

## Research Design of Comparative E-Cigarette Regulations Project

### Introduction

Tobacco use, mostly in the form of cigarettes, killed 100 million people in the 20<sup>th</sup> century, more than all the era's wars combined<sup>1</sup>. If current trends hold tobacco use will kill 1 billion people in the 21<sup>st</sup> century. However, the introduction of electronic cigarettes (e-cigarettes) to the global marketplace has the potential to disrupt the pace of change in combustible cigarette consumption around the world. Most health professionals, have concluded that the absolute risk to the health of an individual using e-cigarettes is significantly less than if that same individual were using combustible cigarettes<sup>2</sup>. No country in the world has banned or severely restricted combustible cigarettes from being sold inside its borders<sup>3</sup>. No medical authority in the world has concluded that combustible cigarettes are safer to use than e-cigarettes<sup>4</sup>. But a significant number of countries have effectively banned the sale and supply of nicotine containing e-cigarettes, pointing to a variety of reasons for their actions. Understanding why the previous three statements can be true, may tell us more about when a society is ready to forego potential future risks to avoid current harm to their population. In other words, this is a case where the ideas of the precautionary principle and harm reduction do battle intellectually and in the gritty realm of real-world policymaking.

E-cigarettes were invented in China in 2003 and the long-term harm the product will cause to human health consequently remains unknown for the time being<sup>5</sup>. E-cigarettes heat a liquid solution of tobacco-derived-nicotine, propylene glycol, vegetable glycerin, and flavorings until that liquid becomes gaseous vapor that can be inhaled by a user<sup>6</sup>. The nicotine in the liquid suspended in a gaseous vapor is inhaled deep into the lungs and expelled in a similar manner to cigarette smoke. Based on a cursory analysis of electronic cigarette product constituents and cigarette smoke constituents there is little reason to expect that electronic cigarettes will be as harmful to the individual user as cigarettes.

### The Harm Reduction vs. Precautionary Principle Debate

A fissure in the health policymaking and regulatory community has developed between those who advocate employing the precautionary principle and harm reduction. The precautionary principle asserts keeping products whose harm has not yet been established off the market until their long-term safety

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<sup>1</sup> Allan Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America* (New York: Basic Books, 2007), 13–14.

<sup>2</sup> Aruni Bhatnagar et al., "Electronic Cigarettes A Policy Statement From the American Heart Association," *Circulation* 130, no. 16 (October 14, 2014): 1418–36, doi:10.1161/CIR.000000000000107.

<sup>3</sup> Kenneth Warner, "The National and International Regulatory Environment in Tobacco Control," *Public Health Research & Practice* 25, no. 3 (2015), doi:10.17061/phrp2531527.

<sup>4</sup> Institute for Global Tobacco Control, "Country Laws Regulating E-Cigarettes: A Policy Scan," *Johns Hopkins Bloomberg School of Public Health*, January 2016, <http://globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes>.

<sup>5</sup> Peter Hajek et al., "Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit," *Addiction* 109, no. 11 (November 1, 2014): 1801–10, doi:10.1111/add.12659; Martinne Geller, "E-Cigs a 'Consumer-Driven' Revolution Born from a Bad Dream," *Reuters*, June 9, 2015, sec. Lifestyle, <http://www.reuters.com/article/2015/06/09/us-ecigarettes-inventor-idUSKBN0OP1YV20150609>.

<sup>6</sup> Bhatnagar et al., "Electronic Cigarettes A Policy Statement From the American Heart Association."

and efficacy is demonstrated<sup>7</sup>. Those who advocate harm reduction say the strategy would provide easier access to and less restrictions on the sale and use of purportedly less harmful products before their long-term safety and efficacy is demonstrated<sup>8</sup>.

A useful analogy to premarket approval of pharmaceuticals by the United States Food and Drug Administration (FDA) helps demonstrate what this difference in approaches means for the current debate. A kind of precautionary principle was invoked by the FDA when it gained the authority to act as a “gatekeeper” on which drugs could be sold in the United States in 1938<sup>9</sup>. The FDA gained the power to require manufacturers to prove that their drugs were safe before they could be sold on the market. This power was most visibly exercised by a medical reviewer in the early 1960s by the name of Frances Kelsey who ardently asked the manufacturers of a new anti-nausea drug call thalidomide for more evidence that their drug was safe before it could be approved for sale<sup>10</sup>. Looking back, this cautious approach likely spared thousands of American babies from the disfiguring, lethal congenital birth defects that affected the lives of so many German and Australian babies who were not protected by a fastidious regulator. A tough premarket approval process protects people from facing unknown risks of being exposed to a new substance.

By contrast, the US FDA has on occasion, turned a blind eye of sorts on strict premarket approval processes when patients faced certain harm in the absence of any treatment for their current condition. I point to the case of AZT amid the AIDS epidemic of the 1980s, when the FDA loosened its three-phase clinical trial requirements on the approval process. AZT was found in just the first of two-required stage 2 clinical trials to substantially improve the mortality rate among those suffering from AIDS. AZT was the first successful treatment for AIDS and while it was not perfect, it represented a turning point from seeing a diagnosis of HIV as a death sentence to becoming something more chronic. The Administration showed that it had the requisite flexibility to bend to the needs of desperate patient groups and that it could relax rules in a show of empathy. When facing a status quo that was certain to cause harm to patients, the FDA acted in a manner intended to reduce harm. Even though longer term, post-market clinical trials uncovered problems with high-dose long-term usage of AZT, and that superior antiretroviral drugs were approved in short order, a strong argument can be made that the approval of a less than optimal HIV treatment that was not subject to the entire orderly premarket approval process reduced population harm.<sup>11</sup>

In the case of nicotine-containing e-cigarettes, there is an argument to be made for invoking the precautionary principle to keep the product off the market and an argument to be made invoking harm reductionist rhetoric that the potential harm of e-cigarette use outweighs the certain harm faced by tobacco cigarette smokers. Determining which framework, precautionary principle or harm reduction, is

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<sup>7</sup> Science and Environmental Health Network, “Wingspread Conference on the Precautionary Principle,” *Science & Environmental Health Network*, accessed February 18, 2016, <http://www.sehn.org/wing.html>.

<sup>8</sup> Amy L. Fairchild and Ronald Bayer, “Public Health. Smoke and Fire over E-Cigarettes,” *Science* (New York, N.Y.) 347, no. 6220 (January 23, 2015): 375–76, doi:10.1126/science.1260761.

<sup>9</sup> Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton, NJ: Princeton University Press, 2014).

<sup>10</sup> *Ibid.*, chap. 3.

<sup>11</sup> *Ibid.*, chap. 6.

invoked and why will enable us to glean a better understanding of how stakeholders make tough choices on such topics. Issues of risk tolerance, social mores, and faith in the power of markets will be raised and considered.

The pro- and anti-tobacco harm reduction debates have become fiercely pitched and may be leading legislators to implement policies that prevent people from obtaining nicotine from a relatively less harmful source than cigarettes. Understanding why stakeholders have taken the positions and actions that they did, can help us understand how these positions may change in the future and what sort of arguments or advocates may persuade stakeholders to change their minds.

### Tobacco Product Regulation

Great progress has been made in countries around the world in a fight against tobacco use and the harm to human health it causes. The world's first public health treaty, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), was created to bring about a globally coordinated movement to adopt policies and practices that cut down on the use of tobacco products<sup>12</sup>. Most of these efforts focus on the combustible cigarette, as this product makes up over 90% of global tobacco product sales and causes an even larger portion of the death and disease wrought by tobacco products. This makes sense. But, many recent policy debates have begun to shift their focus to other tobacco products including smokeless tobacco, cigars, pipe tobacco, waterpipe tobacco, heat-not-burn tobacco and electronic cigarettes because these products have been at times considered the next frontier for the tobacco industry. The debate over applying policies created originally to confront cigarettes to these other tobacco products continues on, but it always helps to remember that there is a predominantly important product, cigarettes, which should never be forgotten in these debates.

### *Tobacco Control Domains and the FCTC*

The WHO FCTC uses what may be an overly clever acronym of MPOWER to describe six basic domains of tobacco control policy that signatory countries to the treaty are encouraged to come into compliance. The MPOWER policies denoted by their boldfaced first letter are:

1. **M**onitor tobacco use and prevention policies: which largely refers to setting up systems that collect good data on the extent of the tobacco epidemic in a country and the progress it is making in beating it back.
2. **P**rotect people from secondhand tobacco smoke: which refers to creating smoking bans in all public places and ensuring that such rules are enforced.
3. **O**ffer help to quit using tobacco: which entails providing tobacco quitlines, access to smoking cessation medications and behavioral therapies.
4. **W**arn people about the dangers of tobacco use: which requires that countries adopt graphic warnings on cigarette packaging and use mass media to spread anti-tobacco/pro-health messages.
5. **E**nforce tobacco advertising bans: which refers to countries adopting policies that ban all forms of direct and indirect tobacco advertising promotion and sponsorship.

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<sup>12</sup> Michael P Eriksen et al., *The Tobacco Atlas*, 5th ed. (American Cancer Society, 2015).

6. **Raise prices of tobacco products:** which requires countries to increase prices of tobacco products through excise tax increases that over time should make tobacco products less affordable to smokers.

The MPOWER policies are rather broad in scope and do not comprehensively describe many of the other policies that the FCTC asks countries to adopt on topics ranging from preventing tobacco industry interference in policymaking to aiding tobacco farmers to transition towards growing alternative crops. For the purposes of this paper, I will note progress that case countries have made on the MPOWER policies as well as accomplishments made outside their scope. It should be noted that the FCTC and its associated working groups do not take a concrete stance on the primary policy of interest to this study, whether sales of e-cigarettes containing nicotine are allowed in a country.

### *Country Practices*

While there is great variation between countries in the amount of progress they have made towards fighting cigarette use, there is consensus between countries on the direction that cigarette policy should head: towards less cigarette use and more control of those markets. There is a little bit of disagreement on the direction that smokeless tobacco policy should head, but mostly this is an argument between Sweden and the rest of the world, which will be elaborated upon later on in this paper. There is a lot of disagreement between countries on the direction that e-cigarette policy should head, and determining why that has happened is the focus of this paper, and eventually my dissertation.

### *Variation in E-Cigarette Regulation*

The range of policy responses to the introduction of e-cigarettes to the global marketplace has been, to put it mildly, varied. These responses range from invoking laws that prohibit the sale of “imitation tobacco products” to prohibit the sale of anything resembling an electronic cigarette to the active promotion of e-cigarettes as a harm reduction tool that offers cigarette smokers a safer source of nicotine. In between are countries that only prohibit the sale of e-cigarettes containing nicotine liquid (e-liquid) and those that offer a pathway to legal sale of nicotine-containing e-cigarettes if the efficacy of these products as a smoking cessation tool or as a reducer of population harm can be proven.

For example, the United Kingdom is pursuing a type of harm reduction strategy and is promoting the use of e-cigarettes to current smokers as a safer source of nicotine<sup>13</sup>. The United States, Italy and Poland have adopted a middle of the road strategy of mild regulation<sup>14</sup>. By contrast, as of mid-2016, at least 28 countries including Brazil, Mexico, Singapore, and Thailand had banned the sale of nicotine-containing e-cigarettes<sup>15</sup>. How these countries reacted so differently to the same product is my concern.

Policy change in this space is still ongoing, as will be evident in my choice of country case studies, most of who have undergone a fundamental reconsideration of their policy choices in the past 3

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<sup>13</sup> Euromonitor International, “Global Tobacco Key Findings Part 2: Vapour Products” (Passport Global Briefing, London, UK, August 2016), [portal.euromonitor.com](http://portal.euromonitor.com).

<sup>14</sup> Ibid.

<sup>15</sup> Institute for Global Tobacco Control, “Country Laws Regulating E-Cigarettes: A Policy Scan”; Thomas Schmid, “Asia’s E-Cig Regulations: Confusion & Uncertainty,” *Tobacco Asia*, May 2, 2016, <http://www.tobaccoasia.com/api/content/12f98562-1b31-11e6-9cf4-0afd25393cb5/>.

years. This is a dynamic policy space, so I will consider factors that are institutional and largely constant over time as well as those that change more often. The official and unofficial reasons that countries have adopted their current policies certainly vary. The same pieces of evidence are cited in justifying diametrically opposing conclusions. The methods used to arrive at those critical pieces of evidence are dramatically different too. So, what follows is a description of a planned effort to untangle a regulatory puzzle.

## Research Plan

### Theoretical Framework: Kingdon's Multiple Streams Approach

This study seeks to learn how the policymaking process differed in a single topic area in similar countries to produce different policy outcomes. The project seeks to determine why the harm reduction frame favoring the legalization of the sale of nicotine containing e-cigarettes overcame the precautionary principle frame that wanted e-cigarettes to not be sold until their safety and efficacy could be proven. I see each idea as existing on opposite ends of a spectrum where the framing or problems, political opportunity calculation, and risk tolerance for testing out unproven solutions guide the choice of policy. John Kingdon's classic work, "Agendas and Alternatives" proposed the Multiple Streams Approach as a framework to describe the policymaking process and to describe "when an idea's time has come"<sup>16</sup>. Kingdon's framework is an addition to a broad theoretical literature on ideas in public policy which includes such contributions as the garbage can model and punctuated equilibrium theory<sup>17</sup>. I will initially focus on Kingdon's approach because it lays out a plan of action for a researcher to look to describe several streams of inquiry when trying to determine the contours of an environment in which an idea rose to prominence.

The multiple streams approach is named after three streams of politics, problems, and policy that are constantly moving and flowing about, but that will occasionally converge into a window of opportunity where policy change is possible. The problem stream is mostly made up of media figures (who can also be politicians) and the events that focus attention on a particular issue. The framing of a problem in this stream provides character to the politics and the policy solutions that are available to address it. If something is not considered a problem, no coupling of the streams will occur and policy change will not happen.

The politics stream is made up of political actors who try and sense the public mood through the problem stream and survey the latitude that they have to address such a problem, usually by looking to the policy stream to see if there are any available solutions that would fix the problem that has become the center of attention. Within the policy stream, actors called policy entrepreneurs, constantly develop solutions to problems, even before they come to the attention of the public. A competent policy entrepreneur will be in position with a solution to a problem that comes to the attention of the public and that is in line with the politics of the moment. The multiple streams approach assumes that when

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<sup>16</sup> John W. Kingdon and James A. Thurber, *Agendas, Alternatives, and Public Policies: [Includes a New Epilogue: Health Care Reform in the Clinton and Obama Administrations]*, Updated 2. ed, Longman Classics in Political Science (Boston, Mass.: Longman, Pearson, 2011).

<sup>17</sup> Paul Cairney and Michael D. Jones, "Kingdon's Multiple Streams Approach: What Is the Empirical Impact of This Universal Theory?," *Policy Studies Journal* 44, no. 1 (February 1, 2016): 37–58, doi:10.1111/psj.12111.

such a palatable policy solution is raised in response to a problem, it will be placed onto the political agenda in what Kingdon terms a “window of opportunity”.

Determining when coupling of streams has occurred and identifying when windows of opportunity for policy change opened and closed will be a focus of this mixed methods project. I’ll trace the origins of case country decisions to specific windows of opportunity in time and try to identify the policy entrepreneurs that brought the policy solutions under consideration to the attention of decision makers.

#### Qualitative Key Document Collection and Review

A first round of document collection of key policy and media sources will allow me to sketch a rough timeline of what happened and the surface-level reasons why e-cigarette policy ended up the way it did in case countries. Policy-relevant documents from regulatory agencies and legislative bodies for all relevant research will be assembled. Submissions from outside stakeholders to the legislatures and regulatory agencies in written form as well as transcripts of testimony given will also be collected. Media stories on the topic of e-cigarettes in each country will be collected from LexisNexis Academic, Tobacco.org, and Johns Hopkins’ TobaccoWatcher tool. Press releases from legislators, regulatory agencies, and other stakeholders commenting on important milestones in the timeline will also be collected. These documents will be entered into MaxQDA, a qualitative data management program, and coded for content area, tone, date, and country. This information will be used to sketch a preliminary portrait of the policy, problem, and political streams.

#### Quantitative Database Assembly and Assessment

Next, I will construct a country-level panel dataset consisting of variables that could potentially predict the adoption of a policy to allow the sale of e-cigarettes using econometric techniques. I will place a bright line standard around evaluating whether e-cigarettes containing nicotine are legally available for sale at brick-and-mortar stores in a country. This involves recoding the Johns Hopkins E-Cigarette Policy Scan data along with other market research and legal sources to a binary outcome variable and assessing whether I agree with their prior interpretation of the law<sup>18</sup>. Because a binary outcome variable will be used, a form of panel logistic regression will be employed for the analysis.

I will examine the role political, institutional, policy, economic, and health indicators in predicting whether a country has allowed for the sale of electronic cigarettes containing nicotine. Institutional variables will likely be contributed by the Varieties of Democracy Dataset<sup>19</sup>. Economic and government finance variables will be taken from the World Bank’s World Development Indicators database<sup>20</sup>. Health indicator data will be taken from the Institute of Health Metrics and Evaluation<sup>21</sup>.

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<sup>18</sup> Institute for Global Tobacco Control, “Country Laws Regulating E-Cigarettes: A Policy Scan.”

<sup>19</sup> University of Gothenburg, Helen Kellogg Institute for International Studies, and University of Notre Dame, “V-Dem,” *V-Dem Institute*, 2016, <https://www.v-dem.net/en/>.

<sup>20</sup> World Bank, “World Development Indicators” (World Bank, 2014), <http://data.worldbank.org/indicator>.

<sup>21</sup> Institute for Health Metrics and Evaluation, “Global Deaths Ranked by Attributable Risk Factor, All Ages, Both Sexes, 1990 and 2013,” Data Visualization, *Global Burden of Disease Compare*, (2015), <http://ihmeuw.org/3000>.

Tobacco control policy variables will predominantly be drawn from the WHO FCTC Policy Implementation Database<sup>22</sup>. I expect to assemble a dataset of around 100 country policies and predictor variables over a period of 10 years since the e-cigarette was introduced, roughly from 2007 through 2017. The results of these preliminary quantitative and qualitative analyses make up the beginning phase of an explanatory mixed methods design wherein, the results observed in the quantitative data will inform which hypotheses are delved into in greater detail in the case study to follow.

### Fieldwork and Elite Interviewing

After the analyses that can be performed while being located stateside are nearing completion, I will begin putting together a semi-structured interview protocol that will be used to test the hypotheses generated in the first phase of the project. My goal is to schedule in-person interviews with bureaucrats, legislative staffers, stakeholders in NGOs, and persons associated with the vaping and tobacco industries in each country.

The project will use elite interviewing, document review, process tracing to reconstruct Kingdon's Multiple Streams of problems, policy, and politics that make up the political agenda setting process<sup>23</sup>. These qualitative techniques will sketch a rich and detailed picture of what makes New Zealand different from Australia, and from there learn lessons and derive hypotheses that can be tested in other cases. The interview process will involve travelling to the countries and sitting down with bureaucrats, politicians, lobbyists, academics, and activists to paint a full picture of whose ideas carried the day in each country. Document review of media sources will assemble a fuller picture of the problem stream in each country, wherein document review of submissions through formal government consultations on policy process will flesh out the problem streams encountered by bureaucratic decision makers. The document review process is under way and the first interviews will happen this summer in Singapore and Australia.

### Primary Cases

This analysis will be centered around an examination of a most-similar pair of cases where Australia and New Zealand have decided to take different policy stances on a crucial topic in public health debates: whether or not to allow the sale of e-cigarettes containing nicotine within their borders. A comparison of most similar cases attempts to determine why countries (or groups, or actors, or agencies, etc.) who are otherwise similar on a whole host of independent variables have produced different outcome variables on a measure of interest. Theoretically, residual differences between the cases will contain the explanation of why different outcomes were produced from such similar countries.

Making the case that New Zealand and Australia are a good pair of countries to use in a public policy most-similar cases study design has been done before by many authors before me<sup>24</sup>. Both countries primarily speak English, are part of the British Commonwealth, and have Westminster-system

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<sup>22</sup> "WHO FCTC Implementation Database," *World Health Organization*, 2014, <http://apps.who.int/fctc/implementation/database/>.

<sup>23</sup> Kingdon and Thurber, *Agendas, Alternatives, and Public Policies*.

<sup>24</sup> Francis G. Castles, Jennifer Curtin, and Jack Vowles, "Public Policy in Australia and New Zealand: The New Global Context," *Australian Journal of Political Science* 41, no. 2 (June 1, 2006): 131–43, doi:10.1080/10361140600672394.



governments. The countries are each other's largest trading partner and economic integration between the states is rather thorough<sup>25</sup>. In fact, when Australia was in the process of becoming an independent Commonwealth in 1900, the law allowing for the creation of the new Commonwealth made explicit that New Zealand could become one of its states<sup>26</sup>. So, because New Zealand is in some senses a state that could have been a subunit of Australia, there is good reason to believe the two countries make a suitable pair for comparison.

Some institutional and demographic differences between the countries exist, namely that Australia has federal government structure, has single member districts in its parliament, and a tiny fraction of indigenous peoples, while New Zealand is a centralized government, has multi-member districts in its parliament, and a significant minority of indigenous peoples. Some of these differences will be considered as I pursue institutional or structural explanations for why each country took its own route on allowing the sale of nicotine-containing e-cigarettes.

### Australia

#### Tobacco Control Progress

Australia has adopted one of the strictest and most successful tobacco control policy regimes in the world. Cigarette smoking rates among men fell from 72% in 1945 to 17% in 2015, and fell from 31% in 1983 to 12% in 2015 for women<sup>27</sup>. This change in habit reflected a concerted effort to change behavior, change social norms, and to hem in the ability of tobacco companies to market and sell their products. Most notable in recent years, Australia passed the world's first plain packaging law for cigarettes<sup>28</sup>. This law mandated the removal of all logos and branding from the cigarette package beyond some white text in a standard size and font stating the brand name on a drab olive box that is mostly covered in ghastly health warning messages. The country was sued by tobacco companies in national and international courts and recently, the final judgements on the legality of the law were handed down, allowing Australia to continue its plain packaging law<sup>29</sup>.

#### E-Cigarette Regulatory Timeline

The Therapeutic Goods Act of 1989 established a system that schedules and regulates different therapeutic compounds for sale in Australia<sup>30</sup>. Currently nicotine, except in forms that are not therapeutic or prepared for smoking, is regulated as a Schedule 7 Dangerous Poison by the Therapeutic Goods Administration (TGA). To be in Schedule 7 a substance must be 1) highly toxic, 2) highly

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<sup>25</sup> Ibid.

<sup>26</sup> Commonwealth of Australia, "Commonwealth of Australia Constitution Act 1900," The National Archives, (1900), <http://www.legislation.gov.uk/ukpga/Vict/63-64/12/section/6>.

<sup>27</sup> Australian Government Department of Health and Ageing, "Tobacco Control Key Facts and Figures" (Australian Government Department of Health and Ageing, June 29, 2016), <http://www.health.gov.au/internet/main/publishing.nsf/content/tobacco-kff>; S. Chapman and M. Wakefield, "Tobacco Control Advocacy in Australia: Reflections on 30 Years of Progress," *Health Education & Behavior: The Official Publication of the Society for Public Health Education* 28, no. 3 (June 2001): 274–89, doi:10.1177/109019810102800303.

<sup>28</sup> Eriksen et al., *The Tobacco Atlas*.

<sup>29</sup> Ibid.

<sup>30</sup> Heather Douglas, Wayne Hall, and Coral Gartner, "E-Cigarettes and the Law in Australia," *Australian Family Physician* 44, no. 6 (June 2015): 415–18.



hazardous to health, 3) handled with special precaution during manufacture, 4) highly likely to cause harm at low exposure<sup>31</sup>. This includes e-cigarettes containing nicotine, and consequently banned the sale of such devices in the country from the earliest appearances of the devices<sup>32</sup>.

When e-cigarettes first turned up in 2010, the TGA emphasized in comments to the press that e-cigarettes were not “a safe alternative to normal cigarettes and not approved for therapeutic use” while the Australia Medical Association emphasized that the devices “could pose a serious health risk”<sup>33</sup>. By 2013, an odd proposal from the Labor party cropped up, offering to study whether conventional tobacco cigarette sales in Australia could be phased out in the coming years to be replaced by e-cigarettes<sup>34</sup>.

Australian media framing of e-cigarettes seems to have struck a broadly negative tone. Even the researchers who were studying the efficacy of e-cigarettes as a smoking cessation tool openly doubted the novel devices would be an effective alternative to conventional nicotine replacement therapies<sup>35</sup>. Most positive mentions of e-cigarettes quoted sources from the UK or New Zealand, with the notable exception of Professor Colin Mendelsohn, who is based at the University of NSW<sup>36</sup>.

In the fall of 2016, a proposal was made by advocates belonging to the New Nicotine Alliance-Australia to the TGA to legalize the sale of certain nicotine-containing e-cigarettes in Australia<sup>37</sup>. The proposal, which would have rescheduled liquid nicotine below a certain concentration, was rejected in early 2017 by the TGA on the argument that nicotine delivered through an e-cigarette is likely to cause dependence, has short-term health hazards, a lack of proof of long-term safety, and a lack of proof that e-cigarettes aid in cessation<sup>38</sup>. By mid-2017, a Federal Court handed down a decision in a suit against three online e-cigarette retailers brought by the Australian Competition and Consumer Commission which was likely the first to levy fines against retailers for making unfounded claims about the presence (or lack thereof) of carcinogens in e-cigarettes<sup>39</sup>.

Throwing a potential wrinkle into this entire study is a more recent development that the Australian Parliament’s Health, Aged Care and Sport Committee opened an inquiry into potential changes to

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<sup>31</sup> Ibid.

<sup>32</sup> AP, “Electronic Cigarettes Contain Toxic Chemicals,” *The Sydney Morning Herald*, July 24, 2009, <http://www.smh.com.au/technology/technology-news/electronic-cigarettes-contain-toxic-chemicals-20090723-duqa.html?FORM=ZZNR6>.

<sup>33</sup> Jill Stark, “Battery-Powered Cigarettes Pose Risks,” *The Sun Herald*, December 12, 2010, First edition, sec. News.

<sup>34</sup> Eamonn Duff, “Cigarette Phase-out Considered as Trial Tests If Vapour Safer,” *The Sydney Morning Herald*, September 15, 2013, <http://www.smh.com.au/national/health/cigarette-phaseout-considered-as-trial-tests-if-vapour-safer-20130914-2trj1.html>.

<sup>35</sup> Fiona Baker, “E-Cigarettes: A ‘Healthy’ Way to Kick the Habit?,” *Sunday Telegraph (Australia)*, March 13, 2013, M edition, sec. Features, Lexis Nexis.

<sup>36</sup> Colin Mendelsohn, “Nicotine Vaping Should Be Legal,” *The Sydney Morning Herald*, August 16, 2016, sec. Opinion.

<sup>37</sup> Angela Gordon, “Call to Legalise Nicotine For Electronic Cigarettes” (New Nicotine Alliance (AU), August 5, 2016), <http://nnalliance.org.au/48-application-to-make-e-cigarettes-with-nicotine-legally-available-in-australia>.

<sup>38</sup> AAP, “FED: Ban on Nicotine E-Cigarettes to Remain,” *Australian Associated Press*, February 2, 2017, sec. Domestic News.

<sup>39</sup> Product Safety Australia, “E-Cigarette Companies to Pay Penalties,” Text, *Product Safety Australia*, (May 8, 2017), <https://www.productsafety.gov.au/news/e-cigarette-companies-to-pay-penalties>.

Australia's E-Cigarette Regulatory regime in May 2017<sup>40</sup>. Whether this inquiry leads to actual changes in the Australia's regulatory policy will be of prime interest to this research. The inquiry was originated by the health minister, MP Greg Hunt, who is a member of the government, so there is a realistic chance that legislation could be a result of the inquiry<sup>41</sup>.

### *New Zealand*

#### *Tobacco Control Progress*

New Zealand has made similarly tremendous success in its fight against tobacco use as cigarette smoking prevalence has declined massively in response to aggressive tobacco control measures including one of the most aggressive programs of annual tax-driven price increases in the world, which have made cigarettes dramatically less affordable to NZ smokers over the last decade<sup>42</sup>. NZ has expressed interest in following Australia in adopting plain packaging on cigarettes and has performed well in every category of the MPOWER interventions recommended by the WHO FCTC.

In March 2011, the New Zealand government declared a public goal for the country to become "Smokefree" by 2025<sup>43</sup>. This goal was adopted in response to a request from the Maori Affairs Select Committee's inquiry into the consequences of tobacco use among the Maori population who smoke at a rate double that of the national average<sup>44</sup>. Whether this actually sets a goal of having zero tobacco users in New Zealand seems to be beyond its real purpose. New Zealand, like Australia, is an exemplar country in all things related to tobacco control policy.

#### *E-Cigarette Regulatory Timeline*

Nicotine-containing products are classified under the Medicines Act 1981 as medicines and, as such, could not be sold or supplied in New Zealand without approval from Medsafe, the country's pharmaceutical regulatory agency<sup>45</sup>. The Smoke-Free Environments Act of 1990 (SFEA) prohibits advertising selling supplying or distributing nicotine containing e-cigarettes.

In 2007, the New Zealand Ministry of Health confirmed that using the newfangled e-cigarette in areas where smoking was banned under the SFEA would be allowed because the new device used no

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<sup>40</sup> Joe Hildebrand, "Gone in 60 Seconds: Govt Backs Vaping Law Then Announces Inquiry One Minute Later," *NewsComAu*, May 29, 2017, <http://www.news.com.au/lifestyle/health/gone-in-60-seconds-govt-backs-vaping-law-then-announces-inquiry-one-minute-later/news-story/5bd2054762d722a2fbc12ec0d26bc75d>.

<sup>41</sup> Ibid.

<sup>42</sup> Alex Mason, "Government Burned over Smoking Tax Rise," *New Zealand Herald*, January 1, 2016, sec. Business, [http://www.nzherald.co.nz/business/news/article.cfm?c\\_id=3&objectid=11568235](http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=11568235).

<sup>43</sup> NZ MoH, "Smokefree 2025," *Ministry of Health NZ*, July 21, 2015, <http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-2025>.

<sup>44</sup> Richard Edwards, Janet Hoek, and Frederieke van der Deen, "Smokefree 2025 – Use of Mass Media in New Zealand Lacks Alignment with Evidence and Needs," *Australian and New Zealand Journal of Public Health* 38, no. 4 (August 1, 2014): 395–96, doi:10.1111/1753-6405.12246.

<sup>45</sup> Judy Li, Rhiannon Newcombe, and Darren Walton, "The Prevalence, Correlates and Reasons for Using Electronic Cigarettes among New Zealand Adults," *Addictive Behaviors* 45 (June 2015): 245–51, doi:10.1016/j.addbeh.2015.02.006.

fire<sup>46</sup>. In 2008, Medsafe said that when it came to classifying and regulating e-cigarettes as a tobacco product, it held “no direct interest in regulation of cigarettes as such”<sup>47</sup>.

In April 2010, Medsafe made an internet pharmacy selling nicotine e-cigarettes withdraw the product from its website after it was advised to have been acting illegally<sup>48</sup>. Medsafe then published a regulatory pathway for e-cigarettes clarifying its stance which classified the devices as a “gadget”, a “medical device” or a “medicine”<sup>49</sup>. As before, all e-cigarettes containing nicotine were classified as medicines. If an e-cigarette was not being marketed for therapeutic purposes and contained no cartridges for nicotine liquid, it could be sold as a gadget, with minimal regulation applied. If an e-cigarette was to be marketed for therapeutic purposes (i.e. to help smokers quit using cigarettes), then it was classified as a medicine if it used closed cartridges to hold its supply of nicotine liquid. If it did not use cartridges, then it could go through the medical device regulatory pathway.

By early 2012, the Ministry of Health enforced its prohibition on the importation of e-cigarettes for the first time, levying civil penalties on retailers in the process<sup>50</sup>. In July of that year, The Treasury and Health Ministry reaffirmed their recommendation that e-cigarettes be regulated under the medicines laws instead of under tobacco control, as per the recommendation of the WHO. The Ministries made such a pronouncement in declining a request from End Smoking NZ Trust to Health New Zealand that inquired about the possibility for the legalizing sales of e-cigarettes<sup>51</sup>.

By 2014, the Ministry of Health commented on the burgeoning e-cigarette market in its Annual Report, primarily outlining the debate in the tobacco control community over whether e-cigarettes were helpful or harmful to public health<sup>52</sup>. Of greater interest to this paper, the Ministry described its own course of action as having “acted on the World Health Organization’s advice, recommending a precautionary approach” and applied existing laws to the issue<sup>53</sup>. The Ministry proposed that in order to face “regulatory challenges”, it needed improved laws. The Ministry reaffirmed that it would assess new

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<sup>46</sup> Martin Johnston, “No Smoke, No Fire, Just Nicotine,” *New Zealand Herald*, December 8, 2007, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=10481095](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10481095).

<sup>47</sup> NZ Herald, “E-Cigarette Seller Hit with Warning,” *New Zealand Herald*, December 31, 2010, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=10697207](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10697207).

<sup>48</sup> Martin Johnston, “Medical Rules Lead to Withdrawal of Electronic Quit-Smoking Aid,” *New Zealand Herald*, April 17, 2010, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=10638910](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10638910).

<sup>49</sup> Medsafe, “Electronic Cigarettes,” *Medsafe*, November 5, 2010, <http://www.medsafe.govt.nz/regulatory/guideline/electroniccigarettes.asp>.

<sup>50</sup> Susan Edmunds, “Sexy and Safe? How New Fake Cigarettes Help Smokers Quit,” *New Zealand Herald*, September 8, 2013, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11121305](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11121305).

<sup>51</sup> NZ Finance and Expenditure Committee, “Customs and Excise (Tobacco Products—Budget Measures) Amendment Bill 22—1” (NZ House of Representatives, 2014), <https://goo.gl/OXzcR5>.

<sup>52</sup> NZ MoH, *Annual Report for the Year Ended 30 June 2014: Including the Director-General of Health’s Annual Report on the State of Public Health and the Minister of Health’s Report on Implementing the New Zealand Health Strategy*. (Wellington, New Zealand: Ministry of Health New Zealand, 2014), <https://www.health.govt.nz/.../annual-report-for-the-year-ended-june-2014-v3.docx>.

<sup>53</sup> Ibid.

evidence around e-cigarettes as it arose and that for the time being New Zealanders could buy their own e-cigarette products from overseas retailers via the internet<sup>54</sup>.

At the end of 2014, a Cochrane Collaboration meta-analysis led by two native New Zealanders, found that nicotine-containing e-cigarettes were helpful in helping smokers quit over the long run compared to placebo, without posing significant health risks on their own<sup>55</sup>.

By 2015, New Zealand's regulatory approach to e-cigarettes paralleled the approach of Australia (and Canada)<sup>56</sup>. At the beginning of 2016, as New Zealand aggressive tobacco control program advanced a fourth consecutive annual cigarette tax increase of 10%, complaints from health groups and taxpayer groups to allow the sale of e-cigarettes grew louder<sup>57</sup>. Throughout 2016, and in years prior, people campaigning for looser laws on e-cigarettes were repeatedly quoted in media sources saying something like, "The British get to use e-cigarettes to quit smoking and it's working out great for them, so why shouldn't we have that right too?"<sup>58</sup>.

By the summer of 2016, Associate Minister of Health Peta Simmonds, recommended the rules prohibiting the sale or supplying of e-cigarettes with nicotine be changed to allow the sale of such products in NZ<sup>59</sup>. The government sought public consultation on a laundry list of issues regarding how e-cigarettes could be legalized and what sorts of restrictions on sales or regulations of the sale of e-cigarettes would be required<sup>60</sup>. On March 28, 2017, the Government of New Zealand announced its intentions to pass legislation in the coming year to formally legalize the sale of e-cigarettes containing nicotine<sup>61</sup>.

Up until the present, the NZ government insisted that "there is no barrier to e-cigarette manufacturers applying to license their products in New Zealand through Medsafe", but no company had yet tried to push their product to be licensed in this manner<sup>62</sup>. In fact, there are seldom few instances where e-cigarette manufacturers anywhere in the world have tried to get their e-cigarette

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<sup>54</sup> Matthew Theunissen, "E-Cig Sales Ban Blasted," *New Zealand Herald*, September 14, 2014, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11324232](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11324232).

<sup>55</sup> Hayden McRobbie et al., "Electronic Cigarettes for Smoking Cessation and Reduction," *The Cochrane Database of Systematic Reviews* 12 (2014): CD010216, doi:10.1002/14651858.CD010216.pub2.

<sup>56</sup> Nick Wilson et al., "Potential New Regulatory Options for E-Cigarettes in New Zealand," *NZ Med J* 128, no. 1425 (2015): 88–96.

<sup>57</sup> Mason, "Government Burned over Smoking Tax Rise."

<sup>58</sup> NZ Herald, "Winston Peters: Obesity, Not Smoking, Should Be Looked at First," *New Zealand Herald*, May 28, 2016, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11646252](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11646252).

<sup>59</sup> Nicholas Jones, "E-Cigarette Sales to Be Allowed under a New Government Proposal," *New Zealand Herald*, August 2, 2016, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11685868](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11685868).

<sup>60</sup> Martin Johnston, "Only Licensed Pharmacies or 'Vape Shops' Should Be Allowed to Sell E-Cigarettes, Otago University Researchers Say," *New Zealand Herald*, September 8, 2016, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11705934](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11705934).

<sup>61</sup> Nicholas Jones, "E-Cigarettes Will Be Legalised: Government," *New Zealand Herald*, March 29, 2017, sec. National, [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11827700](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11827700).

<sup>62</sup> NZ Finance and Expenditure Committee, "Customs and Excise (Tobacco Products—Budget Measures) Amendment Bill 22—1."

products approved as a medicine. The closest examples are in the case of Pfizer's Nicotrol inhaler, which resembles an e-cigarette's method of delivering clean nicotine, but not in much else, and the effort of British American Tobacco to get a nicotine inhaler called Voke approved for sale as a smoking cessation aid in the United Kingdom<sup>63</sup>. Neither Nicotrol nor Voke have been a financial success for their parent companies, making the likelihood of other companies to want to follow them down the labor-intensive path towards approval as a medicine, much less likely.

### Secondary Cases

Once the initial findings are known from the New Zealand and Australian cases, the lessons will be tested in two secondary cases that may have served as role models to at least, New Zealand.

#### Canada

As of June 2017, the Canadian Senate had passed legislation to legalize the sale of e-cigarettes containing nicotine (Bill S-5)<sup>64</sup>. The next step in the legislative process is for the bill to head to the House of Commons, which is led by a Liberal Party government that is not ideologically in line with the Senate, leaning a bit more to the left. Previously, the country's medicines agency, HealthCanada had not given legal status to the sale of e-cigarettes containing nicotine in the country<sup>65</sup>. This bureaucratic inaction did not prevent the development of a bustling gray market in e-cigarettes which proliferated across the country in the form of online and brick and mortar retailers selling nicotine liquid and the e-cigarettes required to consume those liquids<sup>66</sup>. Canada's latest policy changes are being pointed to as an example to follow by inside sources in New Zealand, and the reasons that Canada's left-wing government are legalizing e-cigarettes appear to meaningfully differ than the right-wing governments in the United Kingdom and New Zealand who proceeded ahead with e-cigarette legalization.

#### United Kingdom

The United Kingdom allows the regulated sale of e-cigarettes as consumer products or as medicines. The country's policy is regularly referred to as the most explicitly harm reductionist in the world. The bounds of which products are being allowed to be sold on the market are currently dictated by the European Union's Tobacco Products Directive (EU TPD) of 2016. The TPD specified that e-liquid should be sold in quantities no larger than 10 mL and in nicotine concentrations no higher than 2% of volume. The UK, which is still a member of the EU for the next couple of years, has acceded to this common market standard in defining which products are sold, but the manner in which e-cigarette products are regulated is rather different in manner than other countries.

Public Health England, an executive agency within the UK Department of Health, published a now infamous report in 2015 which made the case that e-cigarettes were 95% less dangerous than

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<sup>63</sup> Martinne Geller, "BAT Quits Nicotine Inhaler to Focus on Vaping," *Reuters*, January 5, 2017, <http://www.reuters.com/article/us-brit-am-tobacco-voke-kind-idUSKBN14P12V>.

<sup>64</sup> "Senate SOCI Committee Meeting No. 45 on Bill S-5 | ECTA of Canada," accessed April 10, 2017, <http://ectaofcanada.com/senate-soci-committee-meeting-no-45-on-bill-s-5/>.

<sup>65</sup> Health Canada Government of Canada, "To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada," notice, *HealthCanada*, (March 4, 2009), [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice\\_avis\\_e-cig-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.php).

<sup>66</sup> Renée O'Leary et al., "Claims in Vapour Device (E-Cigarette) Regulation: A Narrative Policy Framework Analysis," *International Journal of Drug Policy* 44 (June 1, 2017): 31–40, doi:10.1016/j.drugpo.2017.03.004.

cigarettes<sup>67</sup>. The methods by which the authors arrived at this estimate are up for considerable debate as to their validity and replicability, but the thrust of the reports effect was that the UK government acknowledged it favored switching tobacco cigarette smokers over to e-cigarettes, through policy, education, or other strategies.

The United Kingdom is repeatedly held up as the source of tobacco harm reduction ideas and its regulatory practices that seem to aid the spread of e-cigarettes in their population are not found in many other places around the world. Determining why the UK had such a uniquely positive reaction to the introduction of e-cigarettes may shed light on the factors that prevent the precautionary principle from taking hold of public debate.

### Extension Cases

Three more cases and several more sub-cases make up a group of high-resource countries which have taken a varied strategy when it comes to allowing for and regulating the sale of e-cigarettes. These cases will allow for further tests of the hypotheses that are supported in the examination of the primary and secondary cases.

#### Singapore

The country has one of, if not, the lowest adult smoking rates among developed economies<sup>68</sup>. In 2011, Singaporean Customs began confiscating e-cigarettes and related vaporizers from parcels being mailed into the country and until 2015, 15,000 devices were seized and eight people were prosecuted, and fined up to S\$100,000<sup>69</sup>. In 2015, the Singapore Ministry of Health clarified that a prior ban on the sale of products imitating a tobacco product would apply to e-cigarettes, and the products were officially banned from being sold on the island<sup>70</sup>. The Ministry of Health's media strategy could be described as proactive as officials made sure to counter arguments made in the media for e-cigarette legalization with a reiteration of the government policy<sup>71</sup>. The country has a history of avoiding harm reducing ideas and instead pursuing precautionary policies instead, particularly in the fight against illicit drug use<sup>72</sup>. In that vein, the Ministry of Health's official explanation of why it was seeking a ban on e-

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<sup>67</sup> A McNeill et al., "E-Cigarettes: An Evidence Update" (London: Public Health England, August 2015), [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/454516/Ecigarettes\\_an\\_evidenc\\_e\\_update\\_A\\_report\\_commissioned\\_by\\_Public\\_Health\\_England.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454516/Ecigarettes_an_evidenc_e_update_A_report_commissioned_by_Public_Health_England.pdf).

<sup>68</sup> Yuen Sin, "Stubbing out Tobacco Use," *The Straits Times*, December 16, 2015, <http://www.straitstimes.com/singapore/health/stubbing-out-tobacco-use>.

<sup>69</sup> Jalelah Abu Baker, Calvin Yang, and Melissa Lin, "Banned E-Smoking Devices Sold Online," *The Straits Times*, November 11, 2015, <http://www.straitstimes.com/singapore/health/banned-e-smoking-devices-sold-online>; Joyce Lim, "Number of E-Cigarettes Seized Last Year Triples," *The Straits Times*, April 25, 2014, <http://www.straitstimes.com/singapore/health/number-of-e-cigarettes-seized-last-year-triples>.

<sup>70</sup> Singapore HSA Tobacco Regulation Branch, "Prohibition on Certain Products," *Health Sciences Authority*, April 7, 2017, [http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Tobacco\\_Control/Overview/Tobacco\\_Legislation/Prohibition\\_on\\_Certain\\_Products.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Tobacco_Control/Overview/Tobacco_Legislation/Prohibition_on_Certain_Products.html).

<sup>71</sup> Lim Bee Khim, "Adverse Health Effects of E-Cigarettes," *The Straits Times*, June 16, 2015, sec. Forum Letters, [https://www.moh.gov.sg/content/moh\\_web/home/pressRoom/Media\\_Forum/2015/adverse-health-effects-of-e-cigarettes.html](https://www.moh.gov.sg/content/moh_web/home/pressRoom/Media_Forum/2015/adverse-health-effects-of-e-cigarettes.html).

<sup>72</sup> Author's discussion with Singaporean Ministry of Health Officials

cigarettes (as a category of emerging product) was to pre-empt the potential harms the product would inflict on the public health. Even though Singapore is not a liberal democracy like the other countries in this study, it is known to be a technocratic country that is responsive to evidence-based policy suggestions<sup>73</sup>.

#### *United States*

E-cigarettes containing nicotine are currently legally allowed to be sold in the United States. By volume and value, the United States is also by the largest market in the world for e-cigarettes and the continuing legality of e-cigarettes being for sale in this country is of top concern to industry watchers<sup>74</sup>. The legal status of e-cigarettes in the United States has been in flux since their introduction to the market due to the difficulty posed to regulators in trying to categorize the products as first a drug, and then second as a tobacco product<sup>75</sup>. In May 2016, the US Food and Drug Administration (FDA) deemed e-cigarettes to be tobacco products, and in doing so, asserted its regulatory jurisdiction over the product category<sup>76</sup>. While this decision is still being contested in courts, it is expected that some form of FDA supervision over e-cigarettes will endure. No other country has passed legislation putting tobacco products (and all e-cigarettes) under the purview of the food-and-drug regulatory agency, so the experience of the US FDA with regulating e-cigarettes is likely to be an outlier in the world<sup>77</sup>.

#### *European Union*

As an economic union, the EU sets standards for commerce of countries within the single market, including a battery of requirements regulating tobacco products. The Tobacco Products Directive (TPD) was revised in 2014 and was required to come into effect in EU member states by 2016<sup>78</sup>. The TPD included new standards that set requirements around what sort of e-cigarette products could be sold in the EU. These regulations capped the size and nicotine concentration of e-liquid, banned advertising of e-cigarettes where cigarette advertising was banned, and called for member states to set up regulatory structures around the legal sale of these products in EU member states<sup>79</sup>.

The behind-the-scenes battle that led to the TPD's adoption is recounted in marvelous detail by Jacob Hasselbalch in a 2016 paper<sup>80</sup>. The paper recounts a battle of professionals in the public health and medical communities struggling to come to a consensus position over what to think about e-cigarettes and in their place, a community of e-cigarette users stood ready with a solution for lawmakers that allowed for EU-wide sales of nicotine-containing e-cigarettes. Prior to the adoption of the TPD several EU member states including France, Czech Republic, and Slovakia had banned the sale of

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<sup>73</sup> Michael d Barr, "Beyond Technocracy: The Culture of Elite Governance in Lee Hsien Loong's Singapore," *Asian Studies Review* 30, no. 1 (March 1, 2006): 1–18, doi:10.1080/10357820500537021.

<sup>74</sup> Euromonitor International, "Global Tobacco Key Findings Part 2: Vapour Products."

<sup>75</sup> Zachary Cahn and Michael Siegel, "Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?," *Journal of Public Health Policy* 32, no. 1 (2011): 16–31.

<sup>76</sup> Jen Christensen, "FDA to Extend Tobacco Regulations to E-Cigarettes," *CNN*, May 5, 2016, <http://www.cnn.com/2016/05/05/health/fda-e-cigarettes-regulation/index.html>.

<sup>77</sup> Eriksen et al., *The Tobacco Atlas*.

<sup>78</sup> Jacob Hasselbalch, "Professional Disruption in Health Regulation: Electronic Cigarettes in the European Union," *Journal of Professions and Organization* 3, no. 1 (March 1, 2016): 62–85, doi:10.1093/jpo/jov009.

<sup>79</sup> Ibid.

<sup>80</sup> Ibid.



nicotine containing e-cigarettes within their borders<sup>81</sup>. The mechanisms used to create these bans ranged from applying existing law in Belgium to amending existing legislation as was the case in Greece<sup>82</sup>. The revised TPD has forced all EU member states to allow the sale of nicotine-containing e-cigarettes to preserve a common market. The reasons why the current EU policy was adopted as well as the various strategies by which member countries are aligning the TPD with domestic tobacco control and pharmaceutical regulatory policies will be subject to examination during the course of the study.

A special effort to examine the case of EU member Sweden, which has taken a unique course on tobacco harm reduction over the last few decades promoting the sale of a low-carcinogen smokeless tobacco called snus, which is banned from being sold in the rest of the EU<sup>83</sup>. Sweden initially banned nicotine containing e-cigarettes from being sold within its borders, a policy which was only altered after a court decisions that came after the passage of the TPD<sup>84</sup>. The extent to which the precautionary principle was operative in creating this initial ban will be a key question of study in Sweden.

## Hypotheses

The primary candidate explanations for what factors made the difference between Australia and New Zealand are differences in Kingdon's policy stream. Policy entrepreneurs who hawk their own solutions to a particular problem inhabit the policy stream. I hypothesize that different policy entrepreneurs were at work in each country, shaping the view of problems and political opportunities. Potential reasons for these differences are listed in small sections below. These hypotheses will guide the investigation mapping out the multiple streams of policy, politics, and problems in each country.

### Epistemic Networks of Policy Entrepreneurs

A network of people who communicate back and forth within the policy stream can be the source of the ideas that get put into practice by politicians looking for a solution to a problem. Determining the source of the idea to legalize nicotine-containing e-cigarettes or to keep them illegal, whether coming from academics, activists, or industry, from within the country or from abroad, will help determine which environments produced this line of thought. I suspect that the influence of prominent harm reductionist academics based in the United Kingdom on academics based in New Zealand may have something to do with how the harm reductionist arguments gained traction in that country.

### Role of indigenous peoples/disparities perspective in government institutions

Alternatively, the politics streams could be (and likely are) different in each country. While right-of-center political parties are currently in government in both New Zealand and Australia, the position of Maori politicians as key coalition partners in New Zealand may have caused differences in the salience of health disparity politics of indigenous peoples, bringing their concerns to bear in the stream of politics, and in the framing of problems. Maori politicians seem to be firmly in favor of New Zealand adopting tobacco harm reduction policies asking the government to "subsidize" e-cigarette purchases in a

<sup>81</sup> Institute for Global Tobacco Control, "Country Laws Regulating E-Cigarettes: A Policy Scan."

<sup>82</sup> Ibid.

<sup>83</sup> Coral E Gartner et al., "Assessment of Swedish Snus for Tobacco Harm Reduction: An Epidemiological Modelling Study," *The Lancet* 369, no. 9578 (June 22, 2007): 2010–14, doi:10.1016/S0140-6736(07)60677-1.

<sup>84</sup> Jonas Löfgren and Annie Kabala, "E-Cigarettes No Longer Considered Medicinal Products in Sweden," *International Law Office*, May 25, 2016, <http://www.internationallawoffice.com/Newsletters/Healthcare-Life-Sciences/Sweden/Advokatfirman-Lindahl/E-cigarettes-no-longer-considered-medicinal-products-in-Sweden>.

manner similar to nicotine replacement therapy<sup>85</sup>. This should not be construed as a position that is trying to be soft on the tobacco industry as this proposal was preceded by calls to increase the pace of cigarette tax increases, ban the sale of so-called “non-light” cigarettes, and raise the age at which tobacco can be purchased from 18 to 25<sup>86</sup>. When problems become personal to politicians, I expect them to be more open to hearing harm reduction arguments.

### Policy Learning

Jurisdictions learn from the experience of others with adopting a particular policy and based on the outcomes of that policy, may learn to mimic or avoid that pioneering jurisdiction<sup>87</sup>. In their official documents communicating the decision to affirm Australia’s e-cigarette ban and to remove New Zealand’s, the lessons of the US and UK’s experience with legal e-cigarette sales are cited as evidence for New Zealand’s decisions *and for Australia’s*. Both countries are explicitly trying to engage in policy learning and learning opposite lessons. The rub of this hypothesis is to determine whether countries are setting up reasonable evaluation tools for determining the success or failure of another countries policies and if they are following through by acting on those results.

### Point in tobacco epidemic/progress on tobacco control

Countries that have made a great deal of progress in fighting tobacco use may be more or less likely to allow e-cigarettes to be sold in their country. Operationalizing the conceptual amount of progress made in fighting the tobacco epidemic is typically done in one of two ways. First, the usage of tobacco could be categorized into one of the stages of the tobacco epidemic characterized by Lopez<sup>88</sup>. These stages subdivide progress into whether the prevalence of tobacco use is rising (Stage 1 and 2) or falling (Stage 3 and 4), whether deaths from tobacco are lower than tobacco use prevalence (Stage 1), nearly equal to prevalence (Stage 2 and 3), or higher than prevalence (Stage 4). Almost all developed economies have reached Stage 4 of the tobacco epidemic, where tobacco’s share of deaths caused in a country exceeds smoking prevalence, and most developing economies are still in earlier stages. The alternative to measuring progress in this manner is to measure tobacco control policy progress, wherein the progress of developed economies in adopting strong tobacco control policy often lags developing economies (Japan lags Thailand, the US lags Brazil, etc.). Tobacco control scales have been developed to measure progress on adopting MPOWER policies (see Joossens and Raw<sup>89</sup>) and could be used to predict the adopting of e-cigarette sales policy.

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<sup>85</sup> Cleo Fraser, “Taxpayer-Funded Vaping Is Maori Party’s Latest Anti-Smoking Push,” *Newshub*, January 3, 2017, sec. Politics, <http://www.newshub.co.nz/home/politics/2017/02/taxpayer-funded-vaping-is-maori-party-s-latest-anti-smoking-push.html>.

<sup>86</sup> Chris Holden, “Māori Party MP Marama Fox Wants Dairies to Need Cigarette Licenses,” *Newshub*, September 15, 2016, sec. Politics, <http://www.newshub.co.nz/home/politics/2016/09/maori-party-mp-marama-fox-wants-cigarettes-banned.html>.

<sup>87</sup> Charles R. Shipan and Craig Volden, “The Mechanisms of Policy Diffusion,” *American Journal of Political Science* 52, no. 4 (2008): 840–57.

<sup>88</sup> Michael Thun et al., “Stages of the Cigarette Epidemic on Entering Its Second Century,” *Tobacco Control* 21, no. 2 (March 1, 2012): 96–101, doi:10.1136/tobaccocontrol-2011-050294.

<sup>89</sup> L Joossens and M Raw, “The Tobacco Control Scale: A New Scale to Measure Country Activity,” *Tobacco Control* 15, no. 3 (June 2006): 247–53, doi:10.1136/tc.2005.015347; Luk Joossens and Martin Raw, “The Tobacco Control Scale 2013 in Europe” (Istanbul, Turkey: European Conference on Tobacco or Health, March 29, 2014),

The argument for banning sales of e-cigarettes in a country where lots of progress had been made is that allowing a novel product onto the market may “renormalize” smoking and open up a new avenue to tobacco use that was not previously available, and would reverse the positive progress that had been made against tobacco use in that country. The argument for banning sales of e-cigarettes that has yet to make large progress against tobacco use is that the introduction of a new tobacco product with a different harm profile than cigarettes will confuse anti-tobacco messaging that seeks to be clear in its communication that there is no such thing as a safe tobacco product. Theoretically, both arguments could be simultaneously true and the likelihood of banning e-cigarettes could have a curvilinear relationship with progress being made against the tobacco epidemic.

This hypothesis will largely be evaluated directly in the quantitative analysis portion of the project as well as interviews with people who largely live in the political and problem streams.

#### Political support from a government with a libertarian streak

Whether e-cigarette sales represent an expression of policy preferences that are consistent with a political ideology that favors using harm reduction tactics instead of the precautionary principle when formulating public policy, is an angle that seems largely unexplored in the prior literature. In an April 2017 interview with Grover Norquist, the influential President of Americans for Tax Reform, Norquist credited the President Trump’s electoral victory to the conversion of young urbanite vapers in swing states into an interest group similar to gun owners that supported less government regulation on their activity of choice<sup>90</sup>. Now, while this isn’t backed up by any data yet available to the public, the very idea that this hypothesis is being floated merits consideration of whether Vapers have become a group that can be activated to support candidates or parties with a kind of anti-regulatory libertarian streak. I pose this as a libertarian ideal instead of a conservative ideal because very socially conservative states like Singapore and the UAE seem comfortable banning e-cigarette sales, while socially liberal governments like Justin Trudeau’s Labor Party in Canada seem comfortable pairing e-cigarette liberalization with the rest of their socially liberal agenda. Norquist himself, may also agree with the characterization as being more about getting the government out of private life than anything else. Investigation of the political and/or ideological motivations for taking a position on e-cigarettes can be tested using data about the composition of governments in the quantitative work, in document review of the statements of politicians and aligned ideological interest groups and in qualitative interviews with people inhabiting the political stream.

#### Central vs. Federal Systems

One of the most obvious differences between the governmental institutions of the two main case studies of New Zealand and Australia are that Australia is a federal system while New Zealand is centralized. The devolution of regulatory power to Australian states and territories might bring about different policy dynamics than are experienced in a centralized system like New Zealand. A federalized system allows more experimentation with varying kinds of policy at the subnational level, though there are few examples around the world of countries that devolve medicines regulation to lower levels of

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[http://www.europeancancerleagues.org/images/TobaccoControl/TCS\\_2013\\_in\\_Europe\\_13-03-14\\_final\\_1.pdf](http://www.europeancancerleagues.org/images/TobaccoControl/TCS_2013_in_Europe_13-03-14_final_1.pdf).

<sup>90</sup> Molly Ball, “Grover Norquist, the Happiest Man in Washington,” *The Atlantic*, April 18, 2017, <https://www.theatlantic.com/politics/archive/2017/04/grover-norquist-the-happiest-man-in-washington/523206/>.

government. Tobacco control activities, however, are often devolved to states and localities in federal systems, so there is some reason to expect that federal systems take some pressure off the central government to react to new issues in tobacco control<sup>91</sup>. Whether this logic applies to the quandary of whether to allow e-cigarette sales has yet to be explored.

### System receptiveness to pressure groups

There is some reason to believe that the efforts of pressure groups were instrumental in getting the EU TPD passed, to getting New Zealand started on considering the legalization of nicotine containing e-cigarette sales, and potential changes to US statute that would clear up the legal status of e-cigarettes have all been supported by pressure groups with personal interest in getting such changes put into action. Whether certain political systems are more or less susceptible to influence from pressure groups than others has been up for debate in the comparative politics literature for many years. The main debate is between those who believe that the characteristics of political and governmental institutions that matter<sup>92</sup> and those who believe it is the characteristics of the pressure groups that make the difference<sup>93</sup>.

### Conclusion

This project is admittedly sprawling. It seeks at its core to learn what produced different outcomes in seemingly similar country case studies of New Zealand and Australia's differing decisions to allow the sale of nicotine-containing e-cigarettes in early 2017. This research plan sketches out case studies that will inform how the harm reduction frame overcomes the precautionary principle frame, and vice versa, in a public policy debate in two very similar countries. The lessons gleaned there will be tested in several secondary and extension cases using a variety of qualitative and quantitative techniques. The results will become my doctoral dissertation.

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<sup>91</sup> Amy K Ferketich et al., "Clean Indoor Air Ordinance Coverage in the Appalachian Region of the United States," *American Journal of Public Health* 100, no. 7 (July 2010): 1313–18, doi:10.2105/AJPH.2009.179242.

<sup>92</sup> George Tsebelis, *Veto Players: How Political Institutions Work* (Princeton, N.J.: Princeton University Press, 2002).

<sup>93</sup> Cécile Vigour, "Veto Players and Interest Groups in Lawmaking: A Comparative Analysis of Judicial Reforms in Italy, Belgium, and France," *Comparative Political Studies* 47, no. 14 (December 1, 2014): 1891–1918, doi:10.1177/0010414013517082.