Australia. Yet, that is only the end of the beginning of her EXITs story.

Today, e-cigarettes are sold in Australia as medicinal products. It is currently illegal to buy e-cigarettes that contain nicotine without a prescription. E-cigarette devices are available legally for sale, but nicotine liquid sales are illegal unless they are purchased on prescription.

In this regard, as the president of the Australian Drug Law Reform Foundation, Alex Wodak, and associate professor Colin Mendelsohn, chairman of the Australian Tobacco Harm Reduction Association, point out, "Australia imposes a *de facto* ban on vaping and is increasingly out of step with other similar countries, such as New Zealand, the United Kingdom, the European Union, Canada and the United States."[144]

Interestingly, rules on e-cigarettes vary by state across Australia. It is most telling that, despite the legal restrictions, there are 240,000 Australian reduced-risk product users, according to the Australian government's own data.[145]

According to Tony Blakely, of the Centre for Epidemiology and Biostatistics at the University of Melbourne's Melbourne School of Population and Global Health, and Coral Gartner of the School of Public Health at the University of Queensland, "Australia should now commence a process of developing a regulatory framework that balances the risks and benefits offered by these products, as is happening in Canada and New Zealand."[146] Crucially, a growing number of government and opposition legislators are pushing for the ban to be lifted.[147]

This growing appreciation among Australian academics, NGOs, politicians, and consumer organizations that EXITs are a net benefit to public health led to the launch of a parliamentary inquiry into whether e-cigarettes should be legalized.[148] While there is no guarantee that the inquiry will recommend across-the-board legalization, there is a growing probability that the Australian government would implement such a recommendation.

CONCLUSION

> **"Products have risks, but so does product regulation. As with other precautionary efforts, premature and excessive regulation can do more harm than good, and, in the case of e-cigarettes, over-cautious regulation can even kill."[149]**
>
> **Jonathan Adler**

Proposals to ban reduced-risk products reflect the ability of well-intentioned ignorance and well-placed economic interests to coalesce politically in an effort to override the scientific evidence on, and the public health benefits of, e-cigarettes, heat not burn products, and other such devices. These proposals, which are the product of insular, top-down decision-making, are also grossly inconsistent with democratic ideals.

The prohibition of EXITs guarantees three, albeit unintended, consequences: first, a thriving illicit trade in these devices; second, that EXITs become 'cool' "forbidden fruit" attracting more underage users; and, third, more smokers die prematurely.

The eminent American public policy commentator and influential *Washington Post* columnist, George Will, warns that, tragically, "More cigarettes might be sold because of bans on vaping products – because smokers cannot use e-cigarettes to stop smoking, or because teenage vapers will move on to readily available cigarettes."[150] André Picard, the leading Canadian health policy commentator, also argues against outright e-

cigarette bans. He stresses that, ""adopting simplistic measures like banning sales of e-cigarettes is not the way to address this complex issue. How many times does it need to be repeated that prohibition doesn't work? If young people want to get their hands on a Juul or any other form of e-cigarette, they will do so, and easily"[151] on the illicit market. Bans simply do not work.[152] In countries with bans, EXITs thrive anyway.

Michael Siegel adds substantial scholarly weight to the anti-prohibition position. A professor at Boston University's School of Public Health, whose research focuses on tobacco reduction, he calls bans on e-cigarettes "insane public policy." He points out that, with a ban, "It makes it easier to get cigarettes than e-cigarettes." Despite all of the available evidence to the contrary, "It basically says we think vaping is worse than smoking."[153]

For politicians seeking to reduce the harm associated with tobacco consumption, the decision to outlaw EXITs would be an unintentional signal that the health, even lives, of smokers is a low priority item.

While prohibition may not be the answer, for Asian governments there is no generic, cookie-cutter import from the West that may serve as the regulatory silver bullet. Rather, a new generation of innovative products arguably requires innovative policy responses. Adler offers a timely reminder: "The ability of e-cigarette producers to modify and adjust their products in an effort to identify and satisfy consumer preferences has helped maximize their potential as a viable smoking alternative that may help more smokers quit than would have otherwise."[154] Simply put, innovation's embrace by regulators will result in fewer smokers.

A range of regulatory approaches are being applied to EXITs globally. The overriding lesson from the experience of Western governments is that it is possible to advance public health through the smart regulation of EXITs. The experience of these

governments strongly suggests that outlawing EXITs serves no one's interests bar specific rent seeking economic actors who may gain from maintaining monopolistic control of tobacco-related products, or at least minimizing the size and strength of their commercial competitors in the marketplace.

The fact that EXIT bans are an unattractive option does not suggest that the other extreme – a wholly unregulated marketplace – is the best policy option. As *The Economist* magazine argues, "There is a good case for regulating e-cigarettes to ensure quality and safety, and to keep them out of the hands of children. But overly strict regulation could snuff out a new industry with the potential to save smokers from a lot of harm."[155] Bans benefit domestic tobacco companies, but claustrophobic regulatory environments could also benefit these same companies, as draconian regulations will ward off smaller competitors in a tightly controlled domestic market.

Unlike combustibles, crucially EXITs will continue to innovate, which should lead to higher quitting rates. However, heavy-handed regulation will reduce the ability and the incentive to innovate, which will lower demand for these devices, thereby resulting in lower quitting rates. Without question, as Christopher Bullen of the National Institute for Health Innovation at the University of Auckland in New Zealand, warns, "To overregulate now could threaten the existence of e-cigarettes and cut down the options for people who want to quit."[156] In contrast, by regulating advertising, labeling, and general product standards, governments can reasonably ensure the safety of EXITs, which in turn will reduce the number of combustible cigarette smokers.[157]

The policymaking sweet spot, therefore, is Goldilocks-style regulation, that is, a level of regulation that provides the necessary balance between too little and too much regulation.

Regulatory roadmap: Considerations for Asia

Over the past decade, respective American, Australian, British, Canadian, and New Zealand governments have grappled with the issue of making EXIT policy without the benefit of a regulatory roadmap. Fortunately for Asian governments, Western nations' often staccato, at times difficult, progression through the requisite political and regulatory minefields provides the former with the benefit of the latter's imperfect, yet encouraging, experience.

One therefore hopes that Asian stakeholders encourage sensible, evidence-based regulations for EXITs as an alternative to smoking. It is essential that Asian governments consider a plethora of less restrictive regulatory options, which will facilitate proportionate regulation, that is, regulation that recognizes the continuum of risk associated with the various means of tobacco and nicotine consumption. For example, regulation should be proportionate to the actual, documented risk of vaping.[158] Hence, as a minimal starting point, Asian consumers should insist upon accurate absolute and relative risk information about these products to allow them to make informed choices.[159]

Asian governments will decide whether to regulate EXITs as tobacco, medical, or consumer products. Each of these options has been chosen by one or more Western governments and there is no 'perfect' choice to recommend. Nonetheless, should the regulators' aim be to maximize the public health benefits for adult smokers while reducing any potential risks to users and harm to the wider population, especially young people who have never smoked, perhaps EXITs should be primarily regulated as consumer goods rather than as medicinal or tobacco products?[160]

In that light, R Street Institute senior fellow Cameron Smith stresses that, "E-cigarettes and other vapor products…shouldn't simply be slapped with a regulatory paradigm designed for a qualitatively distinct product…Sensible regulation of e-cigarettes and

vapor products are a good idea, but…should set out a paradigm that recognizes the differences between these new products and tobacco cigarettes."[161] Regulating EXITs as medicinal products runs the considerable risk of marginalizing e-cigarettes and HnB products by making them unattractive to smokers and less competitively priced compared with tobacco products.[162]

Consumer protection measures are integral to new regulatory frameworks. EXITs are no exception to this rule. Regulation is certainly necessary to ensure that e-cigarettes do not become popular among non-smoking young people and to consider restrictions about the use of e-cigarettes and HnB devices in places frequented by very young children. Likewise, it is prudent to institute controls on the marketing of e-cigarettes and HnB devices to non-smokers and to apply the same prohibition on sales to children and young people as for tobacco products.[163]

Based upon the American, Australian, British, Canadian, and New Zealand experiences to date, this report recommends that EXIT regulation proceeds according to the following principles, which would encourage their use among smokers while ensuring their safety through a product standards framework:[164]

- **Nicotine-containing e-cigarettes and HnB products should be allowed, not prohibited, as consumer goods and unlicensed medicines.**

- **Sale of all nicotine-containing products to minors should be prohibited.**

- **Regulation of these products should simply follow good manufacturing practice policies, thereby ensuring that the liquids used in e-cigarettes are produced in a quality manner, do not contain contaminants or impurities, are accurately labeled, and are held under conditions to prevent adulteration.[165]**

- **Category-specific rules should be set governing the packaging, labelling, marketing, sales, and vaping in public places that warn people of the risks of the product, minimize their appeal to youth, while encouraging smokers to switch to them.**

Other policy suggestions for Asian countries to regulate e-cigarettes and HnB products include:

- **Banning the sale of EXITs to anyone who cannot legally buy cigarettes.**

- **Banning the practice of cobranding e-cigarette products with cigarettes or marketing in a way that promotes dual use.**

- **Regulations specific to e-cigarettes could include setting the maximum size of e-cigarette refill containers, the maximum concentration of nicotine in e-liquid, the maximum size of liquid tanks, and requirements that e-cigarettes deliver the nicotine doses at consistent levels, and that the packaging include a detailed list of ingredients.**

- **Further limiting access to EXITs by only selling them in stores that are age-restricted where customers are always carded.[166]**

- **Requiring retailers to have sufficient knowledge and training to advise consumers.**

Oxford University's Justine Pila wrote recently, "In our 'post-truth' era of democratic decline, how can institutions be encouraged to live by the liberal standards they profess?"[167] Pila's question encapsulates the challenge this report poses to Asian democracies. The challenge is to ensure that forthcoming regulatory decisions on EXITs are the product of open, transparent, inclusive, interactive, accountable, and evidence-

based policymaking processes that utilize all available instruments of democratic decision-making.

Regardless of the eventual regulatory outcomes, which should be tailored to each nation's specific requirements, Asian democracies will be strengthened – and governments across the continent seen to be stronger by their respective electorates – *if* their policymaking processes follow the general principles embodied in recent (and, in some cases, ongoing) tobacco harm reduction debates across Western democracies.

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