

**Formulating a Regulatory Stance: The Comparative Politics of E-Cigarette
Regulation in Australia, Canada and New Zealand**

by

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Dedication

For Lindsey and Sophia. I love you both to the ends of the earth and am eternally grateful for your tolerance of this project.

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List of Abbreviations

ACCC – Australian Competition and Consumer Commission
ATHRA – Australian Tobacco Harm Reduction Association
BAT – British American Tobacco
CCMOH – Council of Chief Medical Officers of Health (Canada)
CDC – Centers for Disease Control and Prevention (US)
CDOH – Commercial Determinants of Health
EVALI – E-cigarette, or Vaping, product use Associated Lung Injury
FCTC – Framework Convention on Tobacco Control (WHO)
FDA – Food and Drug Administration (US)
GM – Genetically Modified
HESA – House of Commons Standing Committee on Health (Canada)
ICOD – Intergovernmental Committee on Drugs (Australia)
MP – Member of Parliament
NDP – New Democratic Party (Canada)
NHMRC – National Health and Medical Research Council (Australia)
PM – Prime Minister
PMI – Philip Morris International
SFEA – Smoke-Free Environments Act (New Zealand)
TGA – Therapeutic Goods Administration (Australia)
THC – Tetrahydrocannabinol
THR – Tobacco Harm Reduction
WHO – World Health Organization

Abstract

Depending on who is asked, electronic cigarettes (e-cigarettes) are either the worst thing to happen to the fight against tobacco or a godsent technology that will dramatically improve public health. Unlike tobacco cigarettes, where the world has converged on common regulatory policies intent on shrinking the market for those deadly products, jurisdictions diverge immensely in their regulatory goals towards e-cigarettes.

Illustratively, in March 2017, the government of New Zealand announced it would legalize the sale of e-cigarettes. In February 2017, Australia's pharmaceutical regulator rejected a proposal to legalize the sale of nicotine for use in e-cigarettes because evidence of the product's long-term safety was lacking. Previously, the medicines regulator in each country agreed the sale of e-cigarettes with nicotine should not be legal. Within a month, two wealthy, democratic, neighboring former British colonies, with a history of being leaders in tobacco control policy, led by right-wing governments, parted company on this momentous policy issue. Why?

Through a comparative study of Australia, Canada, and New Zealand, this study addresses how the concerns of public health advocates, business, bureaucrats, and politicians around e-cigarettes are translated into regulatory policy. Political science has only begun to apply its theories to the study of public health policies, and most of what drives public health policy outcomes remains poorly understood. Here, a qualitative comparative approach of three most-similar country cases is used to determine what factors enabled e-cigarette regulatory policy change or stasis.

To imbue meaning to the purpose of a regulatory framework, the study introduces an organizing framework called a regulatory stance, which describes the intent of a regulatory framework to alter the size of a market in the future relative to the present. All three case countries began with a prohibitionist regulatory stance towards e-cigarettes, which intended the market for e-cigarettes should make up none of their economies. New Zealand and Canada soon adopted expansionist regulatory stances, meaning that these countries intended on growing the size of their e-cigarette markets. Australia kept its original regulatory stance.

Structured by John W. Kingdon's Multiple Streams Approach to agenda-setting, the case studies examine how and why a country's regulatory stance towards e-cigarettes, changed or did not. I employed qualitative techniques of document collection and key informant interviews to piece together a comparative study of e-cigarette regulatory policy and politics. In the Multiple Streams Approach, the problem and policy streams must become primed before they can merge with the politics stream and open a policy window. The problem stream became primed once the current regulatory policy was deemed a failure when it was rejected by the courts as illegal, rejected by bureaucracies as not worth enforcing, or it failed to advance the fight against smoking. Next, the policy stream became primed once the public health policy community agreed on a consensus alternative regulatory stance expanding the market for e-cigarettes. Finally, the politics stream was primed when conditions in the problem and policy stream granted left-wing politicians' permission to support a regulatory stance change favored by business groups. This freed right-wing politicians to support regulatory stance change without facing a political penalty. Once all stakeholders agreed they would benefit more by adopting the alternative regulatory stance than by continuing with the failed policy, a policy window to change the failed e-cigarette regulatory stance opened.

Chapter 1 Introduction

Depending on who is asked, electronic cigarettes (e-cigarettes) are either the worst thing to happen to the fight against tobacco or a godsent technology that will dramatically improve public health. Unlike tobacco cigarettes, where most countries of the world have coalesced around a series of regulatory policies meant to shrink the market for the products over time, the world has yet to arrive at a consensus best practice regulatory policy for e-cigarettes. As an example, in March 2017, the government of New Zealand announced it would formally legalize the sale of e-cigarettes.¹ In February 2017, Australia's pharmaceutical regulator rejected a proposal to legalize the sale of liquid nicotine for use in e-cigarettes because evidence of the product's long-term safety was lacking.² Previously, the medicines regulator in each country agreed the sale of e-cigarettes with nicotine should not be legal. Within a month, two wealthy, democratic, neighboring former British colonies, with a history of being leaders in tobacco control policy, led by right-wing governments, parted company on this momentous policy issue. Why?

This study addresses how the concerns of public health advocates, business, bureaucrats, and politicians around e-cigarettes are translated into regulatory policy. Political science has only begun to apply its theories to the study of health policies and politics, and most of what drives public health policy outcomes remains poorly understood.³ Here, a qualitative comparative approach of three most-similar country cases is used to determine what factors enabled e-cigarette regulatory policy change or stasis. Structured by Kingdon's Multiple Streams Approach to agenda-setting and policy change, the case studies examine how and why a country's regulatory stance towards e-cigarettes, the intent to alter the size of a market in the future compared to the present, changed or did not.

¹ Nicholas Jones, "E-Cigarettes Will Be Legalised: Government," *New Zealand Herald*, March 29, 2017, sec. National, <https://bit.ly/2U7bK5o>.

² AAP, "FED:Ban on Nicotine e-Cigarettes to Remain," *Australian Associated Press*, February 2, 2017, sec. Domestic News.

³ Eric Breton and Evelyne De Leeuw, "Theories of the Policy Process in Health Promotion Research: A Review," *Health Promotion International* 26, no. 1 (March 2011): 82–90, <https://doi.org/10.1093/heapro/daq051>.

I find that e-cigarette regulatory policy change was precipitated by the rejection of an existing regulatory framework, followed by the reaching of a consensus alternative regulatory framework in the public health community, which was followed by the co-optation of left-wing political parties to favor regulatory policy change.

How can the same product be treated so differently in different jurisdictions? We cannot expect a single explanation to account for all the variance that can be observed. Real-world governments are too messy and complex to say nothing of the countries that they govern. No pre-existing theories readily explain the diversity of approaches that are taken to regulate e-cigarettes. This study will employ a qualitative comparative case study technique to uncover key differences among a set of most-similar countries who started with identical e-cigarette regulatory policies but ended up in different places. This study attempts to explain a divergence in regulatory policy for e-cigarettes among the similarly situated countries of Australia, Canada, and New Zealand.

1.1 E-Cigarettes

In 2003, the modern e-cigarette was invented by a Chinese pharmacist named Hon Lik.⁴ Lik would go on to found the first e-cigarette manufacturer, RuYan (meaning ‘like smoke’), in an effort to propagate the sale of what he thought was a life-saving intervention for tobacco cigarette smokers.⁵ Lik’s device, and those that followed in its wake, heat a liquid solution of tobacco-derived-nicotine, propylene glycol, vegetable glycerin, and flavorings until that liquid becomes a gaseous vapor that can be inhaled by a user.⁶ The nicotine in the liquid suspended in a gaseous vapor is inhaled deep into the lungs, absorbed, and expelled similarly to tobacco cigarette smoke.⁷

A note on terminology: in this study, the device used to consume nicotine liquid will be referred to as an e-cigarette. Although some deride the use of the term e-cigarette as being imprecise or

⁴ Hon Lik, Non-combustible electronic spray cigarette, China CN2648836Y, filed April 29, 2003, and issued October 20, 2004, <https://patents.google.com/patent/CN2648836Y/en>; Hon Lik, Flameless electronic atomizing cigarette, United States US20060196518A1, filed March 8, 2004, and issued September 7, 2006, <https://patents.google.com/patent/US20060196518A1/en>.

⁵ Murray Laugesen, *My Life in Public Health: A Memoir from the Frontlines of Global Disease Eradication, Children’s Health, and Ending Smoking* (Christchurch, N.Z.: Health New Zealand, 2019), chap. 10.

⁶ Jeffrey Drope et al., “Key Issues Surrounding the Health Impacts of Electronic Nicotine Delivery Systems (ENDS) and Other Sources of Nicotine,” *CA: A Cancer Journal for Clinicians* 67, no. 6 (November 2017): 449–71, <https://doi.org/10.3322/caac.21413>.

⁷ Thomas Eissenberg, “Electronic Nicotine Delivery Devices: Ineffective Nicotine Delivery and Craving Suppression after Acute Administration,” *Tobacco Control* 19, no. 1 (February 2010): 87–88, <https://doi.org/10.1136/tc.2009.033498>.

colloquial, it has a commonly understood meaning among the public and will not be confused for anything else.⁸ The verb describing the use of e-cigarettes will often be “vape” or “vaping”.⁹ The term used to refer to the users of e-cigarettes will often be “vaper”. These terms will be used interchangeably with their more formalized counterparts of “e-cigarette use” or “e-cigarette user” to reflect the language used in data sources collected throughout the study. The nicotine-laced liquid solution that is consumed in e-cigarettes will be referred to as “e-liquid” or “nicotine liquid”.

Analyses of e-cigarette product constituents and cigarette smoke constituents suggest e-cigarettes will be less harmful to the individual user than tobacco cigarettes.¹⁰ The absolute long-term risk of e-cigarette use for human health remains uncertain for the time being.¹¹ The most well-known estimate of the relative risk asserted that e-cigarettes are 95% safer than cigarettes.¹² This figure originated from a Delphi process that compared the estimated harms of 12 nicotine products in a July 2013 London workshop.¹³ Evidence updates on e-cigarettes from Public Health England, a United Kingdom Executive Agency, served to amplify the 95% less harmful estimate to the point where this estimate of relative risk has become a core rationale, even evidence, for policy adoption.¹⁴ The accuracy of the 95% safer claim has been widely challenged on grounds that the evidence used is out of date, does not reflect the current market, and downplays the risks of a gateway effect into smoking for youth.¹⁵ The veracity of the 95% safer claim is not going to be resolved here or anywhere else soon, so it is best to consider what to do with the little contested claim that e-cigarettes are safer to use than cigarettes.

⁸ Matthew Olonoff, Raymond Niaura, and Brian Hitsman, “‘Electronic Cigarettes’ Are Not Cigarettes, and Why That Matters,” *Nicotine & Tobacco Research* 21, no. 10 (September 19, 2019): 1441–44, <https://doi.org/10.1093/ntr/nty205>.

⁹ Allison M. Glasser et al., “Overview of Electronic Nicotine Delivery Systems: A Systematic Review,” *American Journal of Preventive Medicine* 52, no. 2 (February 2017): e33–66, <https://doi.org/10.1016/j.amepre.2016.10.036>.

¹⁰ Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems et al., *Public Health Consequences of E-Cigarettes*, ed. Kathleen Stratton, Leslie Y. Kwan, and David L. Eaton (Washington, D.C.: National Academies Press, 2018), chap. 5, <https://doi.org/10.17226/24952>.

¹¹ 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, <https://doi.org/10.1111/add.12659>; Martinne Geller, “E-Cigs a ‘consumer-Driven’ Revolution Born from a Bad Dream,” *Reuters*, June 9, 2015, sec. Lifestyle, <http://reut.rs/1f0W6CP>.

¹² A McNeill et al., “E-Cigarettes: An Evidence Update” (London: Public Health England, August 2015), <http://bit.ly/1gWA2di>.

¹³ David J. Nutt et al., “Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach,” *European Addiction Research* 20, no. 5 (2014): 218–25, <https://doi.org/10.1159/000360220>.

¹⁴ Ann McNeill et al., “Evidence Review of E-Cigarettes and Heated Tobacco Products 2018: A Report Commissioned by Public Health England” (London: Public Health England, February 2018), https://www.politopedia.cl/wp-content/uploads/2018/02/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf.

¹⁵ Thomas Eissenberg et al., “Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes,” *American Journal of Public Health* 110, no. 2 (January 8, 2020): 161–62, <https://doi.org/10.2105/AJPH.2019.305424>.

Modelers, those scientists who employ computer simulations to predict the future based on contingencies and learned behavior from the past have engaged in the debate over the safety of e-cigarettes in a productive manner. Instead of relying on a single relative risk estimate or a single claim about the magnitude of gateway effects relative to smoking cessation effects, modelers have employed a range of estimates to produce simulations of population health outcomes. Most have found positive health effects will accrue to a population that shifts a tobacco cigarette market over to an e-cigarette market, even if relative risk assumptions are much less kind than the 95% figure.¹⁶ For example, a formal simulation of the health benefits that would accrue to the United States, if it were able to transition its tobacco cigarette smokers entirely over to e-cigarettes, estimates that at minimum around 1.6 million premature deaths would be averted and 20.8 million fewer life years would be lost.¹⁷ The stakes around whether a country can transition its population from tobacco cigarettes and onto less dangerous forms of nicotine are massive in its scale. Alternatively, countries might attempt to push to wean their populations from nicotine altogether.¹⁸

These findings have not stopped a proliferating number of concerned scientists and advocates from publishing arguments that cast a skeptical eye towards beliefs that e-cigarettes are a public health panacea. A fissure in the epistemic tobacco control community has developed into two camps who view the usefulness of e-cigarettes as a public health tool from opposite sides of a spectrum.¹⁹ On one end are e-cigarette skeptics who advocate for applying the precautionary principle, which would keep products whose harm has not yet been established off the market until their long-term safety and efficacy are demonstrated.²⁰ On the other end are persons who call themselves harm reduction advocates who say it would behoove society to provide easier access to and fewer restrictions on less harmful products and activities.²¹ In the case of e-

¹⁶ Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems et al., *Public Health Consequences of E-Cigarettes*, chap. 19.

¹⁷ An optimistic scenario places the benefits at 6.6 million fewer premature deaths and 86.7 million fewer life years lost. David T. Levy et al., "Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes," *Tobacco Control* 27, no. 1 (January 1, 2018): 18–25, <https://doi.org/10.1136/tobaccocontrol-2017-053759>.

¹⁸ Patricia A. McDaniel, Elizabeth A. Smith, and Ruth E. Malone, "The Tobacco Endgame: A Qualitative Review and Synthesis," *Tobacco Control* 25, no. 5 (September 2016): 594–604, <https://doi.org/10.1136/tobaccocontrol-2015-052356>.

¹⁹ Amy Lauren Fairchild, Ronald Bayer, and Ju Sung Lee, "The E-Cigarette Debate: What Counts as Evidence?," *American Journal of Public Health*, May 16, 2019, e1–7, <https://doi.org/10.2105/AJPH.2019.305107>.

²⁰ 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>.

²¹ 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, <https://doi.org/10.1126/science.1260761>.

cigarettes, these people call themselves tobacco harm reduction (THR) advocates, and they wish to replace all the tobacco cigarettes in the world with less hazardous products, like e-cigarettes.

Skeptics have attempted to establish a link between e-cigarette use in adolescents and later cigarette smoking behavior, as well as the toxicity to the human body of inhaling vaporized e-liquid.²² These e-cigarette-skeptical scientists have even offered their computer simulation models finding that e-cigarettes will harm public health.²³

Those who defend the e-cigarette's potential as a tool public health have been steadily losing the battle of public opinion as less of the public believes e-cigarettes are less harmful than cigarettes every year.²⁴ Figure 1 demonstrates that in the United States from 2012 to 2019, the ratio of persons who thought e-cigarettes were less harmful than tobacco cigarettes compared to those who thought they were more harmful fell from 14.9 to 1 to just 1.2 to 1.²⁵ In the United Kingdom, the proportion of smokers who believe that e-cigarettes and cigarettes are equally harmful rose from 26.1% in 2014 to 41.8% in 2019, outpacing the proportion who thought e-cigarettes were the less harmful product by that latter date (34.4%).²⁶

²² James C. Salamanca et al., "Formaldehyde Hemiacetal Sampling, Recovery, and Quantification from Electronic Cigarette Aerosols," *Scientific Reports* 7, no. 1 (September 8, 2017): 11044, <https://doi.org/10.1038/s41598-017-11499-0>; Samir Soneji et al., "Association Between Initial Use of E-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-Analysis," *JAMA Pediatrics* 171, no. 8 (August 1, 2017): 788–97, <https://doi.org/10.1001/jamapediatrics.2017.1488>; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems et al., *Public Health Consequences of E-Cigarettes*.

²³ Crucially, this study assumed that youth e-cigarette use *caused* later smoking initiation. The assumption of a strong gateway effect into tobacco smoking yielded most of the power that drove a negative public health outcome. Samir S. Soneji et al., "Quantifying Population-Level Health Benefits and Harms of e-Cigarette Use in the United States," *PLOS ONE* 13, no. 3 (March 14, 2018): e0193328, <https://doi.org/10.1371/journal.pone.0193328>.

²⁴ Leonie S. Brose et al., "Perceived Relative Harm of Electronic Cigarettes over Time and Impact on Subsequent Use. A Survey with 1-Year and 2-Year Follow-Ups," *Drug and Alcohol Dependence* 157 (December 1, 2015): 106–11, <https://doi.org/10.1016/j.drugalcdep.2015.10.014>; Scott R. Weaver et al., "Worldviews and Trust of Sources for Health Information on Electronic Nicotine Delivery Systems: Effects on Risk Perceptions and Use," *SSM - Population Health*, September 29, 2017, <https://doi.org/10.1016/j.ssmph.2017.09.003>.

²⁵ Health Information National Trends Survey, "Compared to Smoking Cigarettes, Would You Say That Electronic Cigarettes Are . . .," National Cancer Institute, March 4, 2020, <https://hints.cancer.gov/view-questions-topics/question-details.aspx?qid=1282>.

²⁶ In 2014, 45.2% of UK smokers thought e-cigarette were less harmful than tobacco cigarettes. Ann McNeill et al., "Vaping in England: An Evidence Update Including Mental Health and Pregnancy" (London: Public Health England, March 2020), 97, <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020>.

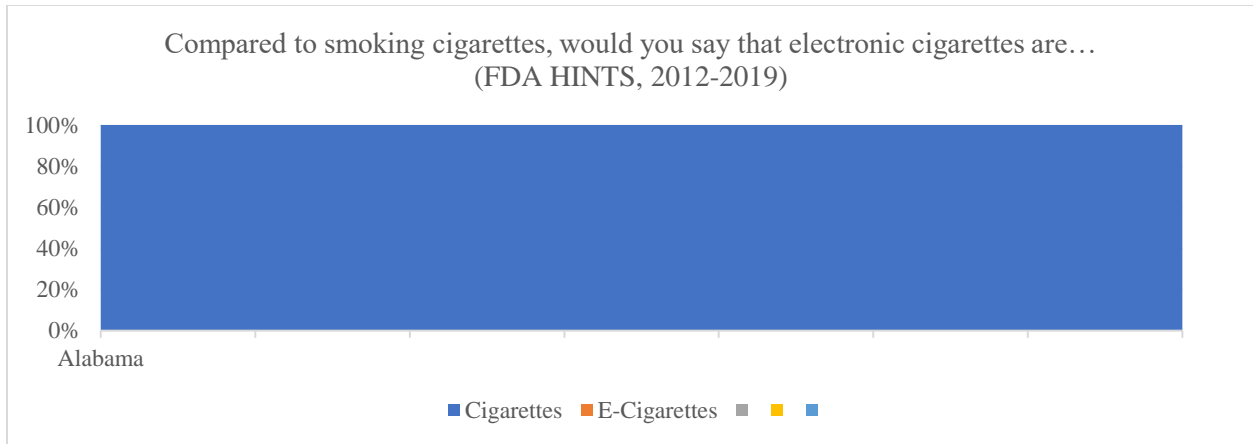


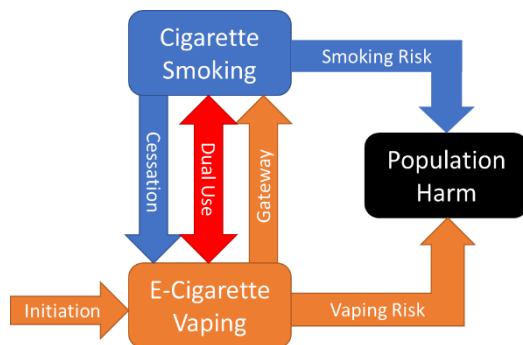
Figure 1: Public Opinion about the Relative Harm of Tobacco and e-Cigarettes in the US

This loss of public faith in a relatively safer product (when compared to the most lethal consumer product of them all) is baffling to many observers. Thirty-year longitudinal studies of the effect of e-cigarettes on human health are twenty years away from being published. Without this information, skeptics advocate it is better to confine battle against tobacco-caused disease to tobacco cigarettes. THR advocates argue that e-cigarettes could be an overwhelmingly positive force for public health. No matter how one frames this debate, e-cigarettes are not a case of pure risk or pure opportunity.

1.1.1 The Risks and Benefits of E-Cigarettes

That risk and opportunity debate breaks down into several contested topics; safety, gateway effect, cessation, youth initiation, and dual use. Figure 2 illustrates a simplified relationship between each topic and how each contributes to eventual population harm. One of the primary purposes that public health entities are interested in e-cigarette regulatory policy is an effort to shape these forces so that they minimize population harm. If regulatory policy can reduce the

Figure 2: Risk Concepts for E-Cigarette Regulatory Policy



safety risk of e-cigarette products, decrease rates of youth initiation, or decrease gateway effects into tobacco cigarette smoking, we might see less population harm. If regulatory policy can decrease dual use or increase tobacco cigarette cessation rates, then we might also see benefits to population health. Each of these risks requires distinct regulatory policy responses but outlining what each risk is and the

evidence supporting the existence of such a risk will provide richer contextual meaning to scholars seeking to understand the topics that will be discussed in the chapters ahead.

1.1.1.1 Health Risks from Use

The direct harms of e-cigarette use are being studied in cell and animal models as well as in humans at an expanding pace. E-cigarettes have been found to replicate some, but not all, of the bodily harms caused by cigarette smoke. Animals exposed to e-cigarette aerosols have suffered decreased functioning of their lungs, liver, and heart as well as injuries to gestating offspring.²⁷ Immunological responses in human subjects raise concerns that e-cigarette use harms immune systems, damages the oral cavity, and raises the risk of developing cancer (relative to not using e-cigarettes).²⁸ Some flavoring compounds used in e-cigarettes, including chemicals used to create butter, cherry, cinnamon, and vanilla flavors, have even been found to be more injurious to lung tissue than others.²⁹ The rechargeable batteries in some lower-quality e-cigarettes have exploded which has maimed and even killed a small number of adult users.³⁰ Children have swallowed the e-liquid their parents use to fill their e-cigarettes, leading to a large number of calls to poison centers, and several cases of fatal nicotine overdoses.³¹

These findings have begun to solidify the conclusion that e-cigarettes are not safe consumer products in an absolute sense. The market can be subject to regulation to address some preventable harms, like requiring the use of child-proof caps on e-liquid or product standards that disallow the sale of butter-flavored products. However, these risks still pale in comparison to the risks to health posed by the tobacco cigarette. The bottom line on the safety of e-cigarettes should, therefore, evoke the logic of the Public Health England reports while disregarding the

²⁷ Anna Merez-Sadowska et al., “A Summary of In Vitro and In Vivo Studies Evaluating the Impact of E-Cigarette Exposure on Living Organisms and the Environment,” *International Journal of Molecular Sciences* 21, no. 2 (January 19, 2020), <https://doi.org/10.3390/ijms21020652>.

²⁸ I.-Ling Chen, Ian Todd, and Lucy C. Fairclough, “Immunological and Pathological Effects of Electronic Cigarettes,” *Basic & Clinical Pharmacology & Toxicology* 125, no. 3 (2019): 237–52, <https://doi.org/10.1111/bcpt.13225>.

²⁹ Janice Gerloff et al., “Inflammatory Response and Barrier Dysfunction by Different E-Cigarette Flavoring Chemicals Identified by Gas Chromatography–Mass Spectrometry in e-Liquids and e-Vapors on Human Lung Epithelial Cells and Fibroblasts,” *Applied in Vitro Toxicology* 3, no. 1 (March 1, 2017): 28–40, <https://doi.org/10.1089/aivt.2016.0030>.

³⁰ John Cotter, “Exploding E-Cigarette ‘lit My Kid’s Face on Fire’ Warns Alberta Father,” CBC, January 28, 2016, <https://www.cbc.ca/news/canada/calgary/alberta-father-calls-for-ban-on-e-cigarettes-1.3423099>; Andrew Russell, “Exploding E-Cigarettes? Here’s What Canadians Need to Know,” Global News, January 27, 2016, <https://globalnews.ca/news/2481734/exploding-e-cigarettes-heres-what-canadians-need-to-know/>; E. Ackley et al., “Too Hot to Handle? When Vaporizers Explode,” *Journal of Pediatrics* 196 (2018): 320-320.e1, <https://doi.org/10.1016/j.jpeds.2017.12.032>.

³¹ M. Quail, “Nicotine Toxicity: Protecting Children from e-Cigarette Exposure,” *Nursing* 50, no. 1 (January 2020): 44–48, <https://doi.org/10.1097/01.NURSE.0000615084.47597.14>.

specific figures around relative risk. E-cigarettes are safer than tobacco cigarettes but not absolutely safe.

1.1.1.2 *Initiation*

Arguably the most important subject of the e-cigarette policy debate has been the question of initiation, or more specifically, youth initiation of e-cigarette use. Young people are using e-cigarettes at an increasing pace, even outstripping the use of tobacco cigarettes in 15 countries as of 2018.³² THR advocates view these statistics as a public health victory because, in most cases, tobacco cigarette smoking has fallen to historic lows while e-cigarette use has been rising in young people. E-cigarette skeptical scientists have tended to view the growth of e-cigarette use in young people as a new vector for nicotine addiction in a new generation. While e-cigarette skeptics persistently point to evidence that nicotine addiction is harmful to young brains, their largest concern over this rising tide of youth e-cigarette use is that it will one day transition to a rising tide of tobacco cigarette smoking.³³ This potential transition into a more harmful activity is referred to as a gateway effect.

1.1.1.3 *Gateway*

The debate over whether the existence of an e-cigarette market spurs growth in the number of young smokers, a gateway effect, is one of the most controversial, important, and lively issues in this policy area. Gateway effects have been purported to exist between tobacco, alcohol, and cannabis to illicit ‘hard’ drugs for decades and progress towards proving their existence has been uneven at best.³⁴ E-cigarette skeptics point to a raft of studies that find that young people who use e-cigarettes are more likely to progress to smoking tobacco cigarettes later in their young lives.³⁵ This finding is often challenged by THR advocates who assert that vaping and smoking might share a common cause, like rebelliousness, anxiety, or parental tobacco use.³⁶

³² More young people vape than smoke in Canada, Colombia, Dominican Republic, Georgia, Iraq, Japan, Morocco, Panama, Poland, Saint Lucia, Switzerland, Trinidad and Tobago, Ukraine, United Kingdom and the United States. World Health Organization, *WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2019: Offer Help to Quit Tobacco Use* (Geneva: World Health Organization, 2019), figs. 11–4; 11–3.

³³ Michelle Ren and Shahradd Lotfipour, “Nicotine Gateway Effects on Adolescent Substance Use,” *Western Journal of Emergency Medicine* 20, no. 5 (September 2019): 696–709, <https://doi.org/10.5811/westjem.2019.7.41661>.

³⁴ Louisa Degenhardt et al., “Evaluating the Drug Use ‘Gateway’ Theory Using Cross-National Data: Consistency and Associations of the Order of Initiation of Drug Use among Participants in the WHO World Mental Health Surveys,” *Drug and Alcohol Dependence* 108, no. 1–2 (April 1, 2010): 84–97, <https://doi.org/10.1016/j.drugalcdep.2009.12.001>.

³⁵ Jasmine N. Khouja et al., “Is E-Cigarette Use in Non-Smoking Young Adults Associated with Later Smoking? A Systematic Review and Meta-Analysis,” *Tobacco Control*, March 2, 2020, <https://doi.org/10.1136/tobaccocontrol-2019-055433>.

³⁶ Peter N. Lee, Katharine J. Coombs, and Esther F. Afolalu, “Considerations Related to Vaping as a Possible Gateway into Cigarette Smoking: An Analytical Review,” *F1000Research* 7 (July 22, 2019), <https://doi.org/10.12688/f1000research.16928.3>.

Disentangling the causal arrow between e-cigarette and tobacco cigarette usage in youth is a monumental task and may likely never be fully resolved.

1.1.1.4 Cessation

Determining whether e-cigarettes aid smoking cessation has been a key question surrounding the novel products since their introduction. The emphasis of this point comes from THR advocates who point to all manner of data ranging from the anecdotal to gold-standard randomized controlled trials to emphasize their preferred conclusion. In the author's view of the body of scientific evidence, nicotine-containing e-cigarettes perform as well as or better than nicotine replacement therapies in aiding smoking cessation. To date at least six published randomized controlled trials evaluating whether nicotine-containing e-cigarettes increase smoking cessation success relative to placebos, financial incentives, behavioral therapy, or nicotine replacement therapy.³⁷ None of the trials has found that e-cigarettes are inferior to their comparator treatments and four of the trials have found that e-cigarettes outperform their comparators in promoting smoking cessation.³⁸ It seems that in a clinical setting, e-cigarettes aid smoking cessation. The rates of successful cessation are far lower than those typically claimed by THR advocates, but they are significant, nonetheless.

These findings speak little to how e-cigarettes are used in more recreational settings. These findings must also be tempered by concerns about gateway effects potentially erasing whatever beneficial population effects e-cigarettes might have on the tobacco smoking rate. The concern is

³⁷ Pasquale Caponnetto et al., "Efficiency and Safety of an Electronic Cigarette (ECLAT) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study," *PLoS ONE* 8, no. 6 (June 24, 2013), <https://doi.org/10.1371/journal.pone.0066317>; Christopher Bullen et al., "Electronic Cigarettes for Smoking Cessation: A Randomised Controlled Trial," *The Lancet* 382, no. 9905 (November 16, 2013): 1629–37, [https://doi.org/10.1016/S0140-6736\(13\)61842-5](https://doi.org/10.1016/S0140-6736(13)61842-5); Scott D. Halpern et al., "A Pragmatic Trial of E-Cigarettes, Incentives, and Drugs for Smoking Cessation," *New England Journal of Medicine* 378, no. 24 (June 14, 2018): 2302–10, <https://doi.org/10.1056/NEJMsa1715757>; Peter Hajek et al., "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy," *New England Journal of Medicine* 380, no. 7 (February 14, 2019): 629–37, <https://doi.org/10.1056/NEJMoa1808779>; Seung-Hwa Lee, Sang-Hyun Ahn, and Yoo-Seock Cheong, "Effect of Electronic Cigarettes on Smoking Reduction and Cessation in Korean Male Smokers: A Randomized Controlled Study," *The Journal of the American Board of Family Medicine* 32, no. 4 (July 1, 2019): 567–74, <https://doi.org/10.3122/jabfm.2019.04.180384>; Natalie Walker et al., "Nicotine Patches Used in Combination with E-Cigarettes (with and without Nicotine) for Smoking Cessation: A Pragmatic, Randomised Trial," *The Lancet Respiratory Medicine* 8, no. 1 (January 1, 2020): 54–64, [https://doi.org/10.1016/S2213-2600\(19\)30269-3](https://doi.org/10.1016/S2213-2600(19)30269-3).

³⁸ Bullen et al., "Electronic Cigarettes for Smoking Cessation"; Walker et al., "Nicotine Patches Used in Combination with E-Cigarettes (with and without Nicotine) for Smoking Cessation"; Caponnetto et al., "Efficiency and Safety of an Electronic Cigarette (ECLAT) as Tobacco Cigarettes Substitute"; Hajek et al., "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy."

made even more complicated when considering the phenomenon of dual using both e-cigarettes and combustible tobacco products.

1.1.1.5 *Dual Use*

The issue of dual use concerns whether e-cigarette users will continue to use both tobacco cigarettes and e-cigarettes for an extended period. Whether e-cigarette users fully stop smoking is widely agreed to be the key to realizing any of the health benefits of vaping. A meaningfully harmful dose of tobacco cigarettes can be as small as smoking one to three sticks per day.³⁹ It is exceedingly rare to find a daily smoker who smokes that little, so discussions of needing to avoid smoking to excess or to preach moderate cigarette smoking as a virtue are nearly meaningless in health terms.⁴⁰ If e-cigarette users continue to smoke tobacco cigarettes, at any level of intensity, then much of the health benefits of e-cigarettes seem to vanish. Additional concern over whether the dual use of e-cigarettes and cigarettes may be more injurious to the human body than tobacco smoking alone concerns e-cigarette skeptics.

1.1.1.5.1 *Summary*

The scientific body of evidence around e-cigarettes is continually building. The evidence base does not point directly to inescapable policy conclusions that all governments must respond to. The establishment of safety evidence is a mixed bag that points to the potential benefits of regulation. But these benefits seem to be countered by the specter of rising youth initiation of e-cigarette use. The findings that e-cigarettes are a successful cessation aid in a medical setting do little to speak to how the products should be regulated as typical consumer goods. Concerns about the dual use of hazardous and reduced hazard products complicate this picture further.

The existence of evidence in this realm do less than we might hope to clear a path towards the adoption of evidence-informed policy. The work of creating regulatory frameworks will eventually confront these scientific evidence bases. The resultant regulations that are created may likely be informed by these findings while being filtered through other lenses and factors

³⁹ Julien Berthiller et al., “Low Frequency of Cigarette Smoking and the Risk of Head and Neck Cancer in the INHANCE Consortium Pooled Analysis,” *International Journal of Epidemiology* 45, no. 3 (June 1, 2016): 835–45, <https://doi.org/10.1093/ije/dyv146>; Kenneth C. Johnson, “Just One Cigarette a Day Seriously Elevates Cardiovascular Risk,” *BMJ* 360 (January 24, 2018), <https://doi.org/10.1136/bmj.k167>.

⁴⁰ These data cast a dim light on the value of warning labels printed on cigarette packs as a result of gentleman’s agreements with tobacco companies in the 20th century imploring smokers to, for example, “For the sake of health, let’s be careful not to smoke too much”. Sarah Milov, “Smoke Ring: From American Tobacco to Japanese Data,” *Osiris* 33, no. 1 (October 2018): 337, <https://doi.org/10.1086/699948>.

that affect the creation of public policy. In order to tame this morass, an organizing concept must be offered to try to sort out what stakeholders are trying to accomplish by regulating this market.

1.2 The Puzzle

With respect to addressing cigarette use, almost every country in the world has decided to head in the same direction, towards achieving a world with less cigarette smoking. Tobacco control, when framed as cigarette control, over time has become a less polarizing policy issue in more and more countries around the world and a single epistemic community has pushed the effort along.⁴¹ The world's first public health treaty, the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), has worked towards creating a global policy consensus around tobacco control policy. In a short time policymakers around the world have agreed that: (1) non-smokers shouldn't be exposed to tobacco smoke in public places, (2) cigarettes should become more expensive over time, (3) consumers should be warned about the health risks of smoking, and (4) normatively, children should not smoke.⁴² Policy convergence on similar tools to combat cigarette smoking has occurred in tandem with this shift in attitudes.⁴³ However, amid the uptake of FCTC policies around the world that were written to address cigarettes, the introduction of the e-cigarette created a dramatic departure between country strategies towards these novel tobacco products.

Global responses to the introduction of e-cigarettes to the global marketplace have been varied in a manner that belies easy explanation. Countries have adopted wildly disparate approaches to regulating e-cigarettes ranging from arresting persons who use e-cigarettes in the Philippines to opening e-cigarette shops in hospitals in England.⁴⁴ These range from invoking laws prohibiting

⁴¹ Dimiter Toshkov, "Policy-Making Beyond Political Ideology: The Adoption of Smoking Bans in Europe," *Public Administration* 91, no. 2 (June 1, 2013): 448–68, <https://doi.org/10.1111/j.1467-9299.2012.02075.x>; Paul Cairney, Donley T. Studlar, and Hadii M. Mamudu, *Global Tobacco Control: Power, Policy, Governance and Transfer* (Palgrave Macmillan, 2012).

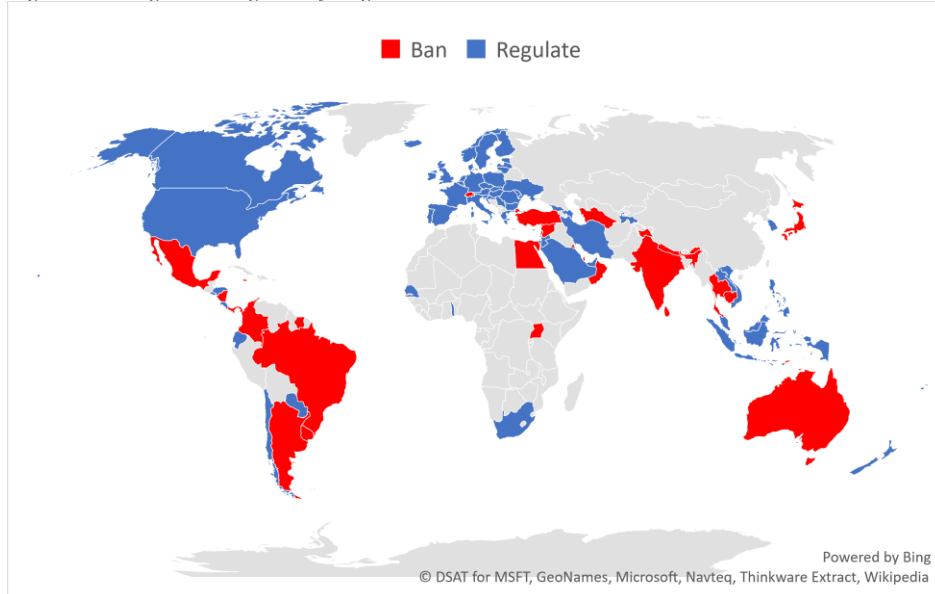
⁴² David Hammond et al., "Tobacco Denormalization and Industry Beliefs Among Smokers from Four Countries," *American Journal of Preventive Medicine* 31, no. 3 (September 1, 2006): 225–32, <https://doi.org/10.1016/j.amepre.2006.04.004>; Ellen Peters et al., "The Impact and Acceptability of Canadian-Style Cigarette Warning Labels Among U.S. Smokers And Nonsmokers," *Nicotine & Tobacco Research* 9, no. 4 (April 1, 2007): 473–81, <https://doi.org/10.1080/14622200701239639>; WHO TFI, *WHO Report on the Global Tobacco Epidemic. 2015, 2015*, (Geneva: World Health Organization, 2015); Cairney, Studlar, and Mamudu, *Global Tobacco Control*.

⁴³ Donley T. Studlar, "Tobacco Control Policy Instruments in a Shrinking World: How Much Policy Learning?," *International Journal of Public Administration* 29, no. 4–6 (April 1, 2006): 367–96, <https://doi.org/10.1080/01900690500437006>.

⁴⁴ Laura Donnelly, "Vape Shops Open on NHS Hospital Sites, in Bid to Stub out Smoking," *The Telegraph*, July 9, 2019, <https://www.telegraph.co.uk/news/2019/07/09/vape-shops-open-nhs-hospital-sites-bid-stub-smoking/>; Christopher Lloyd Caliwan, "PNP Apprehends 243 for Vaping in Public," Philippine News Agency, November 25, 2019, <https://www.pna.gov.ph/articles/1086955>. Ryan David Kennedy et al., "Global Approaches to Regulating Electronic Cigarettes," *Tobacco Control* 26, no. 4 (July 2017): 440–45, <https://doi.org/10.1136/tobaccocontrol-2016-053179>.

the sale of “imitation tobacco products” (banning e-cigarette sales in the process) to the actively promoting e-cigarettes as a harm reduction tool offering smokers a safer source of nicotine. In between are countries that only prohibit the sale of nicotine-containing e-cigarettes and e-liquid and those that offer a pathway to the legal sale of nicotine-containing e-cigarettes if the efficacy of these products as a smoking cessation tool can be proven. By the beginning of 2020, at least 32 countries adopted some kind of ban on the sale of nicotine-containing e-cigarettes without prior authorization while at least 69 countries adopted policies that explicitly allowed the regulated sale of nicotine-containing e-cigarettes (Figure 3).⁴⁵ Countries in gray in the figure are either excluded from the Policy Scan or do not have specific regulations that apply to e-cigarettes.

Figure 3: E-Cigarette Regulatory Regimes in 2020



Examining the world map of these policies we can see that no European Union member bans the sale of nicotine-containing e-cigarettes while Latin America is dominated by bans on the sale of nicotine-containing e-cigarettes. Elsewhere, patterns are decidedly mixed. This study contends that this simple dichotomy is an inadequate method to describe the regulatory frameworks these jurisdictions have adopted. This dichotomy misses the nuance between statute and lived reality on the ground. It misses the nuanced interplay between regulations on the primary substitute

⁴⁵ Institute for Global Tobacco Control, “Country Laws Regulating E-Cigarettes: A Policy Scan” (Baltimore, MD: Johns Hopkins Bloomberg School of Public Health, February 2020), https://www.globaltobaccocontrol.org/e-cigarette_policyscan.

products for e-cigarettes, tobacco cigarettes, and e-cigarette market regulations. There are deeper and more meaningful patterns to be gleaned when these regulations are examined more closely.

Few scholars have attempted to answer why such e-cigarette regulatory policies diverge in such a dramatic manner. Feldman posited in 2016 that a lack of a scientific consensus, the differential influence of corporate interests in policymaking, and the influence of courts as policymaking bodies were responsible for divergence between the US, Japan, and China on this matter.⁴⁶ Newman and Nurfaiza propose that some countries, like Singapore, have intentionally designed their e-cigarette regulatory policies to achieve a particular pro-social outcome while others, like Indonesia, have employed what they call “anti-design” to write a policy that seemed guaranteed to achieve harmful results.⁴⁷ McKee proposed that the THR-friendly approach of England is attributable to the dominance of respiratory physicians in quasi-public-sector Public Health England.⁴⁸ Fairchild, Bayer, and Lee propose that the proof of safety demands by US policymakers were more stringent than those of fellow policymakers in the UK, leading to a US regulatory policy environment that has been rather unfriendly to THR efforts.⁴⁹ While each of these may explain some divergence in policy results, none of these hypotheses derives from a rigorous systematic comparative study. The residual differences between the countries described are immense and diverging governmental, cultural, economic, political, and statutory reasons are not accounted for in these explanations. To shed light on these differences in an inductive, thoroughly documented manner, this study seeks to fill that gap.

1.2.1 Research Questions

Of interest to this study, in early 2017, two similar neighboring countries, New Zealand and Australia, with nicotine bans committed to part ways on their policies. Uncovering why these countries and Canada acted so differently when regulating the same product is the subject of this investigation. The official and unofficial reasons that countries have adopted their current policies 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

⁴⁶ Eric A Feldman, “Regulating E-Cigarettes: Why Policies Diverge,” *Faculty Scholarship at Penn Law*, 2016, 51.

⁴⁷ Joshua Newman and Martha Widdi Nurfaiza, “Policy Design, Non-Design, and Anti-Design: The Regulation of e-Cigarettes in Indonesia,” *Policy Studies* 0, no. 0 (January 3, 2020): 1–18, <https://doi.org/10.1080/01442872.2019.1708887>.

⁴⁸ Martin McKee, “Evidence and E-Cigarettes: Explaining English Exceptionalism,” *American Journal of Public Health* 109, no. 7 (June 5, 2019): 965–66, <https://doi.org/10.2105/AJPH.2019.305132>.

⁴⁹ Fairchild, Bayer, and Lee, “The E-Cigarette Debate.”

different, too. All that precedes is a prologue to asking the research questions that the rest of this study seeks to answer.

1. How and why do countries move along the range of regulatory stances?
2. Why do some countries change their regulatory stances towards e-cigarettes when others do not?

1.3 Chapter Outline

Over the course of the next seven chapters, this study will make the case that e-cigarette regulatory policy change is made possible through a confluence of factors that is precipitated by the rejection of an existing regulatory framework, followed by the reaching of a consensus alternative regulatory framework in the public health community, which is followed by the co-optation of left-wing political parties to favor regulatory policy change. Chapter 2 lays out the theoretical foundations that underlie both the analytical framework, Kingdon's Multiple Streams Approach, and the outcome variable of interest, a country's regulatory stance towards the e-cigarette market. Chapter 2 goes further to present the hypotheses of the variables that could drive the outcomes observed in the case studies and provides the rationale for why those variables would be important. Chapter 3 presents the methods used to collect qualitative and quantitative data, select cases, narrow the scope of the inquiry, and a guide to determining a country's regulatory stance towards a given market.

Chapters 4 through 6 present the core of the work, the case studies of e-cigarette regulatory policy and politics in Australia, Canada, and New Zealand. In those chapters, the narrative of how each country's regulatory stance towards e-cigarettes evolved is structured by and within each of the Multiple Streams consisting of problems, policies, and politics.

Chapter 7 synthesizes the lessons that can be learned by carefully comparing the cases to each other and by reviewing the importance of the various explanatory variables put forward in Chapter 2. Chapter 7 concludes by examining how the important explanatory variables behind regulatory policy change were affected by a large and highly relevant case study that simultaneously impacted all three case countries after my fieldwork had concluded. Chapter 8 summarizes how the findings of this study should inform scholarship in political science, public policy, and public health going forward, and it points to the questions that this study was unable

to address. Lastly, Chapter 8 demonstrates the utility of the regulatory stances concept and makes the case for applying it to studies of comparative regulation more broadly.

1.4 Conclusion

E-cigarettes are products sold on a market to various consumers and are subject to all the economic, policy, social, and political forces that shape their use and their proliferation; not independent agents possessing free will. Those agents who have the free will to shape the e-cigarette market include the companies creating and hawking the products, the people who buy and use them, the organizations who try to shape that market, the politicians who pass the rules to shape the market and the bureaucracies who implement the policies passed by the politicians. These people have agency over the e-cigarette market. It is by studying the motives and choices of these actors and the systems in which they function that we might see how the e-cigarette market was shaped by local context. The use of a qualitative comparative case study that focuses its attention on the politics of regulatory policy change highlights the conditions that were necessary to create change or maintain the status quo. Drawing upon a large and rich qualitative data collection process grounded in a widely used theory explaining public policy change to propose detailed explanations of why regulatory policy change happens, this study seeks to fill large gaps in a literature that sits at the intersection of public health, political science, and comparative regulation.

Chapter 2 Theory

Paul Sabatier, a prolific public policy scholar and creator of the advocacy-coalition framework, claims that “given the staggering complexity of the policy process, the analyst must find some way of simplifying the situation in order to have any chance of understanding it”.⁵⁰ In this study, a strategic simplification of both the operation of the policy process and its outputs are employed to sharpen the presentation of the empirical data. John W. Kingdon’s Multiple Streams Approach (in place of Sabatier’s framework) is used to sharpen the description of how policy change does or does not occur in three case studies. The outputs of that policy change will be described using a novel classification concept, the regulatory stance. This chapter introduces these two major concepts which are employed to simplify and enable some understanding of the policy process described in the three case studies.

First, the case for defining, studying, and utilizing the concept of the regulatory stance is advanced. Namely, the regulatory stance is the summation of a jurisdiction’s policies behind a regulatory framework concerning the effect of those policies that are designed to affect a market’s size. Here, the necessity of using such a concept is laid out and the way the concept will be employed is unpacked. Second, the case for utilizing the Multiple Streams Approach as the guiding framework of the chaotic public policymaking process is advanced. Primarily, the Multiple Streams Approach will be used to identify the development of independent streams of problem, policy, and politics in each case and trace the process by which the streams couple in a policy window. Third, the chapter introduces the explanatory variable that appears to precipitate or prevent policy change in the case studies. Each variable is situated within one of Kingdon’s streams and is advanced as being responsible for altering the likelihood that a change in the e-cigarette regulatory stance will be achieved. The chapter concludes with a brief synthesis of the explanatory variables into a generalizable thesis about the conditions under which regulatory stances might change.

⁵⁰ Paul A. Sabatier, ed., *Theories of the Policy Process*, 2nd ed (Boulder, Colo: Westview Press, 2007), 4.

2.1 Focusing on the Intent of Regulation for Classification

Economists explain the reason that markets need to be regulated is that there is some sort of market failure that must be remedied through collective action.⁵¹ Stretching back to Ancient Egypt, scholars have tackled the subject. New work invoking the contributions of philosophy, political science, psychology, and sociology to the study of regulation continues growing all the time.⁵² Since John Stuart Mill and Henry Sidgwick began a formalized rejection of Adam Smith’s presumption that private enterprise usually maximizes welfare in the 19th century, scholars have identified umpteen kinds of market failures that lead to some form of sub-optimal welfare maximization.⁵³

Markets and the actors within them, when left to their own devices, will behave in ways that empower concentrated or already powerful interests.⁵⁴ These actors will maximize short-run returns at the expense of long-run sustainability. They will fail to solve collective-action problems and leave vulnerable consumers out in the cold. This is not to say that markets are not sometimes a wonderful force, that stimulates innovation, that can solve some of the world’s most pressing problems or create the most perfect widget. But markets fail so often, that we have developed multitudinous governance systems at every level of society to try to address these failures.

2.1.1 The Regulatory Stance

The rationale behind creating regulations for a market is to resolve some form of market failure. Each form of market failure can be resolved by adopting policies intended to change the size of a market in the future relative to the present. The term for the intended effect of the collected policies applying to a market, however broadly or narrowly defined, is a *regulatory stance*.

Table 1: Regulatory Stances Applied to the Common Rationales for Regulating Markets

Rationale for Regulation	Regulatory Stance to Remedy
Negative Externalities	Prohibitionist/Contractionist

⁵¹ M. Korotana, “The Emergence of Regulation: Subversion of Justice or Inadequacy of Private Law,” 2017, <http://bura.brunel.ac.uk/handle/2438/13599>.

⁵² David A. Warburton, “State and Economy in Ancient Egypt: Fiscal Vocabulary of the New Kingdom,” *Orbis Biblicus et Orientalis* 151 (1997), <https://doi.org/info:doi/10.5167/uzh-153588>.

⁵³ S. G. Medema, “The Hesitant Hand: Mill, Sidgwick, and the Evolution of the Theory of Market Failure,” *History of Political Economy* 39, no. 3 (September 1, 2007): 331–58, <https://doi.org/10.1215/00182702-2007-014>.

⁵⁴ Bruce C. Greenwald and Joseph E. Stiglitz, “Externalities in Economies with Imperfect Information and Incomplete Markets,” *The Quarterly Journal of Economics* 101, no. 2 (May 1, 1986): 229–64, <https://doi.org/10.2307/1891114>.

Unequal Bargaining Power	Contractionist
Scarcity and Rationing	Contractionist
Information Inadequacies Led to Over-provision	Contractionist
Planning for the Future to Fix Over-provision	Contractionist
Rationalization and Coordination	Contractionist
Windfall Profits	Expansionist
Anti-Competitive Behavior	Expansionist
Information Inadequacies Led to Under-provision	Expansionist
Planning for the Future to Fix Under-provision	Expansionist
Monopoly	Expansionist/Universalist
Positive Externalities	Expansionist/Universalist
Availability of Service	Universalist/Expansionist
Public Goods	Universalist

Table 1's left column (which is modeled off Baldwin, Cave, and Lodge, 2012⁵⁵) lays out some of the most common rationales and market failures that regulation is designed to remedy. The corresponding column on the right lays out the regulatory stance that each market failure implies is needed to be resolved. For example, if a market is causing negative externalities, that is the market imposes indirect costs that are not priced into a market, leading to overconsumption. Depending on the severity of the negative externality, a regulatory stance that would remedy this overconsumption would either reduce the size of the market or bring the size to zero. This would be the adoption of a contractionist or a prohibitionist regulatory stance, respectively.

On the other end of the spectrum, if a market is not large enough to maximize utility, e.g., in the case of monopoly, then the policies included in adopting a regulatory stance towards that market would seek to expand the size of the market, or grow it to a maximally large point. This would represent the adoption of an expansionist or a universalist regulatory stance, respectively. In cases where regulators have foregone setting a goal for the size of a market in the future, most theorists would argue that is because there is no extant market failure that must be resolved. This would be referred to as adopting a permissive regulatory stance.

Conditions that are required to reach the neoclassical economists' chalkboard model of a perfectly competitive free market (fully rational actors, full information, costless transactions, etc.) are rarely achieved in real life, but failures to satisfy the conditions of such a functioning market can cause either over- or under-provision of goods in a market. For example, failure to

⁵⁵ Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford, UNITED KINGDOM: Oxford University Press, Incorporated, 2012), 24.

satisfy the criterion of full information can lead to over-provision of quack cures for diseases while under-provision of real disease cures may occur when false or incomplete information is available to a sick person or their health care provider. Implicit in the logic of why these market failures are real, is that the resolution of these failures lies in addressing the size of the market.

If we come to accept that a perfectly competitive market is seldom achievable, then we can make the case that the regulatory stances jurisdictions adopt when regulating markets produce a market closer to the size that a perfectly competitive market would achieve. This is not to say that government interference can achieve *perfect* market conditions as government failures are a near-certainty in questions of regulation.⁵⁶ This *more perfectly sized* market would be affected by all manner of policies causing distortions in prices, information, transaction costs, entry and exit, market power, and demand, but it should reap less of the harm caused by inadequate or excessive consumption.

The concept of a regulatory stance, then, simplifies away this issue by focusing on the intent of a policy. Adopting a certain policy cannot guarantee a certain outcome. If this was not the case, then nothing bad would ever happen in the world after policymakers addressed an issue. In the drive to improve societal welfare, a regulatory policy that is designed to improve welfare is typically necessary, but not sufficient, to achieve selected goals. Studying the intent of government policy is a useful endpoint for the comparative politics of regulation because it focuses attention on the decision as it was made rather than focusing on whether an outcome was achieved. Focusing on outcomes sweeps the entire process of policy implementation to the forefront of comparative regulation, straying further from evaluating why a regulatory policy change happened in the first place.

The gap between policies as passed and implemented can be wide. But, that existence of that gap does not invalidate the study of why policies were passed in the first place. That gap necessitates that further attention is paid to the implementation process and the factors that affect the width of said gap.

⁵⁶ Demsetz's "nirvana fallacy" stated that when compared to imperfect contemporary conditions, intervention is often idealized in terms of what it purports to achieve. Harold Demsetz, "Information and Efficiency: Another Viewpoint," *The Journal of Law and Economics* 12, no. 1 (April 1, 1969): 1–22, <https://doi.org/10.1086/466657>.

2.1.1.1 Why a Regulatory Stance?

This study seeks to explain why institutionally and ideologically similar jurisdictions adopted different regulatory stances for the same product. Before entry, an identifiable default pathway to market through which all similarly situated products must follow is posited to exist. For example, after the FDA Act of 1938, all pharmaceuticals sold in the United States needed to prove they were safe to consume, while after the reforms of 1960, pharmaceutical manufacturers were required to include proof of efficacy in the premarket applications to regulators.⁵⁷ Over time, the restrictions on the paths to market and sales growth for pharmaceuticals evolved in reaction to events like the Sulfanilamide Incidents of the 1930s, the Thalidomide tragedy of the early 1960s, and the AIDS crisis of the 1980s. Some decisions caused profits to increase, like allowing for direct-to-consumer advertising, while others stymied sales, like increasing post-market safety surveillance standards.⁵⁸ Developing a theory to describe the choices policymakers arrive at to grow or strangle markets is required to gain a more precise understanding of the way governments manage markets.

The search for such a typology on which a theory could be based landed on Robert Paarlberg's policy options continuum for the regulation of genetically modified (GM) crops as a starting point. Paarlberg sets up a typology of policy options available to policymakers for regulating a market for novel products; preventative, precautionary, permissive, and promotional (Figure 4).⁵⁹ Paarlberg's essential research question was why some countries embraced GM as a promising new technology and tried to foster market growth while other countries sought to rid themselves of this foreboding, novel market.

Figure 4: Paarlberg's Continuum of Policy Options



⁵⁷ Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton, NJ: Princeton University Press, 2014).

⁵⁸ Barbara Mintzes, "Direct to Consumer Advertising Is Medicalising Normal Human Experience," *BMJ: British Medical Journal* 324, no. 7342 (April 13, 2002): 908–11; Peter R. Mansfield and Barbara Mintzes, "Direct-to-Consumer Advertising Is More Profitable If It Is Misleading," *The New Zealand Medical Journal* 116, no. 1182 (September 26, 2003): U610.

⁵⁹ Robert L. Paarlberg, *The Politics of Precaution: Genetically Modified Crops in Developing Countries* (Intl Food Policy Res Inst, 2001), chap. 2.

Paarlberg utilized his continuum to assess the regulatory choices made by countries as to whether they were designed to grow or stifle the market for GM crops. For example, Paarlberg considered whether a country afforded intellectual property rights to private actors who sought to patent a GM crop.⁶⁰ If a country wanted to prevent or slow the spread of GM crops, they could rule that plants or animals do not deserve patent or other sorts of intellectual property protection. Further, the country could decide to allow farmers to plant seeds harvested from GM crops if they wanted to slow the rush of corporate investment to the market. Alternatively, if countries wanted to promote GM crops, they could decide to grant intellectual property rights to plants and animals or they could grant plant breeders the right to prevent farmers from planting seeds harvested from GM crops.

Further, some countries wished to stop the spread of a market product altogether. While some would refer to this as the precautionary principle, as Figure 4 indicates, Paarlberg would term this sort of policy option as prevention. A large literature on the normative and comparative application of the precautionary principle in regulation also exists.⁶¹ The literature focuses on potentially existential threats to humanity like nuclear explosions, endocrine disruptions, prions in the food supply, and other low-probability, highly destructive occurrences.⁶² This literature considers ideas about whether the public's perception of risk or hazard is more important than scientific assessment when setting policy.⁶³ It largely justifies that caution outweighs the benefits of technological change moving faster when there is a lot of risk involved in the new technology.⁶⁴

The reason to avoid the rote application of the precautionary principle in the present study is that such literature is primarily concerned with products that are riskier than established potential substitute products already on the market. The case study of e-cigarette regulation does not fit

⁶⁰ Michael Howlett and Andrea Riccardo Migone, "The Canadian Biotechnology Regulatory Regime: The Role of Participation," *Technology in Society* 32, no. 4 (November 2010): 280–87, <https://doi.org/10.1016/j.techsoc.2010.10.004>.

⁶¹ Joakim Zander, *The Application of the Precautionary Principle in Practice: Comparative Dimensions* (Cambridge University Press, 2010); Brendon Swedlow et al., "Theorizing and Generalizing about Risk Assessment and Regulation through Comparative Nested Analysis of Representative Cases Research Methods and Approaches," *Law & Policy* 31 (2009): 236–70; Cass R. Sunstein, "Irreversible and Catastrophic," *Cornell Law Review* 91 (2005): 841.

⁶² Cass R. Sunstein, "The Catastrophic Harm Precautionary Principle," *Issues in Legal Scholarship* 6, no. 3 (2007), <https://doi.org/10.2202/1539-8323.1091>.

⁶³ Marco Martuzzi and Joel A Tickner, *The Precautionary Principle: Protecting Public Health, the Environment and the Future of Our Children* (Copenhagen: World Health Organization, 2004), http://www.asser.nl/media/2227/cms_eel_96_1_book-precautionary-principle-protecting-public-health-the-environment.pdf.

⁶⁴ Kerry H. Whiteside, *Precautionary Politics: Principle and Practice in Confronting Environmental Risk*, Urban and Industrial Environments (Cambridge, Mass: MIT Press, 2006), chap. 2, <http://hdl.handle.net/2027/mdp.39015066773386>.

very well with this literature because e-cigarettes are widely agreed to be less harmful than the product they intend to replace.

Paarlberg's theory serves as an excellent point of departure for an updated range of regulatory stances. The word "range" used here intends to communicate that jurisdictions can jump from one edge to the range to another via major policy change. The word "continuum" implied that changes in regulatory stances might have to be incremental. Paarlberg's original continuum of regulatory options is also found to be lacking in its ability to be applied to established markets or those that do not involve novel technology which invokes concerns about precautionary approaches. More fundamentally, Paarlberg's continuum has no room for a regulatory stance that seeks to shrink or eliminate an already established market.

Other scholars have proposed similar ranges of regulation. Van de Graaf, Haesebrouck, and Debaere classify European nation's regulatory "attitudes" towards shale gas extraction along with a range that stretches from Opposition to Precaution to Tolerance to Support.⁶⁵ MacCoun, Reuter, and Schelling classify drug control regimes on a classification scheme ranging from pure prohibition to regulatory prescription to a free market.⁶⁶ Others are more reductive still, like Rogeberg, who contrasted regulatory policy options as ranging from Prohibition to Regulation to Laissez-Faire.⁶⁷ These frameworks attempt to sort regulation into a typology on a range from restrictive to open. While these sorts of typologies seem like a straightforward way to evaluate a regulatory framework on its empirical content, they forego the important wrinkle provided by Paarlberg, a theory that speaks to the intent of regulation.

To remedy shortcomings in Paarlberg's continuum of regulatory stances, a proposed revision is advanced here (See Figure 5). In this revised range of regulatory stances, the concept of the intended share of the economy in the future has replaced Paarlberg's concept of the rate of growth. This concept better addresses the classification process of established markets.

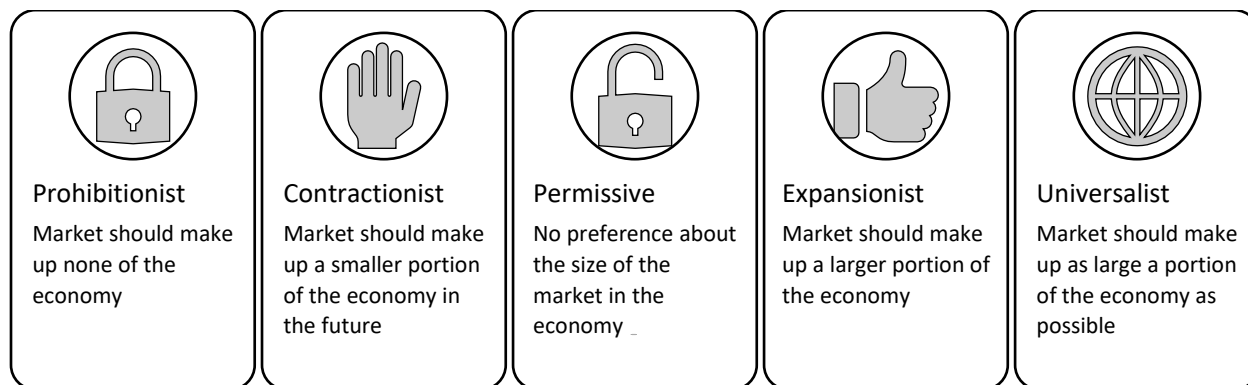
⁶⁵ Thijs Van de Graaf, Tim Haesebrouck, and Peter Debaere, "Fractured Politics? The Comparative Regulation of Shale Gas in Europe," *Journal of European Public Policy* 25, no. 9 (September 2, 2018): 1276–93, <https://doi.org/10.1080/13501763.2017.1301985>.

⁶⁶ Robert MacCoun, Peter Reuter, and Thomas Schelling, "Assessing Alternative Drug Control Regimes," *Journal of Policy Analysis and Management* 15, no. 3 (1996): 330–52.

⁶⁷ Ole Rogeberg, "Prohibition, Regulation or Laissez Faire: The Policy Trade-Offs of Cannabis Policy," *International Journal of Drug Policy* 56 (June 1, 2018): 153–61, <https://doi.org/10.1016/j.drugpo.2018.03.024>.

For example, it is unclear why a government that would seek to depress sales of vodka or coal would be applying a precautionary or preventive policy in Paarlberg’s continuum. No definition of the precautionary principle makes the case for applying precautionary logic to established sources of harm like alcoholic spirits or fossil fuel power plants. Instead, it makes more sense to broaden the useful logic and language of Paarlberg’s continuum to be able to apply equally well to novel *and* established markets by discussing the future share of the economy. To expand the application the useful concept of a regulatory stance to established markets, a reshuffling of the points on the range, and their meaning must be performed. The revised Range of Regulatory Stances functions as well as Paarlberg’s for the classification of regulatory stances towards novel product markets and improves on his work by addressing the classification of regulatory frameworks for established markets. By comparing present and future shares of the economy, the revised range of regulatory stances can conceptually handle policies meant to further grow established markets.⁶⁸

Figure 5: The Revised Range of Regulatory Stances



The regulator's stated or implied preference for how much of the economy should be taken up by a particular market (defined as narrowly as is necessary) in the future relative to the present is bounded along the range summarized in Figure 5: prohibitionist, contractionist, permissive, expansionist, and universalist.⁶⁹ Paarlberg’s precautionary stance is replaced with the new terminology of a contractionist stance. Paarlberg’s promotional stance is changed in name, but

⁶⁸ For example, up-zoning single-family residential areas to encourage townhome construction is setting an expansionist regulatory stance for an established product or market, the townhouse. Yonah Freemark, “Upzoning Chicago: Impacts of a Zoning Reform on Property Values and Housing Construction,” *Urban Affairs Review*, January 29, 2019, 1078087418824672, <https://doi.org/10.1177/1078087418824672>.

⁶⁹ The symbols used in this figure will be echoed and repeatedly used throughout the study to refer to specific regulatory stances.

not in spirit, to an expansionist stance. Expansionist and contractionist should be thought of as antonyms or mirror-image stances. In a nod to symmetry, the universalist stance is added on the opposite end of the range as the prohibitionist stance. Universalist and prohibitionist stances should also be thought of as mirror images of one another.

The regulatory framework for any chosen market in any jurisdiction at any time can be placed at some point along the range of regulatory stances.⁷⁰ This stance will evolve in reaction to new political opportunities and perceived problems. The multitude of policy instruments that can be deployed to stymie or grow demand for a market ought to be applied to determining the extant regulatory stance towards a market. When assessing the overall regulatory stance of a jurisdiction towards a product, it will be necessary to determine how policy in different domains works in concert or cross purposes with one another. A single contractionist policy could make a regulatory stance on balance, contractionist, even if other domains are a mix of permissive and expansionist policies. A single expansionist policy in the presence of several permissive policies in other domains may be on balance, expansionist. The result is a system that interferes in the function of “free markets” while filtering policy design through the political process. Therefore, the overall regulatory stances must be considered holistically across all relevant policy domains.

This framing enables us to discuss in concise terms why certain regulatory stances are considered within the realm of possibility for some markets but out of the realm of possibility for others. For example, it allows us to inquire about the differences between lead paint and cigarettes, or between lawn darts and diesel-powered cars, or between nuclear power plants and exotic derivative investment vehicles. It allows us to ask what force changed a regulatory stance in one country from seeking to grow a market and then to quash its growth years later. It also enables us to compare divergent or convergent regulatory behavior across jurisdictions and to question the mechanisms that underly such behavior. The regulatory stances concept can serve as a common reference point to describe policy choices large and small that advocates and opponents can wield with clarity.

⁷⁰ The process of determining the regulatory stance for a market is explained in detail in Section 3.3.4 Determine the Regulatory Stance for a Market on page 74.

2.1.1.2 The Regulatory Framework

The regulatory framework assembles the disparate components of regulations placed on a market into an overarching organized fashion. In its broadest terms, similarly situated products are assumed to be subject to the same regulatory framework. A regulatory framework sorts these similarly situated products into pathways that are subject to policies across various domains that determine the regulatory stance towards products in said pathway. Figure 6 is a graphical example of such a regulatory framework.⁷¹

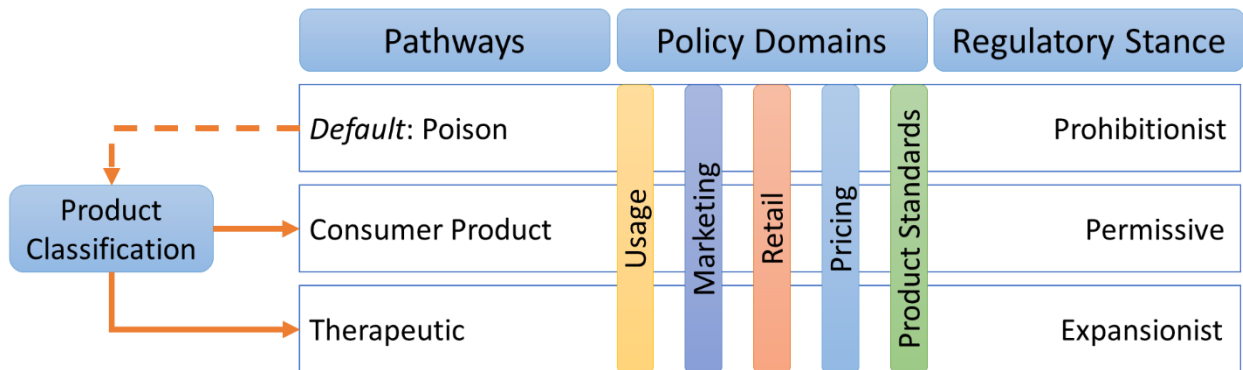


Figure 6: Example Regulatory Framework with Pathways for Similarly Situated Products

The concept of product classification must be considered here too, as it shapes the sorting of products into pathways. Product classification can be performed either premarket or after a product introduction.⁷² Product classification processes may require a product’s producer to do as little as notifying the regulator of market entry and providing basic information about the product, or it could require the sponsor to prove a product meets safety, efficacy, and quality requirements. Those standards are typically codified by norms or by statute.

One theoretical implication that flows from this concept is that if standards to receive one form of premarket approval are strict and the regulatory stance received in return for meeting those standards is not perceived as sufficiently beneficial compared to taking other routes to market, then we would not expect many sponsored products to attempt to meet those premarket approval

⁷¹ Premarket approval is a sorting mechanism between similar products which places them in market sectors towards which the jurisdiction has adopted a regulatory stance.

⁷² As an illustrative example, one could easily describe the regulatory stance towards cigarette brands already being sold on the market in the US as somewhere between permissive and contractionist, while the regulatory stance towards cigarette brands not already on the US market is prohibitionist. This is because the FDA requires premarket approval to sell new cigarette brands introduced after the passage of the 2009 Tobacco Control Act to prove that the brands will not harm the public health while pre-existing brands did not have to traverse such premarket approval processes. Henry Waxman, “Family Smoking Prevention and Tobacco Control Act,” Pub. L. No. HR 1256, § 31, 111 (2009), <https://www.govtrack.us/congress/bills/111/hr1256>.

standards. If there is a sufficiently large gulf in regulatory stances that would apply to similar products if premarket approval were received, then we would expect more applications for premarket approval to be received if the cost of changing the regulatory framework is perceived to be sufficiently high. If the gulf in regulatory stances is low, then we would expect few applications to be received for premarket approval for the more stringent standard.

The exercise of assembling pathways, policies, classifications, and stances into a single conceptual framework crystallizes the inputs, outputs, and implications that flow from a regulatory stance. We can understand how carving new pathways or changing the policies in each pathway alter incentives for both the supply and demand sides of markets. We see how governments can utilize their power to shape markets to their own goals. But the regulatory framework means little without understanding the constituent policy domains that pathways filter through on their way to becoming regulatory stances.

2.2 The Multiple Streams Approach

This study seeks to learn how the policymaking process differed in a single topic area in similar countries to produce different regulatory policy outcomes. Political scientist John Kingdon proposed the Multiple Streams Approach as a framework to understand the chaos and unpredictability of the policymaking process and to help us understand “when an idea’s time has come”.⁷³ Policymaking activity around e-cigarette regulation is an excellent use of the Multiple Streams Approach as the subject is drenched in uncertainty and ambiguity.⁷⁴ Scientific, business, and political uncertainty are all swept into a single series of cases here. An organizing framework that is sufficiently probabilistic and flexible to corral the potential explanations of what drives change and stasis in policy is required to parse the chaos. The Multiple Streams Approach provides that modicum of organization enabling us to draw systematized lessons out from the apparent ongoing chaos.

The multiple streams framework is a key part of the theoretical literature on the public policy process, including such contributions as the garbage can model, advocacy coalition framework,

⁷³ John W. Kingdon, *Agendas, Alternatives, and Public Policies*, Updated 2. ed, Longman Classics in Political Science (Boston, Mass.: Longman, Pearson, 2011).

⁷⁴ Joshua Newman, “The Role of Uncertainty in Regulating E-Cigarettes: The Emergence of a Regulatory Regime, 2005-15,” *Politics & Policy* 47, no. 2 (2019): 407–29, <https://doi.org/10.1111/polp.12294>; Nikolaos Zahariadis, “Ambiguity and Multiple Streams,” in *Theories of the Policy Process*, ed. Paul A. Sabatier and Christopher M. Weible, 3. ed. [new ed., new coll.] (Boulder, Colo: Westview Press, 2014), 25–58.

and punctuated equilibrium theory.⁷⁵ While the Multiple Streams Approach was developed under close observation of the US Congress, the framework's usage in international and comparative contexts has begun increasing over time.⁷⁶ While the US federal government is bogged down by a surfeit of veto players whose unanimous assent to policy change is required for policy to migrate from being placed on the political agenda to enactment into reality, in this study I focus on systems of government where policy change is less surreptitious.⁷⁷ In Westminster-style parliaments, the processes of agenda-setting and policy change can be theoretically merged because a lack of veto players ensures that policies the government puts on the agenda are almost guaranteed to become law.⁷⁸ The Multiple Streams Approach still functions in these settings as a theory of the policy change process, and the study here will be used to draw lessons about the effects of these political institutions on the operation of the streams.

The multiple streams in this approach are named for the parallel streams of *problem*, *policy*, and *politics* which contain actors and ideas that make up the milieu from which policies rise to prominence in the agenda-setting process. Occasionally, the three streams are *coupled* at a *policy window* at the behest of a *policy entrepreneur* who cleverly links the three streams to make agenda-setting possible. At some point before agenda-setting, a focusing event will occur, causing policymakers' attention to swing towards the issue at hand and look for a solution to a perceived problem. To better organize these potential explanatory variables, they are isolated to the stream where they are of influence.⁷⁹ In the case studies at hand, we assume policy decisions occurred at the confluence of problem, politics, and policy streams. Tracing backward from those policy windows within the confines of each stream should uncover the conditions that led to changes (or lack thereof) in the regulatory stance for e-cigarettes. These concepts are explained in the remainder of this section along with their utility to this study.

⁷⁵ 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, <https://doi.org/10.1111/psj.12111>.

⁷⁶ Daniel Béland and Michael Howlett, "The Role and Impact of the Multiple-Streams Approach in Comparative Policy Analysis," *Journal of Comparative Policy Analysis: Research and Practice* 18, no. 3 (May 26, 2016): 221–27, <https://doi.org/10.1080/13876988.2016.1174410>.

⁷⁷ George Tsebelis, *Veto Players: How Political Institutions Work* (Princeton, N.J.: Princeton University Press, 2002).

⁷⁸ R. A. W. Rhodes, John Wanna, and Patrick Weller, *Comparing Westminster* (OUP Oxford, 2009).

⁷⁹ Michael D. Jones et al., "A River Runs Through It: A Multiple Streams Meta-Review," *Policy Studies Journal* 44, no. 1 (February 1, 2016): 13–36, <https://doi.org/10.1111/psj.12115>.

2.2.1 *Why Use Kingdon?*

Kingdon's description of the policymaking (or agenda-setting) process is one of two main options available to adequately explain the process being observed in this study (the other being the advocacy coalition framework). First, the theory is probabilistic instead of being deterministic. It only claims that putting together a problem, a policy, and politics will increase the likelihood of change, rather than guaranteeing change happens. Kingdon's theory is comfortable with the ambiguity that defines much of how the world operates. The Multiple Streams Approach makes the case that only in passing moments of clarity do agenda-setting or policy change occur. Identifying the precursors to these passing moments is, therefore, the work of those seeking to operationalize the multiple streams approach to learn more generally how change happens. Second, the multiple streams approach recognizes a prominent role for knowledge in the policymaking process alongside more material interests. The multiple streams approach allows different actors to rationally act on different motives. Finally, the Multiple Streams Approach serves as an organizing lens to categorize and compare cases across place and time. We can look for a reoccurrence of one factor that appeared in the problem stream in one case to re-appear in an identical or analogical form in another case. Each stream in this study will contain potential explanatory variables that primarily operate within that stream.

Being that serious scholars of public policy have rejected the stages heuristic, I must explain why the primary alternative to Kingdon, Sabatier's Advocacy Coalition Framework, is not being used in the current study.⁸⁰ While both Kingdon and Sabatier's frameworks propose that policy change and agenda-setting are messier processes than the stages heuristic, I prefer to organize this study around the multiple streams approach for several reasons. First, the multiple streams approach is a superior tool to describe the interrelationship between governments, bureaucracies, and advocates as it focuses on more than just the process of advocacy. This study will pay attention to the role of bureaucrats in the policy process and does not exclude their contributions from the process of policy change. Second, the multiple streams approach may be superior in its application in settings where the preferences of actors are unclear or not stable over time, which may be the case in a test of regulation in a novel market with questionable impacts on health and

⁸⁰ Michael Howlett, Allan McConnell, and Anthony Perl, "Moving Policy Theory Forward: Connecting Multiple Stream and Advocacy Coalition Frameworks to Policy Cycle Models of Analysis," *Australian Journal of Public Administration* 76, no. 1 (March 1, 2017): 65–79, <https://doi.org/10.1111/1467-8500.12191>.

wellbeing.⁸¹ Third, the advocacy coalition framework can be tested at a later date using the data captured in this study, making further mention of it here, duplicative. Finally, while components of the advocacy coalition framework fit well into this study, the number of components that framework relies upon is far larger than the components of the multiple streams approach, which would further burden the completion of an already lengthy comparative study.⁸²

2.2.2 Problem Stream

When one group of potential issues lacks a problem to solve, politicians and policymakers, in their limited capacity as human beings, will look to other pressing problems to solve. The problem stream is mostly made up of media figures, advocacy groups, and the events that focus attention on an issue thus serving those problems to actors looking for something to do.⁸³

The two main ways in which the problem stream can become primed to join with other streams is through a focusing event or changes to indicators of an underlying problem. Both these mechanisms sharpen the focus of policy actors and can transform an issue that was previously considered a condition of the world as it is into a problem. If a potential problem continues to be considered a condition of life and not a problem worthy of being addressed, no coupling of the streams will occur, and no policy change will happen. Additionally, more than one problem can precipitate a single instance of agenda-setting or policy change.

A focusing event is a sudden shock to the policy system that causes an issue to rise onto the agenda and into the consciousness of policymakers or the public. A focusing event is sudden, uncommon, and unexpected.⁸⁴ Be it a terrorist attack, an environmental disaster, or the publication of a gripping story in the media, a focusing event that is sufficiently unsettling is often necessary to set an agenda.

An indicator is a less dramatic intervenor than a focusing event. Indicators are the voluminous points of data that are generated by governments, bureaucracy, civil society, business, and

⁸¹ Nikolaos Zahariadis, "Comparing Three Lenses of Policy Choice," *Policy Studies Journal* 26, no. 3 (1998): 434–48, <https://doi.org/10.1111/j.1541-0072.1998.tb01911.x>.

⁸² Adam Wellstead, "Plus Ça Change, Plus C'est La Même Chose? A Review of Paul Sabatier's 'An Advocacy Coalition Framework of Policy Change and the Role of Policy-Oriented Learning Therein,'" *Policy Sciences* 50, no. 4 (December 1, 2017): 549–61, <https://doi.org/10.1007/s11077-017-9307-z>.

⁸³ Ishani Mukherjee and Michael Howlett, "Who Is a Stream? Epistemic Communities, Instrument Constituencies and Advocacy Coalitions in Public Policy-Making," *Politics and Governance* 3, no. 2 (August 26, 2015): 65, <https://doi.org/10.17645/pag.v3i2.290>.

⁸⁴ Thomas A. Birkland, "Focusing Events, Mobilization, and Agenda Setting," *Journal of Public Policy* 18, no. 1 (1998): 53–74.

academia which describe how a situation is developing at any moment. Policymakers use all this information to monitor the progress of problems and conditions. Changes (or a lack of change) in these indicators of subsurface problems can trigger debates to start over whether a problem exists.

Telling a good story about the policy problem can be key to advancing one's preferred problem towards definition in the consciousness of policymakers.⁸⁵ Stone argued that politicians employ 'causal stories' that define a problem by attributing a problem's cause and who or what is to blame for a problem, usually in the context of a potential focusing event.⁸⁶ These causal stories are the backbone of the process of problem definition and serve the function of placing a problem in the context of a potential solution that will prevent the problem from reoccurring, a kind of policy learning.⁸⁷

Causal stories can be employed to prime the problem stream for coupling in the context of either a focusing event or an indicator. The determination of which problems were instrumental to creating policy change will be operationalized through an investigation into the sources of the problems that were recognized in the lead up to and the aftermath of a focusing event that brought e-cigarette regulatory policy onto the political agenda. Two interrelated problems were poised to lead to the problem stream becoming primed for coupling in the current study: the failure of a tobacco control policy, and the rejection of a regulatory framework.

2.2.2.1 Failure of Tobacco Control

The *raison d'être* of the e-cigarette is to wipe out demand for the tobacco cigarette. As policymakers have adopted stronger policy regimes to quash the tobacco market over the last half-century, a great deal of progress has been made towards the goal of wiping out demand for the tobacco cigarette.⁸⁸ Cigarette consumption, smoking prevalence, and even rates of disease caused by smoking have all plummeted in countries with long-running, sustained, and successful tobacco control campaigns.

⁸⁵ Paul Cairney, "Three Habits of Successful Policy Entrepreneurs," *Policy & Politics* 46, no. 2 (April 30, 2018): 199–215, <https://doi.org/10.1332/030557318X15230056771696>.

⁸⁶ Deborah A. Stone, "Causal Stories and the Formation of Policy Agendas," *Political Science Quarterly* 104, no. 2 (1989): 281–300, <https://doi.org/10.2307/2151585>.

⁸⁷ Peter J. May, "Policy Learning and Failure," *Journal of Public Policy* 12, no. 4 (1992): 331–54.

⁸⁸ David T. Levy, Yameng Li, and Zhe Yuan, "Impact of Nations Meeting the MPOWER Targets between 2014 and 2016: An Update," *Tobacco Control* 29, no. 2 (March 1, 2020): 231–33, <https://doi.org/10.1136/tobaccocontrol-2018-054837>.

The introduction of the e-cigarette created a proverbial fork in the road for countries seeking to end their tobacco epidemics. Countries could choose to ignore the e-cigarette and keep it out of their markets if they believed that they were making adequate progress towards their tobacco control goals without its potentially disruptive presence. Alternatively, countries could embrace the e-cigarette and turn its disruptive potential towards achieving their tobacco control goals. Finally, countries could choose to do neither and simply allow the product onto the market without direction.

Tobacco control progress has generally remained an amorphous concept that few countries have set targets on whether they are measuring up to par. One recent trend towards setting tobacco endgame goals has upset that dynamic. Broadly, tobacco endgame goals are targets that are set at a future date where the tobacco-using or cigarette smoking population of a country will be brought below a certain ambitious threshold. Tobacco endgame goals are distinct from tobacco prohibitions like Bhutan's 21st-century tobacco cigarette sales and importation bans.⁸⁹ Instead of setting a target to eliminate the entire tobacco market, an endgame sets a goal of what an acceptable tobacco product market would look like. Endgames clarify what tobacco control is trying to accomplish in a normative instead of a relative sense.

Tobacco endgame goals have been adopted by many countries (listed in Table 2), all of whom have developed economies, strong tobacco control policy regimes, and had much higher smoking rates in the 20th century than at present.⁹⁰ Typically, these endgame goals have sought to reduce tobacco smoking prevalence to a minimal level, defined as 5% of the adult population over the course of at least two decades.⁹¹ If one of these goals is not on track to be reached, a potential problem is created.

⁸⁹ S. Ugen, "Bhutan: The World's Most Advanced Tobacco Control Nation?," *Tobacco Control* 12, no. 4 (December 1, 2003): 431–33, <https://doi.org/10.1136/tc.12.4.431>.

⁹⁰ Judith Mackay, "Designing the Tobacco End Game" (PowerPoint, Tobacco Control Office, Department of Health, Hong Kong, February 14, 2017), <http://tobacco.cleartheair.org.hk/wp-content/uploads/2017/02/2017-02-Endgame.-TCO.-Mackay.pdf>; McDaniel, Smith, and Malone, "The Tobacco Endgame"; Nick Triggle and Hugh Pym, "Pledge to End Smoking in England by 2030," *BBC News*, July 23, 2019, sec. Health, <https://www.bbc.com/news/health-49079515>; Elizabeth Eisenhauer, "A Tobacco Endgame for Canada" (Queen's University, August 30, 2016), <https://www.queensu.ca/gazette/sites/default/files/assets/attachments/EndgameSummit-Backgroundpaper%20.pdf>.

⁹¹ Graham Moon et al., "The Tobacco Endgame: The Neglected Role of Place and Environment," *Health & Place* 53 (September 1, 2018): 271–78, <https://doi.org/10.1016/j.healthplace.2018.06.012>.

Table 2: Tobacco Epidemic Endgame Goals of Various Countries

Country	Target Date	Target Adoption	Adult Smoking Prevalence at Adoption ⁹²
New Zealand	2025	2010	16.4%
Ireland	2025	2013	22.2%
Denmark	2030	2016	17.5%
Finland ⁹³	2030	2016	16.8%
England	2030	2019	17.7%
Scotland	2034	2013	20.7%
Canada	2035	2017	13.8%
Malaysia	2045	2015	17.1%

This problem becomes salient under several further conditions. First, the public needs to be aware of the tobacco endgame target and believe that reaching such a goal is important enough to hold politicians accountable for failing to achieve it. Second, the country must be failing to tangibly reach its goal. If these conditions are met, then we might expect a failure to adequately progress in tobacco control to become a salient problem. In the absence of an endgame goal or the other conditions to achieve salience of a tobacco control progress problem, then we might expect the issue to not become salient. Failure of a tobacco control policy is not a sudden occurrence and it relies mostly on the changes or lack thereof in indicators of progress. But, the establishment of an endgame target, may intentionally, increase political pressure to act on tobacco policy that would not have otherwise existed. This target may become all the more salient if a subgroup of the population with political power sees that its members are not being served by the status quo policy.⁹⁴ Dissatisfaction combined with power is a recipe for policy change through politics.⁹⁵ If no endgame target is set or if the public and politicians are satisfied with the progress being made on tobacco control issues, then we might expect stasis to rule the policy stream and to revise the odds of large regulatory policy change downwards. With no problem to solve, no one will feel the need to change course.

⁹² 2015 or earlier. Marissa B Reitsma et al., “Smoking Prevalence and Attributable Disease Burden in 195 Countries and Territories, 1990–2015: A Systematic Analysis from the Global Burden of Disease Study 2015,” *The Lancet* 389, no. 10082 (May 13, 2017): 1885–1906, [https://doi.org/10.1016/S0140-6736\(17\)30819-X](https://doi.org/10.1016/S0140-6736(17)30819-X).

⁹³ Originally, Finland set a goal in 2010 to achieve 5% smoking prevalence by 2040, but in 2016, they brought the goal’s target date forward by 10 years.

⁹⁴ Signild Vallgård, “Social Inequality in Health: Dichotomy or Gradient?: A Comparative Study of Problematizations in National Public Health Programmes,” *Health Policy* 85, no. 1 (January 1, 2008): 71–82, <https://doi.org/10.1016/j.healthpol.2007.07.004>.

⁹⁵ The example of the Māori in New Zealand will prove to be the test case for this proposition, as this politically empowered but socially disadvantaged indigenous people has not been well served by the tobacco control policy regime in New Zealand of the past and was positioned to dramatically miss the tobacco endgame goals set by that country.

2.2.2.2 *Rejecting the Regulatory Stance*

The second way that a problem might become salient in the current study was that a rejection of the existing regulatory stance for e-cigarettes would serve as a focusing event on the issue of e-cigarette regulation. This might occur through invalidation of policy via the courts or through effective invalidation of a policy by bureaucrats who give up enforcing a policy. The invalidation of a policy in the courts is a much more straightforward focusing event that could occur in a single day, out loud and in public, whereas bureaucrats may keep a non-enforcement decision quiet so as not to incur the wrath of oversight from elected officials.

While it may seem tautological that the very regulatory framework turns into the problem that must be solved by adopting a new regulatory framework, this event likely has roots in other problems and is symptomatic of something else. If a court invalidates a policy, then that means that the legislature passed an ill-conceived law, the bureaucracy interpreted the law in a manner incommensurate with the purpose of the original statute, or perhaps the judicial branch has run amok. If bureaucrats stand down from enforcing a law, that implies that resource constraints have impinged them from doing their job, they believe the policy is of low priority or disagreeable, or institutions are too weak to support the rule of law.

In all these instances, it becomes necessary for countries who wish to implement legally valid statute or for bureaucrats to faithfully execute their jobs to alter the rules under which they operate. Policy change becomes a necessity. If courts uphold policy and bureaucrats faithfully enforce the letter of the law, then we can assume that the regulatory stance is operating as intended. Unless a focusing event arrives to disrupt that conclusion, we can also expect stasis to rule a calm problem stream.

2.2.3 *Policy Stream*

Actors promoting policy ideas that may be applied to solve problems or appeal to a certain political environment occupy the policy stream in the Multiple Streams Approach. The progenitors of these ideas are referred to as the policy community and the ways these actors interact with scientific bodies, international advocacy networks, and governments shape what policy ideas float to the top of agendas when a policy window opens. Policy communities are constantly working to develop policy solutions to address problems, even before problems rise to the attention of the public.

In the current study, some actors might be described as occupying a portion of the policy stream that is drawn from the tobacco industry, the e-cigarette industry, and the community of e-cigarette users, but they always advocated for the same policy positions regardless of where they live. They favored the establishment of an e-cigarette market governed by as few restrictions on the activities of manufacturers, retailers, and users as possible. They only conceded that restrictions establishing a minimum age of sale were necessary limits on this new market. Their influence extends to certain sympathetic politicians from right-wing parties and little further. Consequently, their viewpoints in each case seemed to have little bearing on the policy outcomes. If we are to explain the difference in outcomes, it makes sense to focus on where there are differences in the inputs to the policy stream. Here we focus on three possible explanations that would drive differences in the policy stream's makeup in the cases at hand; the degree of policy community consensus, the role of policy learning, and the support for harm reduction.

2.2.3.1 Policy Community Consensus

When we refer to a policy community needing to seek consensus before the policy stream was primed to couple with other streams, we are referring to the portion of the policy stream that did not maintain a consistent policy position across all cases. In this case, consensus will be defined as the lack of a prominent disagreement over the intent of regulatory policy (regulatory stance), rather than all the smaller details that make up a regulatory framework. The actors in the relevant policy communities whose position on e-cigarette regulation was not constant in each case were broadly drawn from bureaucracies, non-governmental organizations, and academia. These communities are typically composed of highly educated professionals who pride themselves in contributing to or being absorbed in the scientific literature. Their views on the appropriate regulatory stance to adopt towards e-cigarettes varies across place and time while views in the tobacco and e-cigarette manufacturing sector as well as the THR advocacy community do not differ much along those same dimensions.

In each case study, I observe whether the relevant policy community could achieve consensus around an alternative regulatory stance for e-cigarettes. Large policy changes are easier to achieve if the conflict between positions within a policy community is decreased and cooperation

increases.⁹⁶ If a policy community comes together to identify a consensus alternative to the status quo regulatory framework for e-cigarettes, they will be able to present a united front to policymakers and politicians that will spur along with reforms to a regulatory stance. If a policy community remained fractured or was dominated by a contingent that favored the status quo regulatory framework, then there was little impetus to change. This all means that the policy community holds sway with political actors in this area of policy, largely because there does not seem to be an opportunity to gain large amounts of new voters by acting in this policy area.

In the case studies where regulatory policy change happened, actors in the policy stream that could have fought a change in the regulatory stance towards e-cigarettes came to favor it. Here, it is most useful to conceptualize policy community consensus as a downstream reaction to problem definition or the priming of the problem stream. Without a problem that needed to be solved, the status quo bias of actors held sway and no policy community consensus could be reached. Without a problem to fix, inertia will win out and no impetus to identify an alternative consensus policy will take hold.

2.2.3.2 *Policy Learning*

The second possible explanation of e-cigarette regulatory policy differences in the problem stream is the process of policy learning. Policy learning is the process by which stakeholder in the policymaking process acquire and understand information that reduces uncertainty about the effects of policy.⁹⁷ The area of e-cigarette regulation is defined by contested scientific knowledge, so the influence of expertise and credibility remains important to policy actors who are uncertain about the effects of the policies they are considering.⁹⁸ Bureaucracies and politicians seeking to make decisions backed by “the evidence” have repeatedly turned to policy community experts seeking wisdom.⁹⁹ The existence of a global epistemic community of tobacco control advocates and the importance of the knowledge transfers and policy learning it facilitates

⁹⁶ Manuel Fischer, “Coalition Structures and Policy Change in a Consensus Democracy,” *Policy Studies Journal* 42, no. 3 (2014): 344–66, <https://doi.org/10.1111/psj.12064>.

⁹⁷ Stéphane Moyson, Peter Scholten, and Christopher M. Weible, “Policy Learning and Policy Change: Theorizing Their Relations from Different Perspectives,” *Policy and Society* 36, no. 2 (April 3, 2017): 161–77, <https://doi.org/10.1080/14494035.2017.1331879>.

⁹⁸ Newman, “The Role of Uncertainty in Regulating E-Cigarettes.”

⁹⁹ Jenny van der Arend, “Bridging the Research/Policy Gap: Policy Officials’ Perspectives on the Barriers and Facilitators to Effective Links between Academic and Policy Worlds,” *Policy Studies* 35, no. 6 (November 2, 2014): 611–30, <https://doi.org/10.1080/01442872.2014.971731>.

has been well-demonstrated in past literature.¹⁰⁰ However, evidence of the effects of e-cigarettes on human bodies is nascent, conflicting, and subject to disagreement between well-meaning experts.

Claims about one's preferred policy being "evidence-based" abound through the e-cigarette regulation policy literature on all sides of the debate.¹⁰¹ Persons asserting that e-cigarettes are not a safe product to use are likely correct. Those arguing that e-cigarettes are less toxic to human bodies than tobacco cigarettes are likely correct, too. Those arguing e-cigarettes were being used by young people were making evidence-based claims. Those pointing out that cigarettes smoking kept falling among these same people had evidence on their side as well. Credible evidence could be marshaled to make almost any normative case for or against e-cigarettes being a helpful or a harmful market. Not every view will bear out in time as entirely correct, but there is an extant scientific evidence base for most claims that I have run across in my research.

If the process of policy learning is important in determining the pattern of regulatory stance change, a linear process of networks diffusing similar information across multiple venues through emulation or a more advanced form of learning may be evidence in the policies being adopted.¹⁰² Countries may adopt what they view as best practices or what international advocacy networks instruct them are best practices.¹⁰³ No matter how it is defined, policy learning should result in policy convergence over time.

2.2.3.3 Harm Reduction

Debates around the meaning, importance, evidence, and application of harm reduction principles are tightly bound to the debate over e-cigarette regulatory policy. Harm reduction is not merely a framing device or a rhetorical tool to relevant policy communities, though its importance to

¹⁰⁰ Karen Farquharson, "Influencing Policy Transnationally: Pro-and Anti-Tobacco Global Advocacy Networks," *Australian Journal of Public Administration* 62, no. 4 (December 1, 2003): 80–92, <https://doi.org/10.1111/j..2003.00351.x>.

¹⁰¹ Fairchild, Bayer, and Lee, "The E-Cigarette Debate"; Riccardo Polosa and Pasquale Caponnetto, "Time for Evidence-Based e-Cigarette Regulation," *The Lancet Oncology* 14, no. 13 (December 1, 2013): e582–83, [https://doi.org/10.1016/S1470-2045\(13\)70495-9](https://doi.org/10.1016/S1470-2045(13)70495-9); Maurice Swanson, "E-Cig Argument a Smokescreen," *The West Australian*, August 18, 2017, First edition, sec. Opinion.

¹⁰² Claudio M. Radaelli, "Measuring Policy Learning: Regulatory Impact Assessment in Europe," *Journal of European Public Policy* 16, no. 8 (December 1, 2009): 1145–64, <https://doi.org/10.1080/13501760903332647>; Claire A. Dunlop and Claudio M. Radaelli, "Systematising Policy Learning: From Monolith to Dimensions," *Political Studies* 61, no. 3 (October 1, 2013): 599–619, <https://doi.org/10.1111/j.1467-9248.2012.00982.x>.

¹⁰³ John Grin and Anne Loeber, "Theories of Policy Learning: Agency, Structure, and Change," in *Handbook of Public Policy Analysis: Theory, Politics, and Methods*, by Frank Fischer and Gerald J. Miller (Baton Rouge, UNITED STATES: Taylor & Francis Group, 2006), 201–20, <http://ebookcentral.proquest.com/lib/umichigan/detail.action?docID=283245>.

political actors may be may rhetorical and less substantive. Harm reduction is a philosophy that appeals to the sentiments of advocates on all sides of the e-cigarette regulation issue. From its roots in fights against the spread of HIV/AIDS in the 1980s to battles over the safer use of injection drugs in the preceding decades, harm reduction has framed many of the most contentious topics that sit at the intersection between morality, health policy, and politics.

Earlier sections in Chapter 1 explained how e-cigarettes have become wrapped up in a debate over whether the devices are or can be used as a tool for tobacco harm reduction.¹⁰⁴ The remainder of the study will test whether the salience or importance of harm reduction as a policy or political tool affected the fortunes of those who sought to change e-cigarette regulatory policy.

2.2.4 Politics Stream

The politics stream is made up of those actors bound by institutions who try to sense and affect the body politic and determine whether they must address a problem. Usually, they look to the policy stream to see what politically acceptable available solution would fix the problem that has become the center of their attention. Parties seek policies that align with their internal ideologies. This serves as a mechanism of solidifying support from party members for a particular policy as well as sends a strong signal to electorates that parties share the voter's values. If a policy is not judged to be congruent with ideology, then it will not be supported by a political party.

Alternatively, I consider electorally focused models of politics wherein political parties choose courses of action based on what will be most advantageous to their electoral prospects. The problems raised in the policy stream will only matter if they are paired with a political environment that is conducive and sympathetic to their solution.

2.2.4.1 *Federalism*

The form of government could influence the decisions made regarding the regulatory stances towards e-cigarettes which countries could plausibly adopt. Typically, in both federal and unitary states, the central (or supranational) government is tasked with responsibility for regulating the entry of products onto a common market and for creating product standards.¹⁰⁵ Powers to levy taxes and spend are often available to both central and regional governments, though usually in

¹⁰⁴ See pages 16 and 24.

¹⁰⁵ G Majone, "Regulatory Federalism in the European Community," *Environment and Planning C: Government and Policy* 10, no. 3 (September 1, 1992): 299–316, <https://doi.org/10.1068/c100299>.

differing forms.¹⁰⁶ Questions about how business is conducted at the street level are often devolved to the regions. In the case of e-cigarettes, this means that responsibility for different policy domains (see 3.3.5 on page 64) will be the responsibility of different levels of government.

Whether this split responsibility affects the likelihood that countries will change their regulatory stances is not immediately clear.

Governmental forms with more centralized powers may be more likely to respond to change the regulatory stance towards a novel market because they carry the full responsibility of managing such policy. On the other hand, governmental forms with less centralized power may be prompted to respond to a problem sooner because one of the many regional venues has asked the center for assistance with a regulatory problem. In other words, the existence of more policy-making venues might raise the likelihood that the center must react to an issue. Alternatively, the existence of those alternative policymaking venues might ease pressures on the center to respond to a problem.

To further complicate this matter, there are a great variety of federalist systems that operate under a great variety of forms of government. However, this study focuses on two countries with fairly comparable macro-level federal structures, Australia and Canada.¹⁰⁷ The countries operate under similar forms of federation designed by agents of the British Empire, although Canada's reasons for federation included the need to hold together two different linguistic communities while Australia did not. The primary difference between the systems is that Australian states have more influence over the operations of the central government while Canadian provinces have more authority over those who live in their region.¹⁰⁸ While this arrangement leaves Canadian provinces with more fiscal autonomy to, for example levy excise taxes, it provides intergovernmental meetings between Australian states and the federal government with binding legal authority. Determining whether differences in these multilevel governance power arrangements yields differences in outcomes merits attention during the study. To assess the

¹⁰⁶ Liesbet Hooghe, Gary Marks, and Arjan H. Schakel, *The Rise of Regional Authority: A Comparative Study of 42 Democracies* (London ; New York: Routledge, 2010), 18–20.

¹⁰⁷ César Colino, “Varieties of Federalism and Propensities for Change,” in *Federal Dynamics: Continuity, Change, and the Varieties of Federalism*, by Arthur Benz and Jörg Broschek (Oxford: OUP Oxford, 2013), 48–69.

¹⁰⁸ Liesbet Hooghe et al., *Measuring Regional Authority: A Postfunctionalist Theory of Governance. Volume I*, First edition, Transformations in Governance (Oxford, United Kingdom ; New York: Oxford University Press, 2016).

importance of federalism as a predictive variable, this study will pay attention to the order of events and the pressures created and relieved by alternative forms of regional governance.

2.2.4.2 *The Role of the Tobacco Industry*

The interest of the tobacco industry in shaping e-cigarette regulatory policy is well documented.¹⁰⁹ The tobacco industry has invested heavily in buying out, researching and developing, and marketing e-cigarettes in places where such activity is permitted by law.¹¹⁰ The tobacco industry's e-cigarette products are notably absent from markets with prohibitionist e-cigarette regulatory stances. In those markets, sales are dominated by small businesses that import hardware from China and mix e-liquid on-premises.¹¹¹ More than almost any other entity, these companies stand to gain financially from the opening of legal e-cigarette sales.¹¹² Based on the tobacco industry's track record developing and opening tobacco cigarette markets, we might expect their influence to be pivotal in a study of e-cigarette regulatory policy.¹¹³

To evaluate the role of the tobacco industry to explain varying outcomes in regulatory stances, careful attention will be paid to the strategy of actors in the tobacco industry, and how those in policymaking roles and the public health policy community reacted to those strategies. Variance in tobacco industry positions and strategy will be identified and employed to determine whether such changes can aid explanations of varied regulatory policy outcomes.

2.2.4.3 *Left-Wing Party Support*

In an era and region where tobacco smoking is decidedly an activity concentrated among a minority of society, tobacco control policies and placing regulations on tobacco products would not be a large-scale vote-winning issue, we should not expect mainstream political parties to

¹⁰⁹ Marisa de Andrade, Gerard Hastings, and Kathryn Angus, "Promotion of Electronic Cigarettes: Tobacco Marketing Reinvented?," *BMJ (Clinical Research Ed.)* 347 (2013): f7473; Marisa de Andrade et al., "Hostage to Fortune: An Empirical Study of the Tobacco Industry's Business Strategies since the Advent of e-Cigarettes," *Critical Public Health* 0, no. 0 (December 18, 2018): 1–14, <https://doi.org/10.1080/09581596.2018.1552778>.

¹¹⁰ Annalise Mathers, Ben Hawkins, and Kelley Lee, "Transnational Tobacco Companies and New Nicotine Delivery Systems," *American Journal of Public Health* 109, no. 2 (December 20, 2018): 227–35, <https://doi.org/10.2105/AJPH.2018.304813>.

¹¹¹ Emily Chivers et al., "Nicotine and Other Potentially Harmful Compounds in 'Nicotine-Free' e-Cigarette Liquids in Australia," *Medical Journal of Australia* 210, no. 3 (February 2019): 127–28, <https://doi.org/10.5694/mja2.12059>; David Barboza, "China's E-Cigarette Boom Lacks Oversight for Safety," *The New York Times*, December 13, 2014, sec. Business, <http://nyti.ms/1zNA4da>; Adam Jourdan, "'Vaping' a Slow Burner in China, World's Maker of e-Cigarettes," *Reuters*, January 15, 2014, sec. Health, <https://www.reuters.com/article/us-china-smoking-idUSBREA0E1JX20140115>.

¹¹² Euromonitor International, "Global Vapour Products Regulation" (Euromonitor International, December 13, 2017), <http://www.portal.euromonitor.com/portal/analysis/latestresearchindex>.

¹¹³ Chris Holden and Kelley Lee, "Corporate Power and Social Policy: The Political Economy of the Transnational Tobacco Companies," *Global Social Policy* 9, no. 3 (December 1, 2009): 328–54, <https://doi.org/10.1177/1468018109343638>.

bank their election strategies on such a niche issue. Historically, tobacco control policy has advanced through a mix of cooperative agreements with tobacco companies, adversarial political campaigns led by public-health focused non-governmental organizations and the actions of well-meaning bureaucrats and wily policy entrepreneurs.¹¹⁴ Instances, where tobacco control policy has been able to mobilize popular support, are most strongly associated with the proliferation of public smoking bans.¹¹⁵ Therefore, we should ask why lower salience issues like this are ever passed into law.

By the mid-2010s, in developed democracies with populations of smokers making up a shrunken portion of the population than in prior decades, political actions that would defend smoker's rights or the welfare of tobacco companies have not found a large audience of potential voters. Tobacco control has become less of an attack on the lifestyles of a group of voters and has turned into expressions of support for empowered public health interests. Passing tobacco control policies has become a currency for policymakers to signal their negative affect towards the tobacco industry.

All of this speaks to an altered reward structure for politicians entering the realm of tobacco control policy, a realm to which e-cigarette regulation currently belongs. The reward structure to pursue expansionist regulatory stances for tobacco cigarettes seems incredibly limited, as very few voters hold a positive opinion of tobacco companies, as purveyors of a deadly product. Actions that can be portrayed as favoring tobacco company interests (at least in the realm of the tobacco cigarette market) and not business interests, in general, do little to aid a politician's prospects. How then, could a politician vote in favor of an expansionist policy for e-cigarettes? Such a policy will certainly benefit the same disfavored tobacco companies. The reason lies in policy and political community consensus that must be achieved to shield politicians from blame. And this consensus is not formed by political parties meeting in the middle of a left-right ideological spectrum. This consensus comes from the co-optation of politicians from left-wing parties.

¹¹⁴ Theodore Marmor and Evan Lieberman, "Tobacco Control in Comparative Perspective: Eight Nations in Search of an Explanation," in *Unfiltered: Conflicts over Tobacco Policy and Public Health*, ed. Eric A. Feldman and Ronald Bayer (Cambridge, Mass: Harvard University Press, 2004), 275–307.

¹¹⁵ Sarah Milov, *The Cigarette: A Political History, The Cigarette* (Harvard University Press, 2019), chap. 5; Allan Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America* (New York: Basic Books, 2007), chaps. 9, 11.

Left-wing parties in developed democracies have traditionally favored egalitarianism and building stronger social safety nets.¹¹⁶ Left-wing parties that developed from social democracy movements also tended to favor the interests of the working class. Over time, left-wing parties have proved to be the main agents of welfare state expansion, particularly in the realm of health expenditure.¹¹⁷ Left-wing parties favor implementing policies that will improve their population's health more often than their right-wing counterparts.¹¹⁸ Right-wing or classically liberal parties have been skeptical of state intervention into the economy and have often been the source of welfare state retrenchment. Right-wing parties tend to show greater faith in free-market forces and are deferential to the preferences of business interests. In general, right-wing party rule has been found to lead to less development of public health policy, and in particular, much less policy progress on tobacco control.¹¹⁹

The matter of where left-wing and right-wing parties might set their initial preferences on e-cigarette regulation is determined by the interest group each side is most responsive to. Most saliently here, left-wing parties are responsive to the concerns of the public health community, while right-wing parties are responsive to business interests in the tobacco and e-cigarette industry. Right-wing parties whose ideology aligns with classical liberals are more inclined to favor business interests and have widely been willing to support tobacco harm reduction policies without prodding from public health groups.¹²⁰ Determining where each of these interest groups begins on the matter of e-cigarette regulation is a country-specific and context-sensitive matter.

However, I posit that left-wing parties must assent to a change in e-cigarette regulatory policy stance before a policy window opens. This can be attributed to the factors in the policy stream that create a permission structure that actors in the political stream follow. Without the expressed

¹¹⁶ Evelyne Huber and John D. Stephens, *Development and Crisis of the Welfare State: Parties and Policies in Global Markets* (University of Chicago Press, 2010).

¹¹⁷ Michelle Falkenbach, Marleen Bekker, and Scott L. Greer, "Do Parties Make a Difference? A Review of Partisan Effects on Health and the Welfare State," *European Journal of Public Health* 29, no. Supplement_4 (November 1, 2019), <https://doi.org/10.1093/eurpub/ckz133>.

¹¹⁸ Vicente Navarro et al., "Politics and Health Outcomes," *The Lancet* 368, no. 9540 (September 16, 2006): 1033–37, [https://doi.org/10.1016/S0140-6736\(06\)69341-0](https://doi.org/10.1016/S0140-6736(06)69341-0).

¹¹⁹ Johan P. MacKenbach and Martin McKee, "Social-Democratic Government and Health Policy in Europe: A Quantitative Analysis," *International Journal of Health Services* 43, no. 3 (July 2013): 389–413, <https://doi.org/10.2190/HS.43.3.b>.

¹²⁰ Nicky Wagner and Maureen Pugh, "11. Smoking—Nicotine E-Cigarettes" (2017), https://www.parliament.nz/en/pb/hansard-debates/rhr/document/HansS_20170406_053925000/11-smoking-nicotine-e-cigarettes; Nuk Korako, Sam Lotu-Iiga, and David Seymour, "11. Smoking—Electronic Cigarettes and Cessation Services - New Zealand Parliament" (2016), https://www.parliament.nz/en/pb/hansard-debates/rhr/document/HansS_20160823_054675000/11-smoking-electronic-cigarettes-and-cessation-services; Colin Mendelsohn and David Leyonhjelm, "FW: Simon Chapman," June 21, 2017, <https://groups.google.com/forum/#!msg/nicotinepolicy/LmKZOvWL7D0/U8VjmuL7AwAJ>.

approval for policy change from groups trusted by left-wing allies (namely, public-health-oriented non-governmental organizations), agenda-setting and policy change for e-cigarette regulatory stances do not proceed. Whether due to electoral calculation, permission structure, or both; these political conditions will be necessary to achieve a change in an e-cigarette regulatory stance.

2.3 Conclusion

The theoretical framework that structures this study, the range of regulatory stances, will enable the findings of the current study to be tested more widely to determine whether they are broadly generalizable. First, the explanatory factors that precipitate change or shore up the status quo in the cases at hand, which are generalizable in nature (left-wing party support and bureaucratic or legal rejection of the regulatory stance) may well apply in other jurisdictions and in other markets. Associated hypotheses stemming from such observations remain subject to further testing.

Second, the regulatory stances concept is generalizable, testable, and can be subject to any number of alternative scoping conditions that would enable its use in other studies. The regulatory stances concept is a flexible outcome variable that can be determined across market, jurisdiction, and time. Any study of market regulation where the regulatory stance can be determined should be within the scope of its utility. If scholars use the process of determining a regulatory stance, they can employ their chosen framework describing the policy process to explain change, stasis, convergence, and divergence.¹²¹ By enabling comparisons around the fundamental purpose of regulation, the resolution of market failures, scholars can apply the variables they are familiar using in other arenas (ideology, demographics, government form, etc.) to answering questions that impact the operation of markets and the people, countries and institutions that markets affect.

The simplifying concept of a regulatory stance has been introduced as the summed intended effect of a regulatory framework on the growth of a market. A regulatory stance should be thought of as the outcome variable that is being predicted in this study. The Multiple Streams Approach has been advanced as the analytical lens through which agenda-setting and policy

¹²¹ See 3.3.4 Determine the Regulatory Stance for a Market on page 74.

change in this realm can be studied. Eight potentially important explanations of why changes to a regulatory stance occur were advanced as well. These should be thought of as probabilistic input variables. The alignment of input variables is predicted to alter the likelihood of agenda-setting and policy change. The following section illustrates how these variables could be isolated for study. Additionally, it explains how the information that will fill in the details of the Multiple Streams Approach and the regulatory stances was collected, analyzed, and reported.

Chapter 3 Methods

This project consists of three qualitative comparative case studies of how a country changed or maintained its regulatory stance towards e-cigarettes over time. The three chosen case studies employ John Stuart Mill's method of most-similar cases to uncover how three seemingly similar countries behaved differently over time. Each case study will be divided substantively according to Kingdon's streams to ensure that information is gathered to describe parallel streams of activity. After the case studies, the collected findings therein will be analyzed to draw generalizable lessons across the cases, and then beyond their substantive, theoretical, and geographic borders.

This chapter explains why the study is limited in scope, how the cases were selected for study, and the methods by which those case studies were conducted. It reviews the data collection and interpretation processes that underly the construction of the subsequent case study chapters. Particular attention is paid to the methods used to rationalize the policymaking process as well as the assignment of a regulatory stance to the jurisdictions over time.

3.1 Scoping Conditions

This project focuses on explaining the regulatory stances adopted by study countries towards the nicotine-containing e-cigarette market. As laid out in the Introduction, variations in the regulation of this market across borders and time are not readily explained by theories that are already available to scholars of political science and public policy. Second, the regulation of this market is of intense interest to scholars and practitioners of public health. Focusing this comparative study of regulatory policy and politics on this matter enables an exploration of an issue that sits at the nexus of health and politics, with an added portion of general population interest.

E-cigarettes are the class of products that consume liquids primarily containing four ingredients: nicotine, propylene glycol, vegetable glycerin, and flavorings through the heating of the liquid

into the gas phase before ingestion by a user.¹ These products have taken many different forms over the last 15 years, but they are, in my eyes, a distinct market category worthy of study on its own. Nicotine-containing e-cigarettes represent a monumental shift in the regulatory landscape of tobacco products. E-cigarettes hold the unusual status as a reduced-risk substitute product for a lethal, legal consumer good. Many other products meet one or some of these criteria, but e-cigarettes are an interesting case of meeting both. Studying e-cigarette regulation presents a case of high-risk and high-reward decision making. The choices made by policymakers to allow the growth of a market has uncertain consequences. These consequences can be tailored through regulatory decisions that limit the scope of growth or encourage responsible, controlled growth of the e-cigarette market.

The tobacco industry has offered several classes of tobacco products at different points over the preceding decades in response to what they perceive as latent consumer demand for a product that delivers nicotine without the smoke and tar of tobacco cigarettes. Non-combusted tobacco products have primarily arrived in three relevant forms: carbon heated tobacco products, electronic heated tobacco products, and smokeless tobacco. Additionally, two non-tobacco products, new smoking material, and non-nicotine e-cigarettes have sought to be substitutes for the tobacco cigarette that deliver the hand-to-mouth experience of smoking without delivering nicotine. Each of these markets is worth studying, but for various reasons, none stands apart from nicotine-containing e-cigarettes as a better subject for a comparative study of regulatory frameworks. In this section, each product is introduced before an explanation of its exclusion from the scope of this project is advanced.

3.1.1 Carbon Heated Tobacco Products

Starting in the 1980s, American tobacco companies rolled out non-combusted tobacco products that were heated by a carbon rod in the middle of the product.² These products – Accord, Eclipse, and Favor – never gained widespread popularity. This was partially due to the reticence of their manufacturers to admit that one tobacco product may have been more or less risky to the user’s

¹ Glasser et al., “Overview of Electronic Nicotine Delivery Systems.”

² Stephan Risi, “On the Origins of the Electronic Cigarette: British American Tobacco’s Project Ariel (1962–1967),” *American Journal of Public Health* 107, no. 7 (May 18, 2017): 1060–67, <https://doi.org/10.2105/AJPH.2017.303806>.

health than the next. This defensive mentality eventually led to these products being withdrawn from sale without ever gaining a substantial following outside of the commissary on the ground of RJ Reynold's Headquarters.³ Their disappearance from the contemporary market and the lack of sales outside of the United States makes them less interesting subjects for a comparative case study.

3.1.2 Electronic Heated Tobacco Products

The earliest patented heated tobacco products developed in the 20th century used electricity to heat a tobacco stick.⁴ While this technology was not commercialized at the time, by the 21st century new electronic heated tobacco products reached commercial markets and by 2015, these markets finally gained sizeable market share in Japan.⁵ These electronic heated tobacco products share some traits in common with e-cigarettes. Both devices deliver nicotine in a vapor, created by electrically heating a tobacco derivative impregnated or mixed with propylene glycol. Transnational tobacco companies own brands in every nicotine market segment. The largest difference is that transnational tobacco companies control the entirety of the electronic heated tobacco products market while they only control between a minority and a plurality of e-cigarette markets worldwide.⁶ Electronic heated tobacco products are cross-branded with cigarettes to more closely link the brand identities between old products and new.⁷ The novel heated tobacco products have spread rapidly around the world and are expected to grow in market share as the transnational tobacco companies set goals to make the new products a profit center.⁸

The decision in this study to not include these products as a focus except in the most limited circumstances (e.g. *Philip Morris New Zealand v. Ministry of Health*) was made for two

³ Zachary Cahn and Lindsay Eckhaus, "Explaining the Discontinuation of a Non-Tobacco Nicotine Project at Philip Morris: Obstacles to Innovation," *Journal of Public Health Policy* 39, no. 2 (May 1, 2018): 131–42, <https://doi.org/10.1057/s41271-018-0124-1>.

⁴ Herbert A. Gilbert, Smokeless non-tobacco cigarette, United States US3200819A, filed April 17, 1963, and issued August 17, 1965, <https://patents.google.com/patent/US3200819A/en>; Ellis Charles Drummond et al., Smoking device, United States US3258015A, filed February 4, 1964, and issued June 28, 1966, <https://patents.google.com/patent/US3258015A/en>.

⁵ Michal Stoklosa et al., "Effect of IQOS Introduction on Cigarette Sales: Evidence of Decline and Replacement," *Tobacco Control*, June 12, 2019, tobaccocontrol-2019-054998, <https://doi.org/10.1136/tobaccocontrol-2019-054998>.

⁶ David T. Levy et al., "An Economic Analysis of the Pre-Deeming US Market for Nicotine Vaping Products," *Tobacco Regulatory Science* 5, no. 2 (March 1, 2019): 169–81, <https://doi.org/10.18001/TRS.5.2.8>.

⁷ Alex C. Liber, "Heated Tobacco Products and Combusted Cigarettes: Comparing Global Prices and Taxes," *Tobacco Control* 28, no. 6 (November 1, 2019): 689–91, <https://doi.org/10.1136/tobaccocontrol-2018-054602>.

⁸ Stoklosa et al., "Effect of IQOS Introduction on Cigarette Sales."

reasons.⁹ First, the empirical evidence base around electrically heated tobacco products is much less developed than for e-cigarettes, leading to less consensus has developed among the global policy community.¹⁰ Second, the political structure of the regulatory battle is very different from the e-cigarette conflict because it is dominated entirely by transnational tobacco companies instead of consumers.¹¹ It is likely the political considerations around adopting a regulatory stance towards electrically heated tobacco products are inextricable from the regulatory politics around tobacco cigarettes in a more fundamental manner than it is separable from e-cigarettes. The e-cigarette market is populated by dozens of small firms while the electrically heated tobacco market is dominated by the same companies that dominate global tobacco cigarette sales. Heated tobacco consumers have not mobilized into an identifiable community in the manner that e-cigarette users have.¹² Pulling apart the differences between cigarette regulatory politics from e-cigarette regulatory politics was one of the goals of this research and focusing on electrically heated tobacco products will not advance that line of inquiry.

3.1.3 Smokeless Tobacco

Another commonly compared class of products to e-cigarettes are smokeless tobacco products. These products are made from the leaves of tobacco plants and processed to be ingested by sniffing, sucking, or chewing. Smokeless tobacco products are understood to be less deadly to use than cigarettes and other combusted tobacco products, but their relative harm is dependent on the manner of preparation and ingredients used in a product. Smokeless tobacco products have been around since tobacco has been cultivated, much longer than the ubiquitous cigarette. A rash of sales bans in the early 1990s (including bans in my primary case countries of New Zealand

⁹ P J Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC (The District Court of New Zealand 2018).

¹⁰ McNeill et al., “Evidence Review of E-Cigarettes and Heated Tobacco Products 2018: A Report Commissioned by Public Health England.”

¹¹ Stella A. Bialous and Stanton A. Glantz, “Heated Tobacco Products: Another Tobacco Industry Global Strategy to Slow Progress in Tobacco Control,” *Tobacco Control* 27, no. Suppl 1 (November 1, 2018): s111–17, <https://doi.org/10.1136/tobaccocontrol-2018-054340>.

¹² Rikke Tokle and Willy Pedersen, “‘Cloud Chasers’ and ‘Substitutes’: E-Cigarettes, Vaping Subcultures and Vaper Identities,” *Sociology of Health & Illness* 41, no. 5 (2019): 917–32, <https://doi.org/10.1111/1467-9566.12854>; Tessa Langley et al., “‘I Felt Welcomed in Like They’re a Little Family in There, I Felt Like I Was Joining a Team or Something’: Vape Shop Customers’ Experiences of E-Cigarette Use, Vape Shops and the Vaping Community,” *International Journal of Environmental Research and Public Health* 16, no. 13 (July 2, 2019): 2341, <https://doi.org/10.3390/ijerph16132341>.

and Australia) kept the products from growing in global market share.¹³ In those products without sales bans on smokeless tobacco, it is the exceptional case (Sweden and Norway) that have seen smokeless tobacco products take large swaths of market share away from tobacco cigarettes.¹⁴

It might be argued that Sweden and Norway adopted permissive regulatory stances towards smokeless tobacco in contrast to their contractionist stances towards cigarettes.¹⁵ The consequence of replacing cigarette sales with smokeless tobacco in those countries, as well as elucidating the path that policy needed to traverse to be adopted, are cases worth explaining in detail. This policy development is unique to these Nordic countries as the product they have chosen to consume (known as Swedish snus) is indigenous to those countries and is produced domestically.¹⁶ Swedish snus, like most smokeless tobacco, is not a novel product and has been in production for decades and its health effects have been studied for nearly as long.¹⁷ Unfortunately, such a study would produce fewer applicable policy lessons for other countries as relatively few countries have consumers who have demonstrated interest in consuming these products.

3.1.4 New Smoking Material

In 1973, New Smoking Material was introduced to the United Kingdom market as a tobacco substitute by the Imperial Tobacco Company.¹⁸ The product was a manufactured organic material comprised mostly of cellulose, the building blocks of plants, and was marketed under

¹³ G. N. Connolly, "Smokeless Tobacco in Developed Countries: An Epidemic Prevented," in *The Global War* (Proceedings of the Seventh World Conference on Tobacco and Health, Perth, Australia: Western Australian Health Department, 1991); G N Connolly et al., "The Reemergence of Smokeless Tobacco," *The New England Journal of Medicine* 314, no. 16 (April 17, 1986): 1020–27, <https://doi.org/10.1056/NEJM198604173141605>.

¹⁴ Ingeborg Lund and Karl Erik Lund, "How Has the Availability of Snus Influenced Cigarette Smoking in Norway?," *International Journal of Environmental Research and Public Health* 11, no. 11 (November 13, 2014): 11705–17, <https://doi.org/10.3390/ijerph111111705>.

¹⁵ Jessi Hietanen, "Knowledge, Attitudes and Behaviour towards Snus by Its Users in Finland, Norway and Sweden" (Masters, Högskolan i Halmstad, Sweden, Halmstad University, 2018), <http://www.diva-portal.org.proxy.lib.umich.edu/smash/get/diva2:1223656/FULLTEXT02>.

¹⁶ Gunnar Sæbø, "Cigarettes, Snus and Status: Differences in Lifestyle of Different Tobacco User Groups in Norway," *Health Sociology Review* 26, no. 2 (May 4, 2017): 175–89, <https://doi.org/10.1080/14461242.2016.1197043>.

¹⁷ J. Foulds et al., "Effect of Smokeless Tobacco (Snus) on Smoking and Public Health in Sweden," *Tobacco Control* 12, no. 4 (December 1, 2003): 349–59, <https://doi.org/10.1136/tc.12.4.349>.

¹⁸ "New Smoking Material," *The Lancet*, Originally published as Volume 1, Issue 7814, 301, no. 7814 (June 2, 1973): 1226, [https://doi.org/10.1016/S0140-6736\(73\)90534-5](https://doi.org/10.1016/S0140-6736(73)90534-5).

brand names like, ‘Cytrel’.¹⁹ Plans were drawn up to blend New Smoking Material into tobacco cigarettes to decrease exposure to the toxicants inherent in burned tobacco leaf. UK based tobacco companies set out on a sustained campaign to shape tobacco policies that would encourage the growth of the market for New Smoking Material, but after initial test marketing of the product failed with consumers the push for expansionist regulatory policies were scrapped.²⁰

While the lessons from the New Smoking Material experience sound like a prologue for the regulatory battles over e-cigarettes that would take place 40 years later, the parallels between the development of the markets fall apart on closer scrutiny. New Smoking Material never built a substantial evidence base in favor of it being meaningfully less harmful to users than cigarettes.²¹ Possibly, as a result, the product never gained a permanent user base that demanded access to the product be expanded.²²

3.1.5 Non-Nicotine E-Cigarettes

It also must be noted that many e-cigarettes have been sold without any nicotine in their e-liquid. The regulation of this non-nicotine e-liquid does not pose the same potential risks to public health that nicotine-containing e-cigarettes do. Arguments that such e-liquids should be treated as tobacco products are not persuasive, as the products do not contain any derivatives of tobacco plants. Finally, it does not seem as though non-nicotine e-cigarettes are as potent a potential cessation aid or an addiction liability because they lack the key compound that creates a biochemical demand for tobacco products.²³ Knowing this, the regulatory stances of countries towards this market are likely to be of little consequence to public health. Therefore, except in

¹⁹ Kenneth M Friedman, “Editorial: Cigarette Smoking and Public Policy,” *American Journal of Public Health* 65, no. 9 (September 1975): 979–80, <https://doi.org/10.2105/AJPH.65.9.979>.

²⁰ Virginia Berridge, *Marketing Health: Smoking and the Discourse of Public Health in Britain, 1945-2000* (OUP Oxford, 2007), chap. 5.

²¹ Virginia Berridge, “Histories of Harm Reduction: Illicit Drugs, Tobacco, and Nicotine,” *Substance Use & Misuse* 34, no. 1 (January 1, 1999): 35–47, <https://doi.org/10.3109/10826089909035634>.

²² Cr Green et al., “Comparisons of the Composition of Tobacco Smoke and the Smokes from Various Tobacco Substitutes,” *Beiträge Zur Tabakforschung International/Contributions to Tobacco Research* 22, no. 4 (January 1, 2007): 258–89, <https://doi.org/10.2478/cttr-2013-0833>.

²³ Regina El Dib et al., “Electronic Nicotine Delivery Systems and/or Electronic Non-Nicotine Delivery Systems for Tobacco Smoking Cessation or Reduction: A Systematic Review and Meta-Analysis,” *BMJ Open* 7, no. 2 (February 1, 2017): e012680, <https://doi.org/10.1136/bmjopen-2016-012680>.

the cases where regulators struggled to differentiate these products from nicotine-containing e-cigarettes, these products will be limited from further consideration.

3.2 Case Selection

This analysis will be centered around an examination of a most-similar set of country cases that have adopted different regulatory policy choices on a crucial topic in public health: the market for nicotine containing e-cigarettes. John Stuart Mill's method of most-similar cases is employed to conduct this study as the primary interest is determining why such a wide range of policy exists.²⁴ This method captures the causes of the variation in policy models, ideally over a set of cases that should represent the largest width of policy models among the most similar jurisdictions. A comparison of most similar cases attempts to determine why countries that 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.

For this study, the recent history of e-cigarette regulation in a country will be considered as a single case of regulatory action and will not be subdivided into separate cases. It is useful to arrange the country regulatory policies seen in Figure 3 (p. 12) along with the range of regulatory stances for e-cigarettes elaborated upon in Chapter 2.²⁵ Therefore, when we must condense the universe of cases, we are looking at 32 countries with prohibitionist stances, while 62 have explicit permissive or expansionist stances.

In a forward selection process, the original set of 183 countries for which data could be collected was winnowed down to the three country cases. The analysis was chosen to be conducted at the level of the nation-state to remove the influence of common national laws that might over-determine regulatory stance or limit the choices available to jurisdictions.²⁶ This analytical

²⁴ Charles C. Ragin and Howard S. Becker, eds., *What Is a Case? Exploring the Foundations of Social Inquiry*, 9. print (Cambridge: Cambridge Univ. Press, 2005).

²⁵ See page 35.

²⁶ While interesting subnational variation in e-cigarette policy is taking place in federal countries including the United States and India, and that variation crosses the line between jurisdictions banning the sale of e-cigarettes and those allowing their sale. There is not enough variation in policies stances towards e-cigarettes in those same subnational jurisdictions than exists at the national level. Institute for Global Tobacco Control., "Subnational Laws Regulating E-Cigarettes: A Policy Scan" (Johns Hopkins Bloomberg School of Public Health, September 2015), <http://bit.ly/2D1yy0s>.

choice also necessitated removing European Union (EU) member countries from the study sample, to eliminate the influence of the EU's Tobacco Products Directive. The Tobacco Products Directive was revised in 2014 and was required to come into effect in EU member states by 2016.²⁷ The Tobacco Products Directive included set regulatory policy standards for e-cigarettes for each member country and limited the regulatory options available to each country. These regulations removed the ability of countries to ban the sale of the products, to allow over-the-air marketing, and they set product standards capping the size and nicotine concentration of e-liquid bottles. The revised Tobacco Products Directive required all EU member states to preserve a common market, eliminating previous prohibitionist policies in countries like Greece and France.²⁸ The lack of latitude left to member states that wanted to avoid strangle their e-cigarette markets makes EU member states who were not interested in expansionist policies poor case study choices because their compliance with the Tobacco Products Directive almost completely explains policy change. This left 156 countries in the potential sample pool.

It is essential to limit the study to high-capacity countries with some degree of transparency and accountability. Therefore, countries that were not in the high or very high Human Development Index groups as well as the countries that did not have a reasonably open and predictable system of government according to the V-Dem dataset were eliminated from consideration.²⁹ This ensures that similar countries in terms of wealth, health, and education are being compared and that access to candid officials and public records can be assured.

Because cigarette smoking is the *raison d'être* for the e-cigarette, it follows that to compare policy development on e-cigarettes, we should only consider countries that are in the same stage of the tobacco epidemic. The stages of the tobacco epidemic are typically split out over time wherein early stages are characterized first by rising smoking prevalence, followed by a stage where smoking prevalence is rising along with smoking-caused death at a lag of about 30

²⁷ 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, <https://doi.org/10.1093/jpo/jov009>.

²⁸ Kennedy et al., "Global Approaches to Regulating Electronic Cigarettes."

²⁹ 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/>; Selima Jāhāna and United Nations Development Programme, *Human Development Report 2016: Human Development for Everyone*, 2016, http://hdr.undp.org/sites/default/files/2016_human_development_report.pdf.

years.³⁰ Later stages of the epidemic are characterized first, by falling smoking prevalence, and then by falling smoking-caused death.³¹ So-called Stage 4 countries are in the years where smoking prevalence and death seem to be on an inexorable decline. This group countries have seen success in their tobacco control policy and the introduction of the e-cigarette to their markets posed reasonably similar stakes for each.

Table 3: Remaining Cases

Country	Population (Millions)	Smoking Prevalence	Variety of Capitalism	Regulatory Stance (2017)	Regulatory Stance (2020)	System of Government	Form of Government
Canada	37	13.4%	Liberal	Prohibitionist	Expansionist	Parliamentary	Federal
Australia	25	14.4%	Liberal	Prohibitionist	Prohibitionist	Parliamentary	Federal
New Zealand	4.8	15.6%	Liberal	Prohibitionist	Expansionist	Parliamentary	Unitary
Chile	18	25.2%	Liberal	Prohibitionist	Permissive	Presidential	Unitary
United States	323	13.0%	Liberal	Permissive	Contractionist	Presidential	Federal
Costa Rica	4.9	7.6%	Liberal	Permissive	Permissive	Presidential	Unitary
Switzerland	8.6	19.2%	Coordinated	Prohibitionist	Prohibitionist	Mixed	Federal
Japan	127	17.7%	Coordinated	Prohibitionist	Prohibitionist	Parliamentary	Unitary
Uruguay	3.4	19.0%	Coordinated	Prohibitionist	Prohibitionist	Presidential	Unitary
Iceland	0.4	14.4%	Coordinated	Permissive	Permissive	Parliamentary	Unitary
Norway	5.4	14.9%	Coordinated	Contractionist	Contractionist	Parliamentary	Unitary
South Korea	51	21.1%	Coordinated	Contractionist	Contractionist	Presidential	Unitary

At this stage, twelve countries met the requirements for being in the high development group or above, having declining rates of smoking and tobacco-caused death, not being EU member states, and having systems of laws and enforcement above the world average. They are listed in Table 3. Next, we stratify countries by their variety of capitalism into coordinated and liberal market economies.³² The range of e-cigarette regulatory policy choices among liberal economies was similar to coordinated economies in 2017 but by 2020 liberal economies had seen more changes in regulatory policy and represented a wider range of regulatory policy choices. This necessitated choosing to focus on liberal economies.

Finally, when examining the final six choices, it became clear that three countries, Australia, New Zealand, and Canada, represented a tighter cluster of most-similar cases than the others. Chile, Costa Rica, and the United States utilize a Presidential system of government that differs considerably from the other three countries who use variants on a Westminster-style

³⁰ A. D. Lopez, N. E. Collishaw, and T. Pihl, "A Descriptive Model of the Cigarette Epidemic in Developed Countries," *Tobacco Control* 3, no. 3 (September 1994): 242–47.

³¹ Michael Thun et al., "Stages of the Cigarette Epidemic on Entering Its Second Century," *Tobacco Control* 21, no. 2 (March 1, 2012): 96–101, <https://doi.org/10.1136/tobaccocontrol-2011-050294>.

³² Peter A. Hall and David W. Soskice, eds., *Varieties of Capitalism: The Institutional Foundations of Comparative Advantage* (Oxford: Oxford University Press, 2001).

parliamentary system. While half the countries in this final group are federalized (United States, Canada, and Australia) in their form of government, that variable is a less germane factor to choose cases upon than system of government because it speaks less to the fashion in which national regulatory policy is created, the subject of this study.³³

This process of forward selection leaves us with three cases on which the rest of this study concentrates; Australia, Canada, and New Zealand. 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 by many authors before.³⁴ Many others, have added Canada as a triplet to the other two Commonwealth countries of similar age and development status.³⁵ Further, the common link between these countries runs through the United Kingdom, which declared in the Balfour Declaration of 1926 that each country was a dominion, equal in status, to the imperial center. Canada, New Zealand, and Australia all began with nearly identical prohibitionist regulatory stances towards the nicotine-containing e-cigarette market. Over the course of the last seven years, Canada, and then likely New Zealand have moved towards adopting expansionist regulatory frameworks towards this market. This dissertation interrogates the policy process as viewed through a multiple streams approach lens to determine what factors enabled policy change to occur or not.

These countries represent classic Westminster-style systems of Parliamentary government with highly professionalized bureaucracies that work closely with legislators to write policy.³⁶ None of these countries suffer from a lack of technical capacity or resource allocation to their

³³ Rather, the form of government speaks to the size of the country, wherein those with larger populations and landmass are federal, while those which have smaller populations and land mass are unitary.

³⁴ 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, <https://doi.org/10.1080/10361140600672394>; Donley T. Studlar, "The Political Dynamics of Tobacco Control in Australia and New Zealand: Explaining Policy Problems, Instruments, and Patterns of Adoption," *Australian Journal of Political Science* 40, no. 2 (June 1, 2005): 255–74, <https://doi.org/10.1080/10361140500130063>.

³⁵ Sharon Loane and Jim Bell, "Rapid Internationalisation among Entrepreneurial Firms in Australia, Canada, Ireland and New Zealand: An Extension to the Network Approach," *International Marketing Review* 23, no. 5 (September 1, 2006): 467–85, <https://doi.org/10.1108/02651330610703409>; Philip Yetton, Jane Craig, and Jeremy Davis, "Are Diamonds a Country's Best Friend? A Critique of Porter's Theory of National Competition as Applied to Canada, New Zealand and Australia," *Australian Journal of Management* 17, no. 1 (June 1, 1992): 89–119, <https://doi.org/10.1177/031289629201700105>; Studlar, "The Political Dynamics of Tobacco Control in Australia and New Zealand."

³⁶ Rhodes, Wanna, and Weller, *Comparing Westminster*.

bureaucracies, and all have firmly established institutions that are not soon likely to radically change.³⁷ Certain differences in federated structures, election rules, and demographics merit mention as potential sources of divergent policy outcomes, but each will be considered and will be ruled out as causes of such policy divergence.

Importantly in our case, each country has a strong track record of tobacco control policy progress and have demonstrated the capacity for policy innovation in this area. Australia passed the world's first plain packaging law for cigarettes.³⁸ Canada has been a pathbreaker in tobacco control as well, as the country that implemented the world's first graphic health warning labels on cigarette packs in 2001.³⁹ New Zealand has included one of the most aggressive programs of annual tax-driven price increases in the world, making cigarettes dramatically less affordable to New Zealand smokers over the last decade.⁴⁰ Additionally, in March 2011, the New Zealand government of the day was the first in the world to declare a public "tobacco endgame" target date for the country, aiming to reduce smoking prevalence to 5% of the adult population by 2025.⁴¹ Each country has made progress innovating on policy grounds and in reducing their smoking prevalence rates and consumption (Figure 7). What follows here are short descriptions of the e-cigarette regulatory stances and the key events that brought about the set of rules in each case country.

³⁷ New Zealand adopted a new mixed-member proportional electoral system for Parliament in 1996 and Australia has changed their vote-counting procedures to improve the ranked-choice system. However, this point refers to the fact that no pharmaceutical company is going to try to start selling a cancer drug to hospitals without the medicines regulator approving first in any case countries because the rule of law is firmly established.

³⁸ 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. Tobacco companies, in national and international courts, sued the country. Recently, the final judgments on the legality of the law were handed down, allowing Australia to continue its plain packaging law. Simon Chapman and Becky Freeman, *Removing the Emperor's Clothes: Australia and Tobacco Plain Packaging* (Sydney: Sydney University Press, 2014).

³⁹ Donley T Studlar, *Tobacco Control Comparative Politics in the United States and Canada* (Peterborough, Ont.: Broadview Press, 2002).

⁴⁰ Alex Mason, "Government Burned over Smoking Tax Rise," *New Zealand Herald*, January 1, 2016, sec. Business, <https://bit.ly/2It0HfR>.

⁴¹ NZ MoH, "Smokefree 2025," Ministry of Health NZ, July 21, 2015, <http://bit.ly/2DBiF0P>.

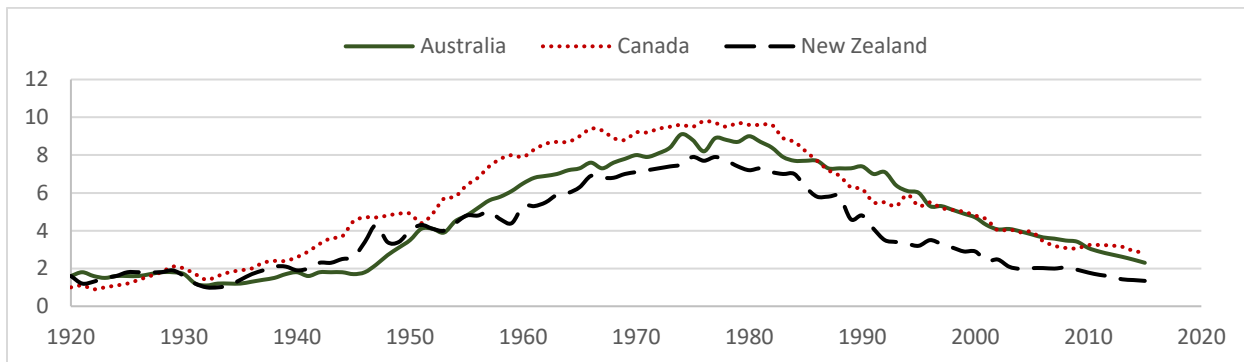


Figure 7: Manufactured cigarettes consumed per adult per day (1920-2015)⁴²

3.2.1 Australia

Australia has maintained a prohibitionist regulatory stance for nicotine-containing e-cigarettes over the course of the study period. Nicotine, except in forms that are therapeutic or prepared for smoking, is regulated as a dangerous poison by the Therapeutic Goods Administration (TGA) and banned from sale in the country without premarket approval from the TGA.⁴³ When e-cigarettes first turned up in 2010, the TGA emphasized that e-cigarettes were not “a safe alternative to normal cigarettes and not approved for therapeutic use”, while the Australia Medical Association stressed that the devices “could pose a serious health risk”.⁴⁴ Law enforcement officers have only grudgingly tolerated the presence of an e-cigarette industry that attempts to skirt regulatory policies on a series of technicalities.

Repeated efforts by THR advocates have been made to open a legal market for e-cigarettes at the Commonwealth level, but thus far all have been rebuffed.⁴⁵ Understanding why this dynamic has persisted while the other cases have managed policy change is key to this study.

⁴² Barbara Forey et al., “International Smoking Statistics: Web Edition” (P N Lee Statistics & Computing Ltd, December 20, 2016), <http://www.pnlee.co.uk/ISS.htm>.

⁴³ Australian Government Department of Health Therapeutic Goods Administration, “2.1 Nicotine,” Text, Therapeutic Goods Administration (TGA), February 2, 2017, <https://www.tga.gov.au/book-page/21-nicotine>.

⁴⁴ Jill Stark, “Battery-Powered Cigarettes Pose Risks,” *The Sun Herald*, December 12, 2010, First edition, sec. News.

⁴⁵ Sarah Martin, “Greg Hunt Digs in on Opposition to E-Cigarettes after Vaping ‘Epidemic,’” *The Guardian*, September 3, 2019, sec. Australia news, <https://www.theguardian.com/australia-news/2019/sep/04/greg-hunt-digs-in-on-opposition-to-e-cigarettes-after-vaping-epidemic>; Katharine Murphy, “Vaping Inquiry: Coalition Agrees to Study Health Effects of e-Cigarettes,” *The Guardian*, September 18, 2018, sec. Society, <https://bit.ly/2NQUDxT>; Debbie Schipp, “Cigarette Smoking: MPs Split on Vaping Debate, e-Cigarette Ban Stays,” *News.com.au*, March 28, 2018, <http://www.news.com.au/lifestyle/health/life-is-short-and-shorter-for-smokers-just-legalise-vaping/news-story/8f1636e55e4be981732c3f69059ce977#.vuelly>.

3.2.2 Canada

Over the course of the study period, Canada moved from holding a prohibitionist regulatory stance towards e-cigarettes to an expansionist stance. In 2009, Health Canada, the country's omnibus health regulator determined that nicotine-containing e-cigarettes must be approved for sale by the regulator as a drug before they could be legally sold.⁴⁶ Actors, namely small retailers, importers, and consumers, in the country's e-cigarette market did not heed Health Canada's instructions and carried on conducting business with little regard for federal regulations, and a thriving gray market arose in these products.⁴⁷ This market was officially illegal, but it conducted business in proper brick-and-mortar storefronts across the country. Health Canada and law enforcement agents resorted to trying to enforce order by recommending shipments of e-cigarette parts to be refused entry into the country at its borders and by issuing cease-and-desist letters to retailers.⁴⁸

Provinces began proposing their own regulatory frameworks for controlling the sale and use of e-cigarettes through 2014.⁴⁹ Around the same time, Health Canada's enforcement officers decided to no longer enforce the country's restrictions on the sale of e-cigarettes because they wished to dedicate their resources elsewhere.⁵⁰ This mix of provincial policy and federal enforcement inaction led provincial medical officers to call on their federal government to put together a proper federal regulatory policy for e-cigarette in September 2014.⁵¹ The federal government of the day took them up on the offer.⁵²

⁴⁶ Health Canada, "Notice - To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada," notices, aem, March 4, 2009, <http://bit.ly/2n4YYoI>; HESA Committee, "Vaping: Toward a Regulatory Framework for E-Cigarettes," Committee Report (41-2) (Ottawa, Canada: House of Commons of Canada, March 2015), <https://bit.ly/2E53GbD>.

⁴⁷ HESA Committee, "Vaping: Toward a Regulatory Framework for E-Cigarettes."

⁴⁸ Hilary Geller et al., "Evidence on E-Cigarettes," § Standing Committee on Health (2014), 4, <http://www.ourcommons.ca/DocumentViewer/en/41-2/HESA/meeting-37/evidence>.

⁴⁹ Derek From, Lauren Millar, and Russell Phillips, "Vaping and the Law: Comparing Legislation Across Canada," Canadian Constitution Foundation, February 2017, <http://bit.ly/2CUK1IT>.

⁵⁰ Simon Kennedy and Nick Whalen, "Evidence - HESA (42-1) - No. 5 - House of Commons of Canada," § Standing Committee on Health (2016), <https://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/meeting-5/evidence>.

⁵¹ Robert Strang et al., "Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems" (Council of Chief Medical Officers of Health, July 25, 2014).

⁵² Lauren Vogel, "Provinces Press for E-Cigarette Crackdown," *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne* 186, no. 16 (November 4, 2014): E593, <https://doi.org/10.1503/cmaj.109-4914>.

In early 2015, the ruling Federal Conservatives produced a unanimous committee report entitled “Vaping: Towards a Regulatory Framework” looking into creating a federal regulatory framework for e-cigarettes.⁵³ Before bureaucrats had time to put together a bill that responded to the reports request for a regulatory framework, a change of government occurred, putting Justin Trudeau’s center-left government in charge of passing an e-cigarette regulatory framework.⁵⁴ In November 2016, Bill S-5, created behind the scenes by Health Canada to regulate e-cigarettes at the federal level, appeared in the Senate.⁵⁵ By May 2018, S-5 received Royal Assent and shifted Canada’s e-cigarette market into wholly legal channels.⁵⁶ S-5 enshrined a regulatory framework for e-cigarettes that granted the product certain competitive advantages over the tobacco cigarette market while empowering health regulators to adequately police the new market.

3.2.3 New Zealand

Like Canada, New Zealand abandoned its previous prohibitionist regulatory stance towards e-cigarettes and is in the process of replacing it with an expansionist stance. 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.⁵⁷ The country’s Smoke-Free Environments Act of 1990 has been interpreted by regulators to prohibit advertising selling supplying or distributing nicotine-containing e-cigarettes.⁵⁸ The country’s enforcement agencies did not pay much attention to implementing such policies, however.

⁵³ L. Vogel, “Health Canada E-Cigarette Response Delayed,” *Canadian Medical Association Journal* 187, no. 12 (September 8, 2015): E374–E374, <https://doi.org/10.1503/cmaj.109-5122>; HESA Committee, “Vaping: Toward a Regulatory Framework for E-Cigarettes.”

⁵⁴ Euan McKirdy, “Canada Election: Justin Trudeau, Liberals Win Clear Majority,” CNN, October 20, 2015, <https://www.cnn.com/2015/10/19/world/canadian-election/index.html>.

⁵⁵ Miglè Malinovskytė, “New Bill Signals Fresh Approach to Canada’s e-Cig Market,” *ECigIntelligence* (blog), August 16, 2017, <https://ecigintelligence.com/new-bill-signals-fresh-approach-to-canada-e-cig-market/>.

⁵⁶ Peter Harder, “An Act to Amend the Tobacco Act and the Non-Smokers’ Health Act and to Make Consequential Amendments to Other Acts,” Pub. L. No. S-5 (2018), <https://bit.ly/2E7CfAo>.

⁵⁷ 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, <https://doi.org/10.1016/j.addbeh.2015.02.006>.

⁵⁸ Nick Wilson et al., “Potential New Regulatory Options for E-Cigarettes in New Zealand,” *NZ Med J* 128, no. 1425 (2015): 88–96.

By mid-2016, center-right National Party Associate Minister of Health Peta Korokaitangi recommended the rules allowing the sale of e-cigarettes to be allowed to begin.⁵⁹ By March 2017, the reigning right-wing government announced its intentions to pass legislation in the coming year to formally legalize the sale of e-cigarettes containing nicotine.⁶⁰ Before the new regulatory policy could be introduced to Parliament, a general election yielded a shift to a predominantly center-left coalition government led by Jacinda Ardern in September 2017.⁶¹

In March 2018, the sale of nicotine-containing e-cigarettes was unexpectedly legalized when the government lost a court case against the tobacco company Philip Morris over whether that company's heated tobacco product could be sold in the country.⁶² The judge ruled that heated tobacco, along with e-cigarettes were legal to be sold but were subject to regulations like other tobacco products.⁶³ To clarify the application of regulations that were written for other tobacco products to e-cigarettes, the government set out on a long consultation to write a new e-cigarette regulatory policy that finally appeared before Parliament in early 2020.⁶⁴ New Zealand had become poised to legalize the sale of e-cigarettes and apply an expansionist stance similar to Canada's.

3.3 Methodological 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 process of writing the selected comparative country case studies involved employing several interlocking qualitative methods to produce a narrative explanation of the cases informed by as rich a dataset as possible. This study employs the simplifying concept of the regulatory stance, to engage in a deeper exploration of the factors that lead to changes or stasis in the regulatory framework for e-cigarettes in three case countries.

⁵⁹ Nicholas Jones, "E-Cigarette Sales to Be Allowed under a New Government Proposal," *New Zealand Herald*, August 2, 2016, sec. National, <https://bit.ly/2Ji1Xnl>.

⁶⁰ Jones, "E-Cigarettes Will Be Legalised."

⁶¹ Eleanor Ainge Roy, "New Zealand Labour Signs Coalition Deal and Makes Winston Peters Deputy PM," *The Guardian*, October 24, 2017, sec. World news, <https://bit.ly/2kqfim8>.

⁶² Marius Zaharia and Diane Craft, "New Zealand Court Gives Philip Morris Nod to Sell Heated Tobacco..." *Reuters*, March 27, 2018, <https://reut.rs/2P5tJKD>.

⁶³ Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC.

⁶⁴ Felix Walton, "Cheat Sheet: What's the Deal with the New Vaping Law?," *The Spinoff* (blog), February 25, 2020, <https://thespinoff.co.nz/politics/25-02-2020/cheat-sheet-whats-the-deal-with-the-new-vaping-law/>.

Bringing the goal of regulation forward sharpens the focus on why individual actors might support or oppose policy change. I use Kingdon's framework to divide and organize events, actors, and forces in the cases into streams that are more easily compared across and within the cases. The documents and key informant interviews provide deeper color and explanation to explain why events progressed the way they did and to eventually explain what caused Australia to maintain a prohibitionist stance towards e-cigarettes while Canada and New Zealand abandoned their old stances for new expansionist policies. This section wraps up with an explanation of how a regulatory stance is determined for any market and an explanation of the policy domains that I used to assess the regulatory stances of case countries.

3.3.1 Substantive Division of the Cases via Kingdon's Multiple Streams Approach

John Kingdon's classic work, "Agendas and Alternatives" proposed the Multiple Streams Approach as a framework to understand the policymaking process and to describe "when an idea's time has come".⁶⁵ The Multiple Streams Approach is a cornerstone of the broad theoretical literature on the public policy process.⁶⁶ While it was not originally designed to enable comparative studies, it has been successfully argued that the Multiple Streams Approach implicitly 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.⁶⁷ 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 policy window where change is possible. The previous chapter laid out the motivation for using the multiple streams as well as introduced the explanatory factors I will test to determine if they are significant predictors of policy change or stasis in the cases ahead.

3.3.2 Document Collection

A primary round of document collection from key policy and media sources enabled the creation of timelines of the events that shaped e-cigarette regulatory stances in case countries. A follow-on round of document collection identified key actors from each of Kingdon's streams in the

⁶⁵ Kingdon, *Agendas, Alternatives, and Public Policies*.

⁶⁶ Cairney and Jones, "Kingdon's Multiple Streams Approach."

⁶⁷ Scott L. Greer, *Territorial Politics and Health Policy: UK Health Policy in Comparative Perspective*, Devolution Series (Manchester ; New York : New York: Manchester University Press, 2004), chap. 1.

important events on the timeline. These timelines were used as the outlines from which case studies grew into fully-formed narrative chapters. Policy-relevant documents from bureaucratic agencies and legislative bodies were collected as well. Media stories about the use, the effects, and the regulation of e-cigarettes in each country were collected from high-quality sources in NexisUni, Factiva, and the websites of leading local news agencies. This information was used to sketch a portrait of each substantive division in each case country. Hundreds of documents were collected in each case and the data drawn from these sources was weaved into the narratives that made up the backbone of each case study that can be checked against the public record.

3.3.3 Key Informant Interviews

The centerpiece of the data collection for this project were key informant interviews with participants in the policy process of each case country. In-person interviews with key stakeholders were conducted between August and November 2018 in Ottawa, Canada; Brisbane, Canberra, Melbourne and Sydney, Australia; and Auckland, Christchurch, and Wellington, New Zealand. The rest of the interviews were performed remotely via telephone or video conference. Memos were written by the author on a near-daily basis to track the thoughts and perspectives being developed during this time in country. Interviewees were asked at the end of a semi-structured interview if they would recommend speaking to other key informants, in a snowball technique. The author interviewed subjects until practical saturation of the cases was reached.

A semi-structured interview protocol (See Appendix A on page 243) was developed and utilized to collect as detailed a picture as possible of the policy process in the Multiple Streams Approach. The interviews and documents collected were employed to triangulate the events and rationales underlying key decisions in the regulatory process and to establish a detailed history of events that led up to policy change or a lack thereof.

Table 4: Key Informant Interviews by Category of Respondent

	Australia			Canada			New Zealand		
	Success	Failure	Success Rate	Success	Failure	Success Rate	Success	Failure	Success Rate
<i>Academic</i>	4	4	50%	5	2	71%	4	2	67%
<i>Bureaucrat</i>	6	8	43%	9	10	47%	4	6	40%
<i>Health NGO</i>	12	1	92%	6	5	55%	9	8	53%
<i>Industry Advocate</i>	1	4	20%	3	3	50%	3	2	60%
<i>Non-Health NGO</i>	7	4	64%	1	1	50%	7	1	88%

<i>Politician</i>	3	9	25%	3	11	21%	5	5	50%
<i>Total</i>	33	30	52%	27	32	46%	32	27	54%

Interviews were sought from six types of key informants: Academics, Bureaucrats, Health Non-Governmental Organizations, Tobacco and Vaping Industry Advocates, Non-Health Non-Governmental Organizations, and Politicians. Table 4 displays the number of respondents who were interviewed for each type of informant in each case country. Interviews were conducted until saturation was reached in each case study. Overall, 50.8% (92 of 181) of persons who were contacted by e-mail, video chat, or phone calls were eventually granted an interview with the author, although that rate varied across informant type. Non-Health Non-Governmental Organizations and Health Non-Governmental Organizations were the most likely to grant interviews, at rates of 71.4% and 65.9%, respectively. Politicians and Tobacco and Vaping Industry Advocates were the least likely to grant interviews, doing so at rates of 30.6% and 43.8% respectively. While these varied response rates may have lessened the depth of the contributions from these actors, it seems as though members of the policy community, rather than the political community played a pivotal role in determining the outcomes in each case study. This made that group’s deeper contribution to the interviewee pool that much more consequential to the findings.

The interviews were transcribed using the aid of the artificial intelligence software Trint.⁶⁸ The interviews stretched over 60 hours in length and produced transcripts that stretched beyond 480,000 words over 850 pages of text. This project did not contain a goal of quantifying responses into thematic categories and the wide stratification across place and occupation would have made that process even less fruitful. Instead, the project intended to use information gathered from these interviews to fill in the gaps in stories gleaned from the public record. This required that the next step in data processing was to read and re-read the transcripts to become immersed and familiar with their extensive content. Initial reads focused on correcting the content for grammar and accuracy. Secondary reads focused on extracting interesting snippets that were highlighted and included in a database. Tertiary work examined some of the binary question options and logging those responses into a separate datafile. Although foregrounded

⁶⁸ Mark Boas, Mark Panaghiston, and Laurian Gridinoc, *Trint* (London, UK, 2017), <https://trint.com/>.

analyses of these binary questions were dropped due to concerns of representativeness, the issue of a perceived failure in tobacco control was highlighted in the problem stream in case study.

Where referenced in this study, insights gathered from interviews are referenced by the first letter of the case country where the interviewee was based (A=Australia; C=Canada; N=New Zealand), by the second and third letters, which reflect the chronological order in which the interviews were conducted, and by the timestamp in minutes in the interview where the information in question was shared, preceded by the @ symbol. To protect the identity of respondents, additional identifying information was kept confidential.

3.3.4 Determine the Regulatory Stance for a Market

As the very concept of a regulatory stance is one of the more novel contributions of this study, I must explain how a regulatory stance for a market was assessed in this study. The process by which I would determine a jurisdiction's regulatory stance for a selected market followed the nine steps of the guidelines illustrated here:

1. **Define the market** being described, as widely or as narrowly as is necessary.

Here, as explained in the scoping conditions (see 3.3.4 on page 62) and the case selection (see 3.1 on page 44) we are examining nicotine-containing e-cigarettes in three case countries. Narrower definitions enable the sketching of more precise regulatory frameworks. Wider definitions are more likely to encompass subjects confronted by political actors.

2. **Determine alternative classifications** that could be possible for similarly situated markets.

These will likely be codified in statute.

3. **Determine how similarly situated markets are sorted** into alternative classifications.

Note which is the default classification (requires the least stringent standards to be met) and the process by which the sorting happens (premarket approval, notification, etc.).

4. **Determine the policies used to regulate the market** in each alternative classification as extensively as possible.
5. **Group relevant policies into parsimonious domains.**

A policy domain should cover a group of related policies and should be used to simplify the enormous complexity of the laws regarding an individual market. The policy domains for e-cigarettes are elaborated upon in the following section on page 64.

6. Identify the market that is a primary substitute for the one being studied.

Regulators can consider more than one substitute product at a time when constructing a regulatory framework for a product. For example, if a regulator wishes to adopt a contractionist policy towards both tobacco cigarettes and nicotine-containing e-cigarettes, they could also be considering using nicotine replacement products that have been approved as therapeutics as a substitute of choice. However, in the current exercise, examining a single substitute product is parsimonious.

We must note that there is always a substitute market to consider. Demand for any market, new or old, has some precursor or alternative.⁶⁹ Utility curves and budget allocation problems always leave the option for gaining some utility by purchasing alternative products. In this sense, almost any product that is not a close complement can be thought of as a substitute. More importantly, we are considering close substitute products here.

7. Determine the advantages or disadvantages granted to each market relative to its substitute within each policy domain and alternative classification.

The relative importance of each advantage or disadvantage in terms of its effect on the ability for a market to grow or shrink should be considered and weighted in the final analysis.

8. Determine where on the range of regulatory stances the balance of policy places the regulation of any market within each domain and alternative classification.

If the market has lots of advantages relative to its substitute, its stance is on the expansionist end of the range. If the market has lots of disadvantages relative to its substitute, its stance is on the contractionist end of the range. If the market is on equal footing with its substitute, its stance should be placed in the middle of the range. As this is a range, certain markets will be subject to

⁶⁹ Christopher Chen, "Food and Drug Administration Food Standards of Identity: Consumer Protection through the Regulation of Product Information.," *Food & Drug Law Journal* 47, no. 2 (1992): 185–206.

regulatory stances placed between points on the range to reflect the relative strength of such a stance.

9. **Assemble a regulatory framework with the resultant regulatory stance for the market,** illustrating the connections between each alternative classification and the policy domains.

The regulatory stance can only be determined within an alternative classification. The contribution of each policy domain to the final regulatory stance is likely unequal, but this proposition should be subject to empirical testing.

This process was conducted in detail for e-cigarettes in the selected case countries at several points in time for the study, and those findings are reported in the case study chapters. A more informal version of the process was conducted to produce the regulatory stances towards e-cigarettes of the countries listed in Table 3. The nine-step process described above is generic and flexible enough that it may be utilized to determine the regulatory stances of other markets in other jurisdictions.

3.3.5 E-Cigarette Regulatory Policy Domains

For this study, five parsimonious policy domains are assessed in the regulatory framework for nicotine-containing e-cigarettes; *usage, marketing, retail, pricing, and product standards*. Each domain may contain dozens of regulations, but for the sake of clarity, a regulatory stance can be adopted within each domain that can be described by its position on the range of regulatory stances. These domains arose as particularly relevant in the case at hand, as policymakers believed these policies shaped the nascent market being regulated.

Table 5 lays out the broad range of policy options that countries can adopt when regulating the novel market of nicotine-containing e-cigarettes in parsimonious policy domains. The characterization of a country's entire regulatory policy choices for a product pathway will not necessarily cleanly fit into a single column, but the process elucidated in 3.3.4 enables a determination of the overall regulatory stance. The table can be read horizontally to understand how change within a policy domain varies across the range of regulatory stances. Alternatively, the table can be read vertically to determine what an ideal-type policy at a single point on the range of regulatory stances might resemble.

Table 5: Policy Domains Across the Range of Regulatory Stances

Policy Domain	Prohibitionist	Contractionist	Permissive	Expansionist	Universalist
Usage	May not use	May not use where substitutes can	Used where substitutes can	Used where substitutes cannot	Used anywhere
Marketing	May not sell	More restrictive than substitutes	Parity with substitutes	Less restrictive than substitutes	Much less restrictive than substitutes
Retail	May not sell	More restrictive than substitutes	Parity with substitutes	Less restrictive than substitutes	Much less restrictive than substitutes
Pricing	May not sell	More tax than substitutes	Tax parity with substitutes	Less tax than substitutes	Subsidized to cost less than substitutes
Product Standards	May not sell	Less appealing/ stricter than substitutes	As appealing/ strict as substitutes	More appealing/ less strict than substitutes	Much more appealing/ less strict than substitutes

The first policy domain listed in Table 5 refers to policies regulating where e-cigarettes may be used. The key issue here is whether e-cigarettes are included in pre-existing regulations over the use of substitute products (read, tobacco cigarettes). The scientific literature establishing the harms of secondhand tobacco smoke is conclusive and important public health gains have been made in the name of protecting bystanders from the harms of secondhand smoke.⁷⁰ The evidence around the health effects of secondhand vapor is nascent, to say the least.⁷¹ But, concerns over the use of cigarette-like products in public space may genuinely confuse the implementation and enforcement of pre-existing smoking bans which rely on social pressure and cues to function.⁷² I assume giving people more places and times to use e-cigarettes relative to tobacco cigarettes encourages market growth while restricting those places and times of use may shrink the market. This policy domain, along with the retail policy domain, is often controlled by local governments, thereby introducing some heterogeneity to the measure within a country at points in time where localities have not reached a consensus policy position.

The second policy domain considered is the broad concept of marketing regulation. This includes advertising, promotion, sponsorship, and the multitudinous other ways in which companies spend money to try to entice consumers to purchase their products. The relative strength of restrictions placed on e-cigarette marketing efforts relative to tobacco cigarettes will determine

⁷⁰ Office on Smoking and Health (US), *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*, Publications and Reports of the Surgeon General (Atlanta (GA): Centers for Disease Control and Prevention (US), 2006), <http://www.ncbi.nlm.nih.gov/books/NBK44324/>.

⁷¹ Cheryl L. Marcham and John P. Springston, “Electronic Cigarettes in the Indoor Environment,” *Reviews on Environmental Health* 34, no. 2 (2019): 105–124, <https://doi.org/10.1515/reveh-2019-0012>.

⁷² Allison W. Watts et al., “Do Students’ Perceptions of School Smoking Policies Influence Where Students Smoke?: Canada’s Youth Smoking Survey,” *Cancer Causes & Control* 21, no. 12 (2010): 2085–92.

the placement of a jurisdiction's policy regime within this domain. If e-cigarettes are given significant marketing advantages, particularly in markets where cigarette advertising is heavily restricted, I expect that decision to redound to the growth of the e-cigarette market.

Consequently, if the marketing of the novel products is strangled, then we would expect the growth of the market to be requisitely smaller than if all marketing forces were unleashed.

Particular attention will be placed on examining the regulations around the messaging allowed in e-cigarette marketing materials.

The third policy domain considered is that of retail policy. This refers to the question of who may sell e-cigarettes to whom and the way that sale is governed. Issues such as licensure and age restrictions will be included here. If the sale of e-cigarettes is regulated in a laxer manner than cigarettes or if the product is more widely available through retailers than cigarettes, that policy choice will cause the market for the products to grow relative to a baseline. If retail restrictions are tougher or if the availability of e-cigarettes at the retail level is less than substitute goods, the market size will be smaller.

The fourth policy domain is that of pricing, which includes regulations on price as well as on taxation. It is well understood that such policies are the strongest available tools to reduce the use of tobacco products.⁷³ Furthermore, scholars argue that excise tax rates for various tobacco products should be set in proportion to their health risks.⁷⁴ Doing so may create a competitive advantage for less-risky products, provided differential tax rates translate into differentially lower product prices.⁷⁵ A contractionist pricing policy would shrink a market by creating a competitive disadvantage relative to substitute products by taxing a product at a higher rate than substitutes. Conversely, an expansionist policy may seek to indirectly create a competitive advantage over a substitute product by providing a tax break. Finally, a universalist policy would

⁷³ WHO, *WHO Technical Manual on Tobacco Tax Administration* (Geneva, Switzerland: World Health Organization, 2010), <http://bit.ly/KmkoYi>.

⁷⁴ Frank J. Chaloupka, David Sweanor, and Kenneth E. Warner, "Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products," *The New England Journal of Medicine* 373, no. 7 (August 13, 2015): 594–97, <https://doi.org/10.1056/NEJMp1505710>.

⁷⁵ Alex C Liber, Jeffrey M Drope, and Michal Stoklosa, "Combustible Cigarettes Cost Less to Use than E-Cigarettes: Global Evidence and Tax Policy Implications," *Tobacco Control* 26, no. 2 (March 2017): 158–63, <https://doi.org/10.1136/tobaccocontrol-2015-052874>.

subsidize one market sector to directly create an incentive for a market to grow as large as possible.

The fifth policy domain to be considered is that of product standards, a broad category that outlines what a product can contain or what it must resemble if it is placed in a particular regulatory pathway. For nicotine-containing e-cigarettes, the product standards domain includes regulations on flavoring, ingredients, child safety requirements, nicotine concentration, as well as packaging and labeling. As before, if e-cigarettes are granted exemptions from policies that are applied to tobacco cigarettes like flavoring restrictions or plain packaging, we should expect the e-cigarette market to grow more quickly. If the products are subject to policies that tobacco cigarettes are not subject to, like nicotine concentration limits, then we should expect a slower rate of market growth. The most likely outcome for this policy domain is that both contractionist and expansionist policies will be applied to e-cigarettes, potentially negating one effect or the other.

3.4 Ethical Considerations

This project received a notice of exemption (HUM00128675) from the University of Michigan's Health Sciences and Behavioral Sciences Institutional Review Board on May 10, 2018. The project involved only minimal risk human subjects research. Informed consent from key informant interviewees was sought before recorded interviews to express the risks that participating in this work may pose to the interviewee. Because this work took place in high-resource countries, the risk of subjects being adversely influenced by a power imbalance in favor of the researcher was remote. This project did not involve working with vulnerable groups. To mitigate the risk of a power imbalance, interviewees were not compensated for their time, and interviews were mostly limited to an hour in length. The effort to publish and share the findings from this study is aimed at advancing the cause of employing regulation to lessen the harms of markets on human health. The findings can be taken into consideration by the communities that were studied and employed in manners that might enable them to reach their pro-social goals.

3.5 Generalizability

Before moving on to the case studies themselves, it is useful to situate what is going to be studied in terms of how the findings here may be able to generalize elsewhere. In the strictest empirical sense, I am studying a case of the regulatory politics of nicotine-containing e-cigarettes in three very similar countries. My findings will highlight the explanatory factors that spurred along a change in the regulatory stance in New Zealand and Canada. These factors may be able to be exploited by those seeking to achieve similar policy change for e-cigarettes in Australia. They may also apply to one of the twenty-plus other countries that may seek to exit a prohibitionist stance for e-cigarettes. These factors could apply to other novel tobacco products like heated tobacco as well. Going further afield, these factors could be extrapolated for use into any market seeking to leave a prohibitionist regulatory stance. The utility of these explanations requires further testing. The story of e-cigarette regulation in Australia, Canada, and New Zealand, then, contains the bud of lessons that could run in a lot of diverse directions, but as always, more research is needed.

3.6 Conclusion

The methods laid out in this chapter enabled the comparative case study to proceed in an orderly and logical fashion from data gathering, to summary, to analysis, and finally, interpretation. Special care was taken to apply these methods to examine the influence of the factors laid out in Chapter 2 as being potentially important explanations of variance. The following chapters employ the methods described here to test those hypotheses in as rigorous a fashion as my methods will allow. The findings from those tests will be summarized in Chapter 7.

Chapter 4 Australia

Stop Trying to Make “We’re Failing” Happen

In January 1948, a seed merchant in Perth, Ross Edwin Symonds, was arrested and charged with the offense of selling a bottle of nicotine insecticide that was not labeled as a poison.¹ Mr. Symonds pleaded not guilty to the charge, claiming that nicotine was not described as a poison in Western Australia’s Pharmacy and Poisons Act, while the Prosecution argued the contrary. Mr. Symonds had been warned two years prior by the area Pharmaceutical Council inspector that he needed to label the bottles of nicotine that he sold as poison to avoid repeating a mysterious “recent serious accident”. Symonds was ultimately let off with a warning, though it is unclear from the historical record why this happened.²

Before Australia’s establishment as a federation in 1900, its progenitor colonies had already passed laws regulating and controlling the use of poisons within their borders.³ Australian newspapers of the era are littered with accounts of suicides and accidental poisonings of people drinking nicotine sulfate.⁴ In a period where the risk of acute poisonings from liquid nicotine insecticide seemed to be a much greater worry than the potential chronic harm from smoked tobacco,⁵ Australia set up a regulatory framework that strictly regulated access for consumers to liquid nicotine while preserving exemptions in poisons laws for the purportedly much safer nicotine source of tobacco prepared for smoking.

At least as far back as the 1950s, nicotine was listed by the National Health and Medical Research Council (NHMRC), the peak medical agency in Australia, on the uniform schedule of

¹ “Court Argument:Is Nicotine Poison,” *Daily News (Perth, WA : 1882 - 1950)*, February 25, 1948.

² “MERCHANT IS CAUTIONED,” *Daily News (Perth, WA : 1882 - 1950)*, March 11, 1948.

³ John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Woden, ACT: Therapeutic Goods Administration, 2007), 1, <https://bit.ly/2Z1YaRC>.

⁴ “Dead Woman Drank Enough Poison To Kill Hundreds,” *Daily News (Perth, WA : 1882 - 1950)*, July 15, 1948; “GOODBYE, MUM!,” *Manjimup Mail and Jardee-Pemberton-Northcliffe Press (WA : 1927 - 1950)*, November 28, 1941; “POISONED SELF WITH NICOTINE,” *Daily Telegraph (Sydney, NSW : 1931 - 1954)*, June 15, 1940.

⁵ James M. Faulkner, “NICOTINE POISONING BY ABSORPTION THROUGH THE SKIN,” *Journal of the American Medical Association* 100, no. 21 (May 27, 1933): 1664–65, <https://doi.org/10.1001/jama.1933.02740210012005>.

poisons that was recommended to be adopted by all regional governments.⁶ In 1982, the NHMRC clarified that tobacco would be exempted from its poisons scheduling.⁷ This decision was later modified to only exempt tobacco prepared for smoking as Australia banned the sale of oral tobacco in 1986.⁸ Largely, this was seen as a matter of practicality, as it avoided creating conflicts between central and regional government regulations on cigarettes.⁹ By 1995, proposals were floated by the Western Australia chapter of the Australian Medical Association to remove the exemption from Schedule 7 for nicotine that was prepared for smoking.¹⁰ This action would have classified cigarettes as a dangerous poison and applied rules that regulated their manufacture, use, and sale, accordingly. Several Australian tobacco companies countered this effort by releasing a report detailing the lost consumer surplus that would be suffered from moving all cigarette sales to pharmacies and the requisite harms that would be suffered from labeling cigarettes as a poison.¹¹ In the end, the proposal did not receive the endorsement of the government of the day, and the exemption for tobacco prepared for smoking from the poisons schedule remained.

In the last decade, several Australian policy actors have examined the relative treatment of liquid nicotine and nicotine contained in tobacco prepared for smoking and concluded the regulatory framework has been set up backward.¹² Tobacco cigarettes, a more lethal product than liquid nicotine used in e-cigarettes, are available at every corner store in Australia, albeit subject to one of the world's most strongly contractionist regulatory stances. Meanwhile, nicotine-containing e-cigarettes are not legally available for sale in the country. Would-be policy entrepreneurs have set out to change the country's regulatory stance. But thus far they have failed to create any change.

⁶ Wreidt and Anderson, "QUESTION — POISONS" (1971), <https://bit.ly/2ktKm49>; AAA @ 11

⁷ Commonwealth Department of Health, "Tobacco Is Specifically Exempted from the Uniform Poisons Schedule, Standard as Adopted by the National Health and Medical Research Council" (94th Session, October 1982).

⁸ Connolly, "Smokeless Tobacco in Developed Countries."

⁹ AAA @ 13

¹⁰ Gabrielle Chan, "AMA in Bid to Put Nicotine on Poisons List," *The Australian*, November 27, 1995, NexisUni.

¹¹ ACIL Economics and Policy, "A REVIEW OF THE ECONOMICS OF LISTING TOBACCO PRODUCTS ON THE POISONS SCHEDULE" (Tobacco Institute Australia, December 1995), xqbj0101, Truth Tobacco Industry Documents, <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=xqbj0101>.

¹² Coral Gartner and Marilyn Bromberg, "One Does Not Simply Sell E-Cigarettes in Australia: An Overview of Australian e-Cigarette Regulations," in *The Regulation of E-Cigarettes*, ed. Lukasz Gruszczynski, Elgar Studies in Health and the Law (Cheltenham: Edward Elgar Publishing Limited, 2019), 275, <http://www.elgaronline.com/view/edcoll/9781788970457/9781788970457.00021.xml>.

In June 2018, a toddler in Victoria died after drinking nicotine-containing liquid from a bottle his mother was using to refill her e-cigarette¹³. The mother was not found to be negligent in the case. But, the echoes of the consequences of liquid nicotine being possessed in the home are unmistakable.

This chapter shows why Australia's regulatory stance towards the e-cigarette market has not changed. The reasons why change has not come to the Australian e-cigarette market are three-fold. First, no significant problem with the country's e-cigarette regulatory stance has been convincingly advanced in the media that could be solved by changing the prevailing e-cigarette regulatory framework. Second, lacking any impetus to find common ground, THR advocates and the broader Australian public health policy community, have failed to find a consensus alternative regulatory policy to the status quo that is acceptable to mainstream political parties. Finally, mainstream political parties have determined there was little political benefit and significant risk to changing the regulatory stance towards e-cigarettes. The confluence of these factors enabled Australia to maintain an e-cigarette regulatory stance that descended directly from a past era's concerns regarding liquid nicotine's reputation as a poison.

4.1 Regulatory Stances Towards E-Cigarettes

Australia does not have a legal market for nicotine-containing e-cigarettes, but some 120,000 people claimed to have currently used e-cigarettes in 2016.¹⁴ THR advocates repeatedly claim (without citing data) that nearly double this figure were using e-cigarettes by 2018.¹⁵ Growth in the market has been anecdotally linked to rapidly rising tobacco taxes which have made Australian cigarettes the most expensive in the world.¹⁶ Regulators are aware that vapers have gained access to nicotine-containing e-cigarettes even though such products are prohibited under state and territory law.¹⁷ Figure 8 illustrates Australia's current nicotine-containing e-cigarette regulatory framework in visual terms.

¹³ Australian Associated Press, "Toddler Died after Consuming Liquid Nicotine While Mother's Head Was Turned, Coroner Says," *The Guardian*, July 8, 2019, sec. Australia news, <https://bit.ly/3146iT7>.

¹⁴ It is not known what proportion of these people are using nicotine-containing e-cigarettes. Moira Hewitt, "National Drug Strategy Household Survey 2016" (ADA Dataverse, 2018), <https://bit.ly/2IDIcPB>.

¹⁵ AT, AN, AR

¹⁶ Jill Stark, "Banned E-Cigarettes May Be a Health Hazard, but Buying Them's a Wheeze," *Sunday Age*, December 12, 2010, First edition, sec. News, Lexis Nexis.

¹⁷ AI @ 13

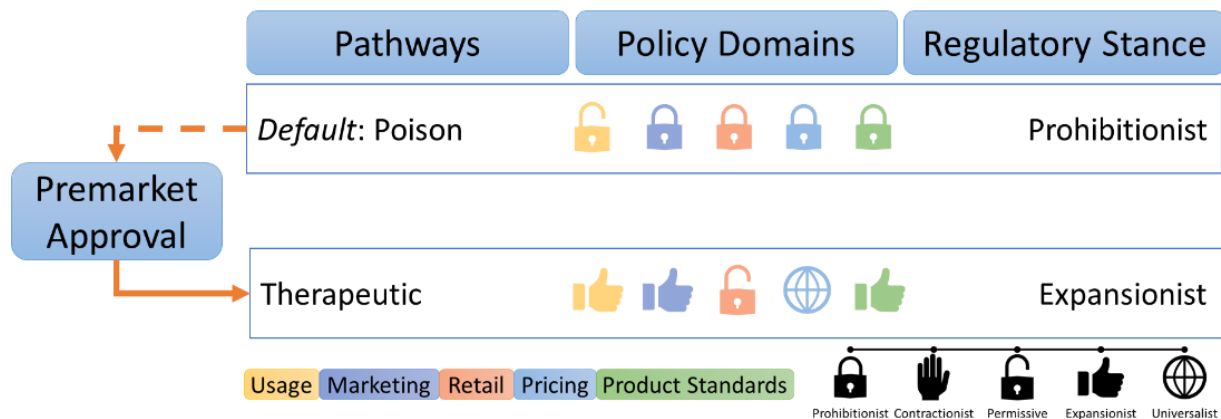


Figure 8: Australia's Regulatory Framework for Nicotine-Containing E-Cigarettes

Australia maintains two product pathways for nicotine-containing e-cigarettes. The first pathway classifies all nicotine-containing products, that are not specifically exempt from poison regulations, to be dangerous poisons. As will be covered below, nicotine-containing e-liquids have not received such an exemption from the TGA and are thereby subjected to a default pathway that ends in a prohibitionist regulatory stance. E-cigarette skeptics point out that a separate pathway to market for the products does exist, wherein if the TGA receives and approves a premarket application to sell an e-cigarette as a therapeutic, that product would be granted the benefits of an expansionist regulatory stance. However, no manufacturer has yet proven the safety, quality, and performance of such a device as a smoking cessation product in an application to the TGA making the therapeutic pathway for e-cigarettes largely a theoretical exercise to date. However, it is worth detailing the policy domains that apply to the product in each pathway to understanding why they are assigned their respective regulatory stances.

The use of e-cigarettes has been restricted to the same places as tobacco cigarettes in every Australian state and territory.¹⁸ This puts e-cigarettes on equal footing with tobacco cigarettes and is the only permissive policy domain afforded to the market in the country. Outside of this, every other policy for e-cigarettes should was prohibitionist.

E-cigarette marketing is conducted in an informal manner in Australia. Such activities are not regulated by specialized rules from the Commonwealth government that do not apply equally to all consumer products (e.g., truth-in-advertising standards). Advertisements for a therapeutic

¹⁸ Kyle Eu Soon Saw et al., "The Medium Is Not the Message: A Content Analysis of Public Information about Vaping Product Regulations in Australia," *Drug and Alcohol Review* 38, no. 5 (2019): 569–78, <https://doi.org/10.1111/dar.12961>.

device would be more widespread than is allowed under the strict tobacco advertising ban in effect for cigarettes. Smoking cessation devices are marketed under relatively lax guidelines in the country, and a future therapeutic e-cigarette would be no exception to this standard.¹⁹

E-cigarettes in Australia are not legally available for retail sale, which places them at a huge disadvantage compared to tobacco cigarettes, which are one of the most widely available consumer goods in the country.²⁰ If an e-cigarette was approved for sale as a therapeutic, the product would have certain retail advantages over tobacco cigarettes, including being subject to a lower minimum age of purchase standards or not being subject to a retail display ban, and some disadvantages like not being as widely available for sale or requiring a doctor's prescription to be able to purchase the product.

Excise taxes have been solely collected by the Commonwealth government since state and territory tobacco retailer fees were invalidated by the courts in 1997.²¹ Due to the lack of legal products on the market, the Commonwealth government has no specific regulations that apply to e-cigarette taxation or pricing. If an e-cigarette were to be approved as a therapeutic good, that product like, other smoking cessation therapies could be subsidized by the Repatriation Pharmaceutical Benefits scheme which would substantially cut the cost of using the product.²²

As e-cigarettes are not yet legally available in Australia, no product standards have been created yet at the commonwealth level. If an e-cigarette were to be placed in the therapeutic pathway, it would gain distinct advantages boosting its growth potential. A therapeutic product would not be subject to flavoring restrictions if the manufacturer proved that a flavored product met safety, quality, and performance standards.²³ Importantly, a therapeutic e-cigarette would not be subject to the plain packaging and graphic health warning regulations that apply to tobacco products,

¹⁹ Alexandra Roach, "JWT Sydney Wins Johnson & Johnson's Nicorette and Regaine," AdNews, March 27, 2012, <https://bit.ly/2m07jg1>.

²⁰ AW; Generally; Joseph R. DiFranza, "Research Opportunities Concerning Youth and the Family Smoking Prevention and Tobacco Control Act," *Nicotine & Tobacco Research* 14, no. 1 (January 2012): 54–61, <https://doi.org/10.1093/ntr/ntq149>.

²¹ M Scollo and M Bayly, "13.2 Tobacco Taxes in Australia," in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2019), <https://www.tobaccoinaustralia.org.au/chapter-13-taxation/13-2-tobacco-taxes-in-australia>.

²² EM Greenhalgh, S Stillman, and C Ford, "7.16 Pharmacotherapies," in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2018), <https://www.tobaccoinaustralia.org.au/chapter-7-cessation/7-16-pharmacotherapy>.

²³ Johnson & Johnson Pacific, "QuickMist Cool Berry," NICORETTE® Australia, November 24, 2016, <https://www.nicorette.com.au/QuickMistBerry>.

making them potentially more pleasant to own. These factors could combine to produce a therapeutic product that is more appealing to users than tobacco cigarettes.

Law enforcement officers have viewed efforts to sell the devices as breaking state law if the liquid contains nicotine. But, because police do not carry nicotine testing kits on their person, they have only infrequently cracked down on retailers. Thus far, just one person in Australia has been prosecuted for possessing nicotine e-liquid.²⁴

The prohibitionist framework has kept transnational tobacco companies from entering the market, leaving small businesses as the only players. The requisite unprofessional nature of the Australian e-cigarette industry has enabled a narrative about its legal uncertainty and proclivity for spreading what was perceived to be misinformation about vaping to spread.²⁵ Mislabeling has been a big problem wherein e-liquids labeled as containing no nicotine are consistently found to contain nicotine.²⁶ Initial e-liquid testing efforts in New South Wales found 70% of all e-liquid sold in vape shops contained some nicotine.²⁷ Legally evasive behavior on the part of small e-cigarette companies about truth-in-advertising standards, decisions to relocate headquarters abroad, and to set up shops that only sell component pieces of e-cigarettes to skirt local prohibitions on sales of whole devices deepened this perception.²⁸

4.1.1 Institutional Actors

Australian regulatory policy has been led by the development of strong institutions with a great deal of trust placed in their hands to protect the Australian people. These institutions had the authority to set initial policy regulating e-cigarettes to meet their preferences and have created the inertia that tobacco harm reduction (THR) advocates have struggled to overcome ever since. Commonwealth e-cigarette regulatory policy was formed over time as the product of consensus made among a policy community largely defined by the influence of peak health bodies as well as State and Commonwealth government health departments over politicians. Politicians across the political spectrum have been able to point to these institutional decisions as the basis for their

²⁴ Tim Clarke, "Court Ruling Keeps Ban on E-Cigarettes," *The West Australian*, March 11, 2016, First edition, sec. News.

²⁵ AE; AN @40

²⁶ Chivers et al., "Nicotine and Other Potentially Harmful Compounds in 'Nicotine-Free' e-Cigarette Liquids in Australia."

²⁷ AV @ 12

²⁸ AI @ 53-54; AT @ 36

policy positions and few actors believe that it is wise to overtly challenge the conclusions of institutions.

The only Commonwealth agency that is currently tasked with regulating the e-cigarette market is the Australian Competition and Consumer Commission (ACCC). The Therapeutic Goods Administration (TGA) and National Health and Medical Research Council (NHMRC) have each weighed in on the matter of nicotine e-cigarettes several times each. The NHMRC and TGA have consistently concluded that maintaining Australia's current e-cigarette regulatory framework is appropriate and is supported by the relevant scientific evidence. The combined influence of these regulatory agencies' decisions about e-cigarettes over political decisionmakers has been palpable and serves to maintain regulatory policy stasis.

4.1.1.1 ACCC

The ACCC enforces truth in advertising standards, a set of rules stating companies cannot lie to consumers.²⁹ In 2015, ACCC bureaucrats became upset when they discovered everyone from 7-Eleven's to pharmacies in the country were selling e-cigarettes with problematic claims of absolute safety.³⁰ The agency confronted all sorts of claims being made by e-cigarette retailers claiming that their wares were 'safe' and 'contained no carcinogens', 'expelled water vapor', and 'contained no harmful chemicals'.³¹ The ACCC also concluded that cartoons and flavoring were being employed to market e-cigarettes to children.³²

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.³³ All three companies later defaulted before the

²⁹ AM @ 8

³⁰ Frank Chung, "E-Cigarette Makers Facing Court over 'No Toxic Chemicals' Claims," NewsComAu, June 20, 2016, <https://bit.ly/2TveQQC>.

³¹ Amy Bainbridge, "Carcinogen Formaldehyde Found in Some E-Cigarettes, ACCC Alleges," Text, ABC News, June 20, 2016, <https://www.abc.net.au/news/2016-06-20/tests-allege-e-cigarettes-have-cancer-causing-ingredients/7526364>.

³² Product Safety Australia, "E-Cigarette Companies to Pay Penalties," Text, Product Safety Australia, May 8, 2017, <https://bit.ly/2ZV2cwl>.

³³ A further challenge faced by the regulator was that no e-cigarette company had tested the chemicals in their devices or the vapor that their customers were inhaling in laboratories. Establishing the presence of formaldehyde, a carcinogen, in the products was particularly tricky because the heating of propylene glycol (a primary ingredient in e-liquid) produces formaldehyde. So, while formaldehyde may not be present in the e-liquid bottle, it is produced at sufficiently high temperatures in a high-power e-cigarette. Product Safety Australia; Maciej Lukasz Goniewicz et al., "Levels of Selected Carcinogens and Toxicants in Vapor from Electronic Cigarettes," *Tobacco Control* 23, no. 2 (March 2014): 133–39, <https://doi.org/10.1136/tobaccocontrol-2012-050859>.

Commonwealth government could collect monetary judgments.³⁴ The ACCC saw absolute claims of safety and chemical contents disappear after their enforcement actions.

4.1.1.2 NHMRC

The NHMRC is the senior advisory body to the Commonwealth government on health and medical matters. The agency also serves as the largest funder of health and medical research in the country. NHMRC's governance structure is made up of chief medical officers of the Commonwealth and regional governments states and territories who meet and make key decisions.

In March of 2015, the NHMRC's released its peer-reviewed CEO Statement on E-cigarettes which found insufficient evidence for the safety of the products. It concluded, "there is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms".³⁵ The statement recommended health authorities utilize a precautionary approach to e-cigarettes until such evidence of their safety and efficacy was produced. It has not become public or even internal bureaucratic knowledge who wrote the CEO statement, although some interviewees claimed the NHMRC report reflects the combined decision of all the states.³⁶ In 2017, NHMRC updated the CEO statement to add greater detail and more recent research.³⁷ In sum, the expertise of the NHMRC has been leveraged to maintain regulatory policy stasis on e-cigarettes, as its reports have been repeatedly cited to justify support for the country's prohibitionist regulatory stance.³⁸

4.1.1.3 TGA

In 1989, the Commonwealth government passed the Therapeutic Goods Act which, along with creating the modern Therapeutic Goods Administration (TGA), an institution that regulates the country's supply of medicines and chemicals, shifted control of poisons scheduling from the states and territories to the Commonwealth government.³⁹ Australians broadly perceive the TGA

³⁴ Gartner and Bromberg, "One Does Not Simply Sell E-Cigarettes in Australia," 263.

³⁵ Australian Government Department of Health Therapeutic Goods Administration, "Electronic Cigarettes," Text, Therapeutic Goods Administration (TGA), March 30, 2015, <https://bit.ly/29IR7cS>.

³⁶ AH @ 45, AI @ 8, AF2 @ 58-59

³⁷ Anne Kelso, "CEO Statement: Electronic Cigarettes," NHMRC, April 3, 2017, <https://bit.ly/2McnbrB>.

³⁸ Martin, "Greg Hunt Digs in on Opposition to E-Cigarettes after Vaping 'Epidemic.'"

³⁹ Heather Douglas, Wayne Hall, and Coral Gartner, "E-Cigarettes and the Law in Australia," *Australian Family Physician* 44, no. 6 (June 2015): 415–18; McEwen, *A History of Therapeutic Goods Regulation in Australia*, 137.

as a point of pride in the country for ensuring the safety, affordability, and quality of their medications.⁴⁰

Currently, nicotine, except in forms that are not therapeutic or prepared for smoking, is regulated as a Schedule 7 Dangerous Poison by the TGA.⁴¹ To be in Schedule 7 a substance must be 1) highly toxic, 2) highly hazardous to health, 3) handled with special precaution during manufacture, 4) highly likely to cause harm at low exposure.⁴² When the standard is rigorously applied, it should include the nicotine liquid used in e-cigarettes, leading to the automatic decision to ban the retail sale of such devices in the country from the earliest appearances of the devices.⁴³ Whether the consequence of such a decision was in the best interest of the public health was a matter up for debate.

When the TGA was first confronted with the existence of nicotine-containing e-cigarettes in October 2008, the jurisdictional member of the National Drugs and Poisons Schedule Committee from Victoria had brought the issue forward to ask whether nicotine-containing e-cigarettes could be sold without a license.⁴⁴ The representative from Victoria was concerned that the devices posed a public health risk, were being marketed irresponsibly and that contemporary poisons scheduling might exempt the products from control.⁴⁵ The TGA maintained its classification of nicotine as a dangerous poison. That committee decided that Victoria should change its laws to clarify that Schedule 7 drugs not prepared for therapeutic use should not be licensed for sale in the state.⁴⁶

In December 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”.⁴⁷ Close observers explained that population health criteria are central to the TGA's considerations on the scheduling of chemicals and medicines and that these concerns were paramount in the case of

⁴⁰ AA@ 63; Australian Government Department of Health Therapeutic Goods Administration, “TGA Consumer Survey 2018,” Text, Therapeutic Goods Administration (TGA), December 20, 2018, <https://bit.ly/2MiiVqt>.

⁴¹ Gartner and Bromberg, “One Does Not Simply Sell E-Cigarettes in Australia,” 252.

⁴² Douglas, Hall, and Gartner, “E-Cigarettes and the Law in Australia.”

⁴³ AP, “Electronic Cigarettes Contain Toxic Chemicals,” *The Sydney Morning Herald*, July 24, 2009, <http://bit.ly/2ru4iFI>.

⁴⁴ National Drugs and Poisons Schedule Committee, “Record of Reasons of Meeting 54” (National Drugs and Poisons Schedule Committee, October 2008), 128, <https://bit.ly/2Z3ChRT>.

⁴⁵ National Drugs and Poisons Schedule Committee, 129.

⁴⁶ National Drugs and Poisons Schedule Committee, 143.

⁴⁷ Stark, “Battery-Powered Cigarettes Pose Risks.”

scheduling e-cigarettes.⁴⁸ This ruling clarified the regulatory pathway to commercial markets for a nicotine-containing e-cigarette would run through the therapeutic approval process. However, to date, no nicotine-containing e-cigarette has gained approval for sale as a therapeutic product in Australia.⁴⁹

This has not prevented several attempts at gaining such approval for an e-cigarette from taking place. Inquiries on the matter were made to the TGA very early on as a 2008 statement from a TGA spokeswoman indicated that at least one company had approached the agency to determine how to legally sell e-cigarettes in Australia. That inquiry was rebuffed, citing the agency's conclusion that they suspected the devices were going to be classified as a dangerous poison and following that, heavily regulated unless they could prove that they were therapeutics in which case, a different set of regulations would kick in.⁵⁰ FOI requests to the TGA revealed British American Tobacco's Nicoventures subsidiary met privately with TGA officials in late 2013, presumably in an effort to put an e-cigarette through the therapeutics pathway, but no such product approval ever materialized.⁵¹ In another case, three e-cigarettes were accidentally approved and subsequently rejected by the TGA in 2014 under an expedited existing "self-listing" scheme typically used for low-risk medicines.⁵² A court case the following year pitted Nicovations, another subsidiary of British American Tobacco, against the TGA on a question that the Federal Court of Australia ultimately concluded that regulators would have to be the ones with the final say over how a product would be classified.⁵³ The dispute was over whether Nicovations could apply to have their Voke inhaler sold over the counter, but the TGA's reticence to allow this ultimately led to the withdrawal of the application for a final time.

4.1.2 The Regulatory Stance

The current regulatory stance towards nicotine-containing e-cigarettes in Australia has kept transnational e-cigarette and tobacco companies out of the market. There are currently two ways

⁴⁸ AI @ 31

⁴⁹ Gartner and Bromberg, "One Does Not Simply Sell E-Cigarettes in Australia."

⁵⁰ Andrew Tillett, "Electronic Ciggies 'Beat Smoke Bans,'" *The West Australian*, August 19, 2008, First edition, sec. Main, NexisUni.

⁵¹ Conor Duffy, *Big Tobacco Pushes E-Cigarettes as "Medicine,"* 7.30 Report (Australian Broadcasting Corporation, 2014), <https://ab.co/2XEeAUD>.

⁵² Elise Worthington, "E-Cigarettes Accidentally Approved, Left on Therapeutic Goods Administration Register for Two Months," *Australian Broadcasting Corporation (ABC) News*, November 14, 2014, <http://global.factiva.com/redirect/default.aspx?P=sa&an=ABCNEW0020141114eabe0008n&cat=a&ep=ASE>.

⁵³ J Robertson, *Nicovations Australia Pty Ltd v Secretary of the Department of Health*, 2016 FCA 394 (Federal Court of Australia 2016).

that Australians can legally purchase a nicotine-containing e-cigarette under the current regulatory framework; the personal importation scheme or through a compounding pharmacy.⁵⁴ Despite the legality of such a venture, no interviewee could name an Australian compounding pharmacy that was actively marketing nicotine-containing e-cigarettes. The personal importation scheme enables Australians to ask a medical doctor to apply to the TGA to allow the importation of medicines from abroad which are not approved for sale by the agency under a compassionate access rule. A company hawking personal importation scheme compliant products, Nicovape, arose in this regulatory gray area to facilitate obtaining such a prescription to purchase nicotine-containing e-cigarettes from abroad Australia, in their case from New Zealand.⁵⁵ Few healthcare providers are even aware of the personal importation scheme, and some providers have told patients there was no legal way to obtain nicotine-containing e-cigarettes in Australia.⁵⁶ Centralized records are not kept on the size of the market for personal importation scheme compliant e-cigarettes, but all indications point to its size being insubstantial.⁵⁷

The prohibitionist stance is successfully suppressing the market, keeping it dormant and immature.⁵⁸ Overall, this regulatory framework will continue successfully suppressing the Australian market for nicotine-containing e-cigarettes until a company receives approval to sell an e-cigarette as a therapeutic product.⁵⁹ Otherwise, to substantially grow the market, the regulatory framework itself must be altered.

Over time, elite resistance (bureaucrats, government officials, and the mainstream public health community) to such change has been cultivated by a variety of actors who are skeptical of the role of e-cigarettes can play in public health in venues at Commonwealth as well as state and

⁵⁴ Gartner and Bromberg, “One Does Not Simply Sell E-Cigarettes in Australia,” 258.

⁵⁵ AA @ 62; AN @ 30-31

⁵⁶ AD @ 3-5; Stephanie K. Bell et al., “Vaporised Nicotine and Tobacco Harm Reduction for Addressing Smoking among People Living with HIV: A Cross-Sectional Survey of Australian HIV Health Practitioners’ Attitudes,” *Drug and Alcohol Dependence* 177 (August 1, 2017): 67–70, <https://doi.org/10.1016/j.drugalcdep.2017.03.023>; Gillian S. Gould et al., “Do Clinicians Ask Pregnant Women about Exposures to Tobacco and Cannabis Smoking, Second-Hand-Smoke and E-Cigarettes? An Australian National Cross-Sectional Survey,” *International Journal of Environmental Research and Public Health* 14, no. 12 (December 2017): 1585, <https://doi.org/10.3390/ijerph14121585>.

⁵⁷ Australian Government Department of Health Therapeutic Goods Administration, “Liquid Nicotine and Personal Importation for Use in Electronic Cigarettes,” Text, Therapeutic Goods Administration (TGA), June 4, 2014, <https://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes>.

⁵⁸ AZ @ 31

⁵⁹ Juul Lab’s recent actions to secure trademarks in Australia may indicate it is possible a producer may submit a product for the therapeutic pathway. Philip Morris International is submitting its heated tobacco device, IQOS, to the TGA for premarket approval, as well. James Frost, “Vaping Giant JUUL Swoops Down Under,” Australian Financial Review, June 20, 2019, <https://bit.ly/30rL8hy>; Stephanie Bedo, “Big Twist in Vaping Debate,” *News.Com.Au*, December 13, 2019, sec. Lifestyle, <http://global.factiva.com/redir/default.aspx?P=sa&an=NLNEWW0020191213efcd002s1&cat=a&ep=ASE>.

territorial levels of government. A concerted attempt to change this framework led by THR advocates began ramping up in 2016 but has yet to see any success. The remainder of this chapter examines the creation, solidification, and successful defense of Australia’s regulatory framework for nicotine-containing e-cigarettes from attempts to have it changed.

4.2 Problem Stream

E-cigarette regulation does not occupy the Australian public’s attention as a significant problem. Public opinion surveys have found most Australians are not aware that nicotine-containing e-cigarettes are not legally available for sale.⁶⁰ But like most policy issues, the subject occupies much of the time and attention of the policy community whose jurisdiction includes e-cigarettes, even when they have other important responsibilities.⁶¹ A series of public inquiries designed to upend the pre-existing regulatory framework began picking up focus and intensity around 2016. These efforts have, thus far, produced no policy change favoring THR advocates.

Largely, this can be attributed to the fact that there has not been a focusing event that has transformed the matter of e-cigarette regulation from a condition into a problem. THR advocates seeking to change the country’s regulatory stance towards e-cigarettes have consistently failed to find a widely acknowledged public problem that changing e-cigarette regulation would solve. At best, they have leveraged the subject to serve as a hobbyhorse for the right-wing media to gripe about the Australian nanny state’s overreach into the lives of ordinary citizens. Less convincing, has been the effort to brand all of Australian tobacco control policy as a public health failure in need of dramatic revision. An interviewee put it more succinctly, “there was no crisis that needed to be solved”⁶². In the absence of such a problem, there has been little incentive for the streams to couple. Meanwhile, the Australian public remained rather unconcerned about the subject.

4.2.1 Tobacco Control Progress and Skeptics’ Framing

To date, tobacco use in Australia has followed the same pattern that many other wealthy democracies have through the stages of the tobacco epidemic, as smoking rose and then slowly fell over time.⁶³ Initially, in the first half of the 20th century, tobacco usage (especially the

⁶⁰ “Exclusive Poll Shows WA Voters Overwhelmingly Support Vaping Legalisation,” *Legalise Vaping Australia*, July 26, 2018, <https://bit.ly/30yipI7>; “New Poll: Australians Want e-Cigarettes Legalised,” *Australian Retailers Association* (blog), June 18, 2018, <https://bit.ly/2xKnvEt>.

⁶¹ AW @ 5; AI @ 57-58

⁶² AZ @ 22

⁶³ Lopez, Collishaw, and Piha, “A Descriptive Model of the Cigarette Epidemic in Developed Countries.”

smoking of newfangled cigarettes) rose among men, reaching rates as high as 72% adult male smoking prevalence in 1945.⁶⁴ From there, male smoking began a slow decline. Female smoking continued to rise through the early 1980s, peaking at around 35% of all adults.⁶⁵ Afterward, female smoking declined too. The most recent estimates of smoking prevalence, which were gathered in 2016 estimate that 17% of males and 13% of females over the age of 14 in Australia are current smokers.⁶⁶ Significant disparities in smoking rates still exist, with Australia's indigenous peoples, Aborigines and Torres Strait Islanders, as well as those suffering from substance abuse or mental illness being disproportionately likely to remain as current smokers.⁶⁷ However, this shortcoming is not seen as a failure by the public health community, but rather an opportunity to improve smoking cessation service delivery to these adversely impacted populations.⁶⁸

Throughout the 1980s, anti-tobacco sentiment continued to grow throughout the country. This was both a cause of the decision to implement public-sponsored educational campaigns about the dangers of tobacco use and a result of the public successfully receiving the messages these campaigns spread. Australia has explicitly stated in its National Tobacco Strategy that the goal of its tobacco control policy is to decrease cigarette smoking prevalence.⁶⁹ The fundamental indicator of success in tobacco control policy under the National Tobacco Strategy continues to be cigarette smoking prevalence.⁷⁰ Most policies that advance that goal have been viewed favorably by policymakers, while any policy that jeopardizes that goal has come to be viewed with skepticism. Australian institutions have felt no need to resort to risky measures like growing the e-cigarette market to decrease cigarette smoking prevalence when existing approaches to tobacco control are, in their judgment, working well.⁷¹ Additionally, the Commonwealth government has not yet put forward a tobacco endgame goal, even though the country would be

⁶⁴ EM Greenhalgh, M Bayly, and MH Winstanley, "1.3 Prevalence of Smoking—Adults.," in *Tobacco in Australia: Facts and Issues*, by MH Winstanley and MM Scollo (Melbourne: Cancer Council Victoria, 2019), sec. 1.3.2, <https://www.tobaccoinustralia.org.au/chapter-1-prevalence/1-3-prevalence-of-smoking-adults>.

⁶⁵ Greenhalgh, Bayly, and Winstanley, "1.3 Prevalence of Smoking—Adults."

⁶⁶ Greenhalgh, Bayly, and Winstanley, fig. 1.3.1.

⁶⁷ "Social Inequity in Line of Fire," *The West Australian*, October 21, 2015, First edition, sec. Health.

⁶⁸ Marie McInerney, "Some 'Easy' Wins for Tobacco Control, at a Time of Flagging Momentum," *Croakey* (blog), October 18, 2017, <https://croakey.org/some-easy-wins-for-tobacco-control-at-a-time-of-flagging-momentum/>.

⁶⁹ Intergovernmental Committee on Drugs and Standing Committee on Tobacco, *National Tobacco Strategy 2012-2018* (Canberra: National Drug Strategy, 2012).

⁷⁰ Intergovernmental Committee on Drugs and Standing Committee on Tobacco.

⁷¹ AL @ 5; AW @ 50

well-placed to do so. The lack of an ambitious target to be missed, combined with a general feeling of adequate progress having been made on issues of tobacco control did not increase the odds that the e-cigarette regulatory stance would be called not question as a problem.

4.2.2 Freedom Framing

Australian media, which has one of the most concentrated ownership structures in the world, is dominated by NewsCorp and the various entities owned by tycoon Rupert Murdoch.⁷² Rupert Murdoch himself was on the board of tobacco giant, Philip Morris from 1989 to 1998.⁷³ Murdoch might be one of the people most responsible for the rise of right-wing populist politics in English-speaking countries.⁷⁴ Australia's media is bifurcated between the Fairfax and Murdoch press, a phenomenon that is mirrored in the Labor/Coalition or left/right political split.⁷⁵ The Murdoch press has been found before to play up frames favoring "personal responsibility" and downplaying the potential of political or policy solutions to public health issues like problem gambling⁷⁶. By contrast, the Fairfax press has been more eager to place the fault at the hands of politicians for societal problems.⁷⁷

The first mentions of e-cigarettes in the Australia media occur in early 2007 in the Murdoch press.⁷⁸ The articles highlight the reduced-risk potential of the novel products and then predicts that the products will not be widely available in Australia. By 2009, the TGA confirmed their

⁷² Tim Dwyer, "FactCheck: Is Australia's Level of Media Ownership Concentration One of the Highest in the World?," *The Conversation*, December 11, 2016, <http://theconversation.com/factcheck-is-australias-level-of-media-ownership-concentration-one-of-the-highest-in-the-world-68437>.

⁷³ Mike Daube and Simon Chapman, "The Australian's Dissembling Campaign on Tobacco Plain Packaging," *Med J Aust* 201, no. 4 (August 18, 2014): 191–192. Rupert's daughter-in-law Sarah Murdoch has even been observed vaping in public.; AW @ 71

⁷⁴ David McKnight, "Rupert Murdoch's News Corporation: A Media Institution with A Mission," *Historical Journal of Film, Radio and Television* 30, no. 3 (September 1, 2010): 303–16, <https://doi.org/10.1080/01439685.2010.505021>; Jonathan Mahler and Jim Rutenberg, "How Rupert Murdoch's Empire of Influence Remade the World," *The New York Times*, April 3, 2019, sec. Magazine, <https://www.nytimes.com/interactive/2019/04/03/magazine/ruPERT-murdoch-fox-news-trump.html>.

⁷⁵ John Sinclair, "Political Economy and Discourse in Murdoch's Flagship Newspaper, *The Australian*," *The Political Economy of Communication* 4, no. 2 (January 12, 2017): 3–17.

⁷⁶ Helen E. Miller et al., "How the Causes, Consequences and Solutions for Problem Gambling Are Reported in Australian Newspapers: A Qualitative Content Analysis," *Australian and New Zealand Journal of Public Health* 38, no. 6 (December 2014): 529–35, <https://doi.org/10.1111/1753-6405.12251>.

⁷⁷ Andrea S Fogarty and Simon Chapman, "Advocates, Interest Groups and Australian News Coverage of Alcohol Advertising Restrictions: Content and Framing Analysis," *BMC Public Health* 12 (August 31, 2012): 727, <https://doi.org/10.1186/1471-2458-12-727>.

⁷⁸ Reuters Life, "It's a Health e-Ciggie - SMOKING SIMULATOR," *Sydney MX*, May 10, 2007, sec. Local, <http://global.factiva.com/redir/default.aspx?P=sa&an=NLSYMX0020070510e35a0000y&cat=a&ep=ASE>; Kate Sikora, "The Electronic Cigarette to Beat the Pub Smoke Bans," *The Advertiser*, November 16, 2007, State edition, sec. News; Alan Moran, "Butt out of Individual's Private Pleasure," *Herald-Sun*, July 14, 2007, sec. BUSINESS, <http://global.factiva.com/redir/default.aspx?P=sa&an=HERSUN0020070713e37e0004c&cat=a&ep=ASE>.

suspicion.⁷⁹ Thereafter, news stories focused on trying to determine how e-cigarettes fit into Australia's legal and public health landscape. Media attention to e-cigarettes increased rapidly between 2013 and 2014.⁸⁰ Australian media did no favors to consumers who were trying to determine what the regulatory framework governing e-cigarettes in Australia truly was.⁸¹ Media reports regularly conflicted over basic issues like the legality of sales or using e-cigarettes in public places.⁸² Incidents of people violating smoking bans by using e-cigarettes percolated to the surface even as the rules over whether such behavior was illegal were still unclear.⁸³

The Murdoch media has directed public interest on the issue of e-cigarettes more than its competitors, largely within a freedom framing that posits the existence and ongoing tyranny of an overrun 'nanny state'.⁸⁴ THR advocates got traction in the Murdoch press through the publication of editorials advancing their point of view.⁸⁵ The Murdoch press even went so far as to claim that 2 million Australians were using e-cigarettes in 2016, a figure that is at least ten times as large as reality.⁸⁶ While the Murdoch press continued to push the narrative that e-cigarettes were a matter concerning personal freedom, few other media outlets ran with this frame. Further diminishing the prospects of this frame catching hold of public attention was that the form of freedom that having access to an e-cigarette market entailed, was only appealing to libertarian sentiments on the right-wing of the Australian political spectrum. As less than 10% of Australian are thought to hold such ideological sentiments, the market for such ideas is not enormous, and this framing fell on many deaf ears.⁸⁷

⁷⁹ Stephen Cauchi, "Close, but No Cigarette," *Sunday Age*, March 8, 2009, First edition, sec. Extra.

⁸⁰ Saw et al., "The Medium Is Not the Message," fig. S1.

⁸¹ Saw et al., "The Medium Is Not the Message."

⁸² Joseph Catanzaro, "E-Cigarette a Hot Item to Beat Indoor Smoke Bans," *The West Australian*, January 18, 2011, Second edition, sec. General; Saw et al., "The Medium Is Not the Message."

⁸³ "Puff Justice Court Confusion over E-Cig Smoking Fine," *MX (Australia)*, November 4, 2013, 1-Melbourne edition, sec. GENERALNEW.

⁸⁴ AH @ 16-17; Josephine Chau et al., "Talking about a Nanny Nation: Investigating the Rhetoric Framing Public Health Debates in Australian News Media," *Public Health Research & Practice* 29, no. 3 (September 25, 2019), <https://doi.org/10.17061/phrp2931922>.

⁸⁵ Terry Barnes, "Government Is Not Seeing the Light on Vaping," *Herald Sun*, June 7, 2016, sec. OPED, NexisUni; Colin Mendelsohn, "BANNING E-CIGS COULD INCREASE CANCER," *Daily Telegraph*, January 12, 2017, Telegraph edition, sec. OpEd; Colin Mendelsohn, "If Teens Are Going to Smoke, Better It Be an e-Cigarette," *Daily Telegraph*, August 9, 2016, <https://bit.ly/2R7x09Z>.

⁸⁶ Miranda Devine, "Even Heroes Have No Chance with ICAC," *Daily Telegraph* (blog), March 29, 2016, <https://www.dailytelegraph.com.au/blogs/miranda-devine/even-heroes-have-no-chance-with-icac/news-story/b6b50267b8f1c174df8d7ddda6780ab9>.

⁸⁷ Sinclair Davidson, Tim Fry, and Breanna Pellegrini, "How Do Australian Classical Liberals Vote," *Policy*, Summer 2007.

4.2.3 Health Framing

Over time, the Murdoch press built a frame that e-cigarettes would be a boon to public health. They argued that tobacco control in Australia was a policy failure and that e-cigarettes are helping other countries make progress against cigarette smoking overseas.⁸⁸ The indicator most often used to make the case for this supposed failure was the 2016 National Drug Strategy Household Survey saw a non-significant drop in the smoking prevalence compared to three years prior.⁸⁹ THR advocates claimed that a stall in historic declines in smoking prevalence was attributable to traditional tobacco control policies reaching the end of their useful life.⁹⁰ Some THR advocates made the case that vaping is needed in Australia because tobacco control had worked for a well-to-do population but that low socioeconomic status, indigenous, and persons with mental illness were being left behind by the current policy regime.⁹¹ They compared Australia's lack of progress on smoking reduction relative to the UK and US and began to attribute blame to e-cigarette regulatory policy.⁹²

Skeptics effectively buried the attempt to brand Australian tobacco control as 'failing'. They did this by appealing to policymaking elites with a consensus of expert organizations who all reassured politicians there was nothing to worry about.⁹³ Skeptics retorted that the Australian government had become complacent because they thought they had finished handling tobacco issues and they made the case that two data points (2013 and 2016) do not make a trend.⁹⁴ In their minds, the two relevant national indicators were the adult cigarette smoking rate and the youth e-cigarette use rate. The youth e-cigarette use rate in Australia has risen, but not nearly as

⁸⁸ AT @ 14-15; AU@ 11-14; Bruce Felmingham, "Tobacco Tax Fails the Poor," *Sunday Tasmanian*, May 2, 2010, 1- edition; Terry Barnes, "Plain-Packaged Wowsers," *Daily Telegraph*, August 21, 2017, Telegraph edition, sec. Letters; David Penberthy, "Interfering Councils Need to Just Butt Out," *The Advertiser*, May 18, 2014, Advertiser edition, sec. News.

⁸⁹ Greenhalgh, Bayly, and Winstanley, "1.3 Prevalence of Smoking—Adults.," fig. 1.3.1; Elizabeth Ingram, "Teenage Smoking and Drinking down, While Drug Use Rises among Older People," Australian Institute of Health and Welfare, June 1, 2017, <https://bit.ly/2ZUaVzb>.

⁹⁰ AT @ 6; AN@ 42

⁹¹ AD @ 10

⁹² James Paterson, "We're Making It Harder for Smokers to Quit," *Herald Sun*, August 10, 2017, sec. OPED, NexisUni.

⁹³ Some e-cigarette skeptics claimed that stalls in the smoking rate decline may be due to immigration-driven population increases drawn from places with much higher smoking rates than Australia, like Indonesia and China. The National Drug Strategy Household Survey data does not appear to square with this view. Smoking rates among Australians who speak English at home are double that of those who do not speak English at home and from 2013 to 2016, smoking rates among the non-speakers of English at home fell by nearly 40% while rates among those who spoke English at home stayed flat. AW @ 10; EM Greenhalgh, MH Winstanley, and M Bayly, "1.8 Trends in Prevalence of Smoking by Country of Birth," in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2017), fig. 1.8.1, <https://www.tobaccoinustralia.org.au/chapter-1-prevalence/1-8-trends-in-prevalence-of-smoking-by-country-of->.

⁹⁴ AW @ 13; AH @ 31

much as comparator nations, like the US or Canada. The adult cigarette smoking rate has steadily declined for over two decades. The sole exception to this was the non-significant drop in cigarette smoking prevalence observed in 2016 compared to 2013.

It did not hurt that the right-wing politicians like David Leyonhjelm and Tim Wilson who tried to claim they had an interest in promoting the public health had little credibility on the issue they could draw on as they had been opponents of traditional tobacco control efforts, like plain packaging in the past.⁹⁵ Their claims to be concerned about stagnating smoking rates were not seen as generally credible. Outside of the context of peak health body lobbying, the lack of representation in political circles from communities that are still impacted by tobacco has caused the issue of tobacco use to fade away as an urgent problem altogether.⁹⁶ Without a defined problem to solve, the process of opening a policy window was stunted from the start.

4.3 Policy Stream

The Australian e-cigarette regulatory policy stream was made up of two distinct groups of actors, the THR advocates, and the e-cigarette skeptics. Each group contained an assortment of academics while the skeptics also contained peak health bodies and bureaucrats and their home institutions. Expertise-based Australian institutions have not changed their prior positions on e-cigarettes to accommodate political forces who disagree with their priors. Initial decisions to continue treating nicotine as a poison followed institutional protocols. Follow-on decisions did not change this framing and reinforced the choice to describe the precautionary policy approach to e-cigarettes.

Over time, the e-cigarette regulatory policy stream was marked by several milestone events. Initially, bureaucrats follow the plain meaning of the poisons statute and prohibit the import of liquid nicotine. An incumbent public health community supports this decision and develops policy recommendations that regional governments should abide by. Then, some THR advocates advanced their policy solution, adopting an expansionist regulatory stance for nicotine-containing e-cigarettes. Other THR advocates with more mainstream credibility, did not back up the most expansionist policies preferred by the most vociferous THR advocates. E-cigarettes

⁹⁵ AH @ 22-23

⁹⁶ This includes low socioeconomic status persons, persons with mental illness, and indigenous peoples.

skeptics countered, defending the status quo prohibitionist stance as a policy success and not in need of reform. The result has been regulatory policy stasis.

4.3.1 Skeptics Form a Consensus Health Frame

The primary policy entrepreneurs in the Australian public health community have been consistent skeptics towards e-cigarettes. The public health community has remained united on the issue of e-cigarette regulation and sequestered any infighting amongst a small group of public health researchers. Nicola Roxon, the former Labor health minister who is credited with ushering the first in the world plain packaging legislation through the political process, once told an audience, “one of the strengths of the tobacco control sector is they always said the same thing. So, people who have worked in the obesity space or healthy eating would all come in and ask for different things. As a government it was too hard to work out, ‘What do we actually do?’”⁹⁷ Roxon keyed into the importance of consensus formation to the public health policy community in Australia.

Over time, Australian tobacco control policy entrepreneurs have built up the country’s (and their own) reputation as a world leader in tobacco control policy. The track record of entrepreneurs who have successfully gained passage of a litany of creative and innovative tobacco control policies is extensive and impressive. An early example: tobacco companies began sponsoring arts and sporting events in the 1970s to fight off their declining fortunes, as a part of their well-established “mass-and-class” strategy to position tobacco companies as essential participants in society.⁹⁸ This strategy of becoming essential sponsors of public events eventually led to a masterstroke tobacco control policy idea in the late 1980s in the state of Victoria. There, the drive to eliminate tobacco advertising and sponsorship culminated in a ban on both activities at the state level. But to smooth over implementation concerns about lost sponsorship funds a hypothecated tobacco tax increase was set aside to provide public sponsorship as a bridge away from tobacco dollars for groups that had previously been sponsored by the tobacco industry.⁹⁹

⁹⁷ AC @ 15

⁹⁸ Richard Kluger, *Ashes to Ashes: America’s Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris* (Random House Digital, Inc., 1997), chap. 17.

⁹⁹ Simon Chapman and Melanie Wakefield, “Tobacco Control Advocacy in Australia: Reflections on 30 Years of Progress,” *Health Education & Behavior* 28, no. 3 (June 2001): 274–89, <https://doi.org/10.1177/109019810102800303>.

This led to the distinctive rebranding of the Winfield Socceros as the Australian Quit Socceros and the Sterling Manikato Stakes as the Diabetes Australia Manikato Stakes.¹⁰⁰

In 2011, Australia passed the world's first plain packing regulation for tobacco products which had the effect of stripping tobacco logos from all product packaging the following year.¹⁰¹ Public health campaigners successfully convinced the reigning Labor government to keep discussions on the matter focused on issues of health rather than on tobacco industry threats of trade disputes.¹⁰² Australia battled with the tobacco industry to defend the policy from legal challenges in national and international courts and trade dispute settlement venues for six years after the policy was passed as well as through a change in government from Labor to Coalition until victory had been awarded to the Australian government in every venue.¹⁰³ The policy has a large and sustained effect on reducing cigarette sales in the country.¹⁰⁴

The mainstream public health policy community has stayed organized through explicit knowledge exchange efforts intent on creating a consensus position. For the matter of e-cigarettes, in July 2014 the public health community organized a 115-person "Tobacco Harm Reduction Forum" in Melbourne which attempted to air the discussion that was a prologue to reaching consensus.¹⁰⁵ The meeting included the broad range of academic and peak health body voices but it excluded THR advocates who were perceived as interlopers.¹⁰⁶

In late 2014, the first step towards potentially altering the regulatory framework for e-cigarettes was taken when the Coalition government under PM Abbot approached the Intergovernmental Committee on Drugs (ICOD) to commission a discussion paper about the options available to

¹⁰⁰ R Galbally, C Borthwick, and M Blackburn, "Australia: Sports and Arts: Tobacco-Free, Tobacco Control, and Health Promotion," in *Tobacco: The Growing Epidemic: Proceedings of the Tenth World Conference on Tobacco or Health, 24–28 August 1997, Beijing, China*, ed. Rushan Lu et al. (Springer Science & Business Media, 1997), 445; Nick Richardson, *30 Years of VicHealth: 1987-2017*. (Melbourne, Vic.: Victorian Health Promotion Foundation, 2017), 51–53, <https://www.vichealth.vic.gov.au/-/media/ResourceCentre/PublicationsandResources/General/VicHealth-30th-anniversary.pdf?la=en&hash=A23252699C39C6E7823194998F88E24279CDBAB4>.

¹⁰¹ Holly Jarman, "Attack on Australia: Tobacco Industry Challenges to Plain Packaging," *Journal of Public Health Policy* 34, no. 3 (August 1, 2013): 375–87, <https://doi.org/10.1057/jphp.2013.18>.

¹⁰² Eric Crosbie et al., "Advancing Progressive Health Policy to Reduce NCDs amidst International Commercial Opposition: Tobacco Standardised Packaging in Australia," *Global Public Health* 13, no. 12 (December 2, 2018): 1753–66, <https://doi.org/10.1080/17441692.2018.1443485>.

¹⁰³ Holly Jarman, "Normalizing Tobacco? The Politics of Trade, Investment, and Tobacco Control," *The Milbank Quarterly* 97, no. 2 (2019): 449–79, <https://doi.org/10.1111/1468-0009.12393>.

¹⁰⁴ André Bonfrer et al., "Assessing the Sales Impact of Plain Packaging Regulation for Cigarettes: Evidence from Australia," *Marketing Science*, July 16, 2019, <https://doi.org/10.1287/mksc.2019.1164>.

¹⁰⁵ David Hill et al., "Tobacco Harm Reduction Forum Proceedings," *QuitVic*, March 11, 2015, <https://bit.ly/30uU8T7>.

¹⁰⁶ Attila Danko, "Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia: Submission 222" (Parliament of Australia, July 4, 2017), <https://bit.ly/2YHTeWN>.

regulate e-cigarettes by the end of 2015.¹⁰⁷ The ICOD tapped Dr. Becky Freeman of the University of Sydney to lead the team writing the paper.¹⁰⁸ Freeman and her colleagues framed e-cigarettes as hazardous to health and existing in a murky area of business and lack of scientific evidence. Topics like hazards to breathing, explosions, a renormalization of smoking, secondhand vapor dangers dominate their report.

The ICOD paper team was confident that Australia already had the correct regulatory framework for e-cigarettes, and it concluded there was no reason to change. From the beginning, they believed there was never a sense that their purpose was to justify softening Australia's regulations towards e-cigarettes, even if that direction was never overtly given by ICOD or other public sector actors.¹⁰⁹ The Coalition government heeded their advice.¹¹⁰ Instead of calling for Commonwealth policy changes, the ICOD report called for standardizing regulatory policy at the state and territory level, where a great deal of confusion had arisen about what activities regarding e-cigarette usage, marketing, and retailing were legal in which jurisdictions.¹¹¹ The ICOD report ended up framing every report that proceeded it on the matter of e-cigarette regulation by starting from the assumption that regulatory stasis on e-cigarettes was the proper choice to make.

4.3.1.1 Opinion Leaders

Among THR advocates, a persistent theory of what drives Australian tobacco control policy was that one health advocate, Professor Simon Chapman, unduly influenced the actions of bureaucrats, politicians, and journalists. Chapman was viewed by THR advocates as bullying his way to create near-unanimity in peak health group's opposition to changing e-cigarette regulatory policy. This conclusion overlooks the contributions of a united policy community beyond Chapman, especially the influence of the Cancer Councils and Chapman's contemporary, Mike Daube. Daube is a politically well-connected skeptic, dating back to his days working as

¹⁰⁷ Sean Parnell, "Paper to Look at Risks of E-Cigs," *The Advertiser*, December 10, 2014, Australian edition, sec. The Nation, NexisUni.

¹⁰⁸ Simon Chapman mentored Becky Freeman along with a vast portion of the Australian public health community and even a few of the politicians "Dr Becky Freeman," The University of Sydney, 2019, <https://sydney.edu.au/medicine-health/about/our-people/academic-staff/becky-freeman.html>.

¹⁰⁹ AZ @ 21

¹¹⁰ AZ @ 33

¹¹¹ Becky Freeman et al., "Discussion Paper: Options to Minimize the Risks Associated with the Marketing and Use of Electronic Nicotine Delivery Systems [ENDS] in Australia" (Intergovernmental Committee on Drugs, May 1, 2016), 17, <https://bit.ly/2yPSQX5>.

the Director-General for the Western Australia Health Department. Mike Daube's initial rhetoric on e-cigarettes echoed his work for ASH UK in the 1970s when he analogized smoking tobacco substitutes like Cytrel and New Smoking Material as "like jumping out the 36th floor of a building instead of the 39th".¹¹² In Daube's first known comment to the media on e-cigarettes, he quipped "Smoking these is like saying jumping off the 10th floor of a building is healthier than jumping off the 40th floor".¹¹³ In Daube's mind, the old and new product categories were intimately related. This message resonated inside of e-cigarette skeptical circles and served to unite the policy community behind the current precautionary policy approach. Daube's extended history in Australian bureaucracy and politics has made him even more well-connected to decisionmakers than Chapman and has enabled him to have sway in pivotal circles.

Cancer Council Victoria formed the backbone of peak health body e-cigarette messaging efforts as are much more heavily funded by research grants than the other cancer councils and provide much more technical capacity than other peak bodies.¹¹⁴ While the organization itself feels that e-cigarettes detract from what the organization wants to be focused on, they provide so much essential information to other actors in Australia on the subject that they end up framing discussions on their terms.

These opinion leaders, led by Chapman, Daube, and Cancer Council Victoria, within the policy community have forged a consensus viewpoint on these matters that attempts to maintain a population-level approach to solving the matter of cigarette smoking. The skeptics have managed to make certain that the institutions governing the informational and regulatory environment around e-cigarettes, (NHMRC, ICOD, TGA, ACCC, and the Commonwealth Department of Health) consistently supported the position that the e-cigarette regulatory framework in Australia should not change. These reports and regulatory actions reinforced a consensus among policymaking elites in the country. This consensus consistently cited the evidence reviews and positions statements put out by e-cigarette skeptics, who were viewed by government officials and bureaucrats as credible arbiters of the scientific data and who would later act as the arbiters of whether Australia had a problem that needed fixing by changing the e-cigarette regulatory

¹¹² V. Berridge, "Issue Network versus Producer Network? ASH, the Tobacco Products Research Trust and UK Smoking Policy.," *Clio Medica (Amsterdam, Netherlands)* 75 (2005): 101–24.

¹¹³ Tillett, "Electronic Ciggies 'Beat Smoke Bans.'"

¹¹⁴ "Cancer Council Victoria," Text, Australian Charities and Not-for-profits Commission, June 26, 2019, <https://bit.ly/33xDxAy>; "Cancer Council Australia," Text, Australian Charities and Not-for-profits Commission, July 18, 2019, <https://bit.ly/2YKntfV>.

framework. Their credibility has been built up over decades of policy fights and spans all levels of government and across most of the political spectrum. This has allowed them to be called to testify at every inquiry, to serve on every committee report, and to advise on political and bureaucratic decisions relevant to e-cigarette regulation. Consequently, they have been listened to.

4.3.2 THR Advocates Dissent from the Consensus

THR advocates tried to mobilize in response to this consensus, but they were primarily represented by a few smoking cessation specialists, tobacco and vaping retailer interests, libertarian think-tanks, stray academics, and two small health bodies. The varied motives of THR advocates never allowed them to converge on a single policy solution or even a single defined problem.

The THR advocacy community is anchored by several nominal consumer groups including the Australian Tobacco Harm Reduction Association (ATHRA) and Legalize Vaping Australia.¹¹⁵ ATHRA was founded in 2015, by Atilla Danko, an emergency department physician, who wanted to model a campaign on the work of a UK pressure group.¹¹⁶ Danko eventually recruited, Colin Mendelsohn, a Sydney-based general practitioner, to join his organization. Mendelsohn's first mention of e-cigarettes in the media came in early 2016 coinciding with the publication of an op-ed in the *Medical Journal of Australia*.¹¹⁷ Mendelsohn rose to prominence to become the primary THR policy entrepreneur in Australia. For over two decades, Mendelsohn maintained a small public role emphasizing the importance of getting smoker's cessation treatment in clinics with medication and nicotine replacement therapy.¹¹⁸ Mendelsohn has received financial support from pharmaceutical companies including Pfizer and GlaxoSmithKline for his research. Mendelsohn's research credentials are not top-level, as his primary contribution to the scientific literature on smoking cessation since 2001 consists of review articles, perspectives, and letters to

¹¹⁵ Legalize Vaping Australia is a campaign that is being run by the libertarian Australian Taxpayers Alliance who hired three young men to ride around Australia in a bus campaigning for relaxing e-cigarette regulatory policies. Ariel Bogle and Stephen Hutcheon, "Smoke and Mirrors: The Nanny State Critics behind the Vape Debate," *Australian Broadcasting Corporation News*, August 30, 2019, <http://global.factiva.com/redirect/default.aspx?P=sa&an=ABCNEW0020190829ef8u000m9&cat=a&ep=ASE>.

¹¹⁶ Rebecca Urban, "Doctor Lobbies for 'life-Saving' Vaping," *The Australian*, August 24, 2015, Australian2 edition, sec. The Nation, Lexis Nexis.

¹¹⁷ Colin P. Mendelsohn, "Electronic Cigarettes: What Can We Learn from the UK Experience?," *The Medical Journal of Australia* 204, no. 1 (January 18, 2016): 14–15, <https://doi.org/10.5694/mja15.00725>.

¹¹⁸ D Buckley, "Nicotine Patch 'Better than Gum,'" *The Advertiser*, April 4, 1994, Lexis Nexis; Peter Jean, "Nicotine Health Risk to Foetus: Research; High Blood Pressure and Cardiovascular Disease," *Canberra Times*, July 22, 2011, Final edition, sec. A, Lexis Nexis.

the editor with just a single piece of evidence-producing research published to his name.¹¹⁹ Later in 2016, Mendelsohn began tacitly endorsing the heated tobacco product being offered by PMI as a potential solution to smoking in Australia by calling it, “a much safer alternative to smoking”.¹²⁰ ATHRA eventually suffered severe reputational damage once it came to light that the group had accepted contributions from Knowledge Action Change, a UK-based, Philip Morris International-sponsored outfit.¹²¹

Two peak health groups representing patients with mental illnesses or substance use disorders, the Royal Australia and New Zealand College of Psychiatrists and the Drug and Alcohol Nurses of Australasia also considered themselves to THR advocates.¹²² Finally, a few academics namely, Ron Borland of Cancer Council Victoria, as well as Wayne Hall and Coral Gartner of the University of Queensland identify publicly as THR advocates.

The policy preferences of the consumer groups like ATHRA and Legalize Vaping Australia and the right-wing politicians aligned with them diverged radically from the THR health groups and academics. The former group of policy entrepreneurs sees e-cigarettes as a market-based solution that will cure Australia of the harms caused by smoking-related illness. THR-supporting academics and health groups strongly disagree with this view and favor the expansion of an e-cigarette market being implemented in tandem with harsher, more contractionist regulatory policy for tobacco cigarettes.¹²³ By contrast, THR-supporting consumer groups envisioned that very little regulatory intervention would be needed in the market for e-cigarettes or tobacco cigarettes.

This market solution looked to be politically appropriate for the right flank of the Coalition government but has remained out-of-bounds for all others in the center or left of Australian

¹¹⁹ Dennis Thomas et al., “The Effectiveness, Safety and Cost-effectiveness of Cytisine versus Varenicline for Smoking Cessation in an Australian Population: A Study Protocol for a Randomized Controlled Non-inferiority Trial,” *Addiction* 114, no. 5 (May 2019): 923–33, <https://doi.org/10.1111/add.14541>.

¹²⁰ David Hurley, “Smokeless Cigarettes Taking Hold,” *Northern Territory News*, November 18, 2016, NTNews edition, sec. News, Lexis Nexis.

¹²¹ Knowledge Action Change describes itself as a “private sector public health agency”. AW; Esther Han, “‘Independent’ Doctor-Led Vaping Group Accepts Tobacco-Tainted Funding,” *The Sydney Morning Herald*, October 15, 2018, <https://bit.ly/2J7fTVj>.

¹²² Gartner and Bromberg, “One Does Not Simply Sell E-Cigarettes in Australia,” 274.

¹²³ AB@ 30; Wayne Hall, Kylie Morphett, and Coral Gartner, “A Critical Analysis of Australia’s Ban on the Sale of Electronic Nicotine Delivery Systems,” *Neuroethics*, March 18, 2019, <https://doi.org/10.1007/s12152-019-09402-x>; Coral Gartner et al., “Vape Club: Exploring Non-Profit Regulatory Models for the Supply of Vaporised Nicotine Products,” *International Journal of Environmental Research and Public Health* 15, no. 8 (August 2018): 1744, <https://doi.org/10.3390/ijerph15081744>.

politics. This has left THR advocates to hawk policy solutions that are acceptable to a subset of the ruling Coalition government that receive little support from elsewhere in Australian civil society. Those health groups and academics who favored THR policies received even less support as colleagues and policymakers who were skeptical of e-cigarettes shunned their proposals. They were not able to find policymakers who agreed with their brand of THR policy and were willing to advance the cause. In the face of a unified community of skeptics backing the policy status quo, no coherent alternative was put forward to policymakers who might have sympathized with the cause of the THR advocates.

4.4 Politics Stream

During the 20th-century tobacco manufacturers slowed the process of regulating their products in Australia. During the 1950s when the medical and scientific communities began the collective process of realizing the health harms of tobacco smoking, the right-wing Country Party (later National Party) maintained a policy of protecting and promoting tobacco growing as an economic development engine in the northern parts of the country.¹²⁴ Through the 1960s, the left-wing Australian Labor Party worked with partners across the Commonwealth to begin considering cracking down on advertising practices of the tobacco industry and to begin using tobacco tax rises to discourage smoking. This putative policy position eventually resulted in the banning of advertising on television and radio except after the left-wing won federal elections in 1972, but the policy was not implemented until 1976.

Australia continued to pass stronger tobacco control policies through the 1990s as more advertising restrictions were placed on print, billboard, radio, and film advertising (Tobacco Advertising and Prohibition Act of 1992) under the Keating-Labor government.¹²⁵ The Howard-Coalition government continued to strengthen a prior restriction on tobacco sponsorship (Tobacco Advertising Prohibition Amendment Act of 2000) while state and territory

¹²⁴ John Ballard, “The Politics of Tobacco Control in Australia: International Template?,” in *Unfiltered: Conflicts over Tobacco Policy and Public Health*, ed. Eric A. Feldman and Ronald Bayer (Cambridge, Mass: Harvard University Press, 2004), 89–113.

¹²⁵ C Grace, “11.3 Commonwealth (National) Legislation,” in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2016), <https://www.tobaccoinaustralia.org.au/chapter-11-advertising/11-3-commonwealth-legislation>.

governments of every political stripe continued to pass evermore comprehensive bans on public smoking throughout the 2000s.¹²⁶

By the time that e-cigarettes arrived in Australia, the political positioning of the governing coalition Commonwealth government prevented the adoption of a potentially politically risky expansionist regulatory stance towards e-cigarettes. Instead, the Coalition government pursued uncontroversial, though still consequential, tobacco control policies like large annual cigarette excise tax increases.¹²⁷ The Coalition government had no appetite to risk losing votes to the Labor party over a policy that would be easily characterized as serving the interests of tobacco companies.

The leadership role on the issue that was taken by Senator David Leyonhjelm served as a signal to other political actors that e-cigarettes were the political purview of the far-right wing of Australian politics. THR advocates proposed policies that did not align with the values of the Australian or elite politicians. The policy solutions proposed in the form of potential regulatory frameworks proposed expansionist regulatory stances in a country that had little appetite for such a policy that would have clearly rewarded tobacco companies. Risk-averse Coalition government leadership decided that there was little upside to following Leyonhjelm and pursuing a change in the regulatory framework for e-cigarettes.

4.4.1 Skeptics Push Regional Regulation into Effect

The Australian states and territories consistently moved in the direction of a shared regulatory framework governing the usage and retailing while leaving the matter of setting product standards to the Commonwealth.¹²⁸ This approach towards regional consensus took place in broad, nonpartisan fashion as state after state passed laws to regulate e-cigarette retailing and usage like tobacco products.

Skeptic's momentum continued to build as e-cigarette skeptics scored victory after victory in every Australian regional government through the passage of policies that strictly aligned e-

¹²⁶ C Grace, "15.7 Legislation to Ban Smoking in Public Spaces," in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2016), <https://www.tobaccoinaustralia.org.au/chapter-15-smokefree-environment/15-7-legislation>.

¹²⁷ Katherine T. Hirono and Katherine E. Smith, "Australia's \$40 per Pack Cigarette Tax Plans: The Need to Consider Equity," *Tobacco Control* 27, no. 2 (March 1, 2018): 229–33, <https://doi.org/10.1136/tobaccocontrol-2016-053608>.

¹²⁸ AI @ 9

cigarette regulations to existing rules applied to tobacco cigarettes. In 2009, Victoria lawmakers passed rules making it “illegal to manufacture, sell, supply, purchase or otherwise obtain, possess or use an electronic cigarette or cartridge containing nicotine”.¹²⁹ In July 2014, before the 6th Conference of the Parties to the FCTC, the WHO released a report that derided e-cigarettes as a harm reduction tool and stated that young people and pregnant women should not use the devices.¹³⁰ In September 2014, Queensland lawmakers cited the WHO report as they made their state the first to update its tobacco control policies to explicitly apply to e-cigarettes under a Liberal-National Party government.¹³¹ After Western Australia won a court case against an e-cigarette retailer, public health groups decided that the legal case in New South Wales for enforcing their statutory ban on sales of e-cigarettes was weaker, so it necessitated passing a new law.¹³² New South Wales included e-cigarettes into their tobacco regulations in votes taken after a short delay in September 2015 (for retail and marketing regulations) and April 2018 (for usage regulations) under a Coalition government.¹³³ New South Wales Labor had promised to take stricter action against e-cigarettes had they won the intervening election in mid-2015, singling out the fact that they would have banned e-cigarette advertising altogether while the Coalition mostly left the unprofessional marketing efforts of vape shops alone.¹³⁴ In April 2016, the Australian Capital Territory passed laws regulating the retail, marketing and usage of e-cigarettes under a minority Labor government.¹³⁵ In September 2016, Victoria regulated the retail,

¹²⁹ Stark, “Banned E-Cigarettes May Be a Health Hazard, but Buying Them’s a Wheeze.”

¹³⁰ WHO, “Electronic Nicotine Delivery Systems,” Provisional agenda item, Conference of the Parties to the WHO Framework Convention on Tobacco Control (Moscow: World Health Organization, July 21, 2014), http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1.

¹³¹ “Health and Other Legislation Amendment Act 2014,” Pub. L. No. 2014–65 (2014), <https://bit.ly/2SUnCHB>; Michael Hansel, “World Health Organisation Report on E-Cigarettes Prompts New Laws in Queensland,” *Mondaq Business Briefing*, September 24, 2014, <http://global.factiva.com/redir/default.aspx?P=sa&an=BBPUB00020140924ea9o0000a&cat=a&ep=ASE>.

¹³² AV @ 10; Clarke, “Court Ruling Keeps Ban on E-Cigarettes.”

¹³³ Lobbying efforts from British American Tobacco towards the Coalition government were thought to have delayed the passage of the regulations from July into September 2015. The company sought to avoid the inclusion of amendments that would have placed marketing restrictions for e-cigarettes on par with tobacco cigarettes. Australian Associated Press, “E-Cigarettes: NSW Bans Vaping in Public Places with \$550 Fine for Offenders,” *The Guardian*, April 12, 2018, sec. Society, <https://bit.ly/2JNwcCQ>; “Public Health (Tobacco) Amendment (E-Cigarettes) Act 2015,” Pub. L. No. 2015–16 (2015), <https://bit.ly/2ORapRq>; Harriet Alexander, “State Delays Action to Restrict E-Cig Use,” *St George Leader*, June 16, 2015, First edition, sec. News.

¹³⁴ Kirsty Needham, “NSW Labor Would Ban ‘vaping’ in Smoke-Free Zones,” *The Sydney Morning Herald*, February 21, 2015, <https://bit.ly/331eVQd>.

¹³⁵ “Tobacco and Other Smoking Products Act 1927,” Pub. L. No. A1927-14 (2018), <http://www.legislation.act.gov.au>.

marketing and usage of e-cigarettes under a Labor government.¹³⁶ In September 2017, Tasmania regulated the retail and usage of e-cigarettes under a Liberal government.¹³⁷

By November 2017, all state and territory governments agreed on a national approach to regulating e-cigarettes at the level of regional government that tried to instill the Commonwealth government's precautionary approach.¹³⁸ In Western Australia, this has resulted in the *de jure* prohibition on sales of e-cigarettes, with or without nicotine.¹³⁹ In 2019, the Northern Territory and South Australia became the last regional governments to update their policies to explicitly cover e-cigarettes, passing strict bills into law under majority Labor and Liberal governments, respectively.¹⁴⁰

In public opinion surveys, e-cigarette users favored the adoption of an e-cigarette regulatory framework that was vastly more expansionist than the status quo.¹⁴¹ This contrasted with the viewpoint expressed by Australians who did not use the products, who largely favored the current prohibitionist framework.¹⁴² 60% of the Australian public in the National Drug Strategy Household Survey for 2016 said that they supported strong regulation on e-cigarettes.¹⁴³ Smoke-free public places are popular in the country and public vaping seemed to violate a tacit agreement to maintain clean air as evidenced by 70% of respondents to a 2015 poll in New South Wales said they wanted to keep vaping out of public places.¹⁴⁴ These data point to the popularity of the legislation passed to regulate e-cigarettes with the Australian public.

¹³⁶ "Tobacco Amendment Act 2016," Pub. L. No. 2016–55, 32 (2016), <https://bit.ly/315t50N>.

¹³⁷ "Public Health Amendment (Healthy Tasmania) Act 2017," Pub. L. No. 2017–42 (2017), <https://bit.ly/2ZV1QWx>.

¹³⁸ Australian Government Department of Health, "Principles That Underpin the Current Policy and Regulatory Approach to Electronic Cigarettes (E-Cigarettes) in Australia" (Australian Government Department of Health, January 11, 2018), <http://www.health.gov.au/internet/main/publishing.nsf/Content/principles-underpin-current-policy-regulatory-approach-electroniccigarettes-eeCigarettes-australia>.

¹³⁹ Gartner and Bromberg, "One Does Not Simply Sell E-Cigarettes in Australia," sec. 4.1.

¹⁴⁰ Office of Parliamentary Counsel, "Tobacco and E-Cigarette Products Act 1997" (2019), <https://bit.ly/2ZhEkTv>; Natasha Fyles, "Tobacco Control Legislation Amendment Act 2019," Pub. L. No. 56, G15 (2019), <https://bit.ly/2SS8WIX>.

¹⁴¹ Doug Fraser et al., "Vapers' Perspectives on Electronic Cigarette Regulation in Australia," *International Journal of Drug Policy*, Nicotine: Science, Regulation and Policy, 26, no. 6 (June 1, 2015): 589–94, <https://doi.org/10.1016/j.drugpo.2015.01.019>.

¹⁴² Daniel A. Erku et al., "Nicotine Vaping Product Use, Harm Perception and Policy Support among Pharmacy Customers in Brisbane, Australia," *Drug and Alcohol Review* 38, no. 6 (2019): 703–11, <https://doi.org/10.1111/dar.12984>.

¹⁴³ AI @ 55-56

¹⁴⁴ Kirsty Needham, "Poll Shows 70 per Cent Want E-Cigarette Vaping Banned in Public," Sydney Morning Herald, February 14, 2015, <https://bit.ly/2K71iYf>.

The process of changing these state and territory laws was mostly cooperative and good-natured, with only occasional objections being levied by libertarians and vape shop owners.¹⁴⁵ The fact that no regional government remained a holdout from this policy consensus, indicates how broad-based acceptance of the skeptics' view towards e-cigarettes is in the country. Regional governments of every ideological makeup set a tone that reflected and likely limited the latitude with which the Commonwealth government could approach the subject.

4.4.2 THR Advocates Latch onto David Leyonhjelm

The likelihood of changing the Commonwealth e-cigarette regulatory framework declined as leadership on the matter was taken up by Senator David Leyonhjelm, the lone member in Parliament of the Liberal Democratic Party. David Leyonhjelm served in the Australian Senate for New South Wales from 2013 to 2019 because of an “institutional fluke”.¹⁴⁶ Leyonhjelm is ideologically a right-wing libertarian. He voted for gay marriage, favors major expansions in gun rights, wants to legalize the sale of marijuana, and has become an icon among men’s right’s activists for his near-defamatory comments against Greens senator, Sarah Hanson-Young.¹⁴⁷ Leyonhjelm is not widely perceived as credible on health issues.¹⁴⁸ Making him an even less suitable figure to helm the cause of THR advocates, Leyonhjelm’s party, the Liberal Democrats, were one of only two political parties (Liberal Democrats and National) still accepting tobacco donations after 2014.¹⁴⁹

In 2015, as part of Senator Leyonhjelm’s agreement to vote with the Coalition government, he was granted an inquiry into what he termed “Nanny State” issues including bicycle helmets, pornography, computer game ratings, alcohol sales laws, and even swimming pool fencing.¹⁵⁰

¹⁴⁵ Crystal Jones, “Retailer Fuming at New Laws on E-Cigarettes,” *NewsMail and Rural Weekly*, October 4, 2014, NexisUni; Barnes, “Government Is Not Seeing the Light on Vaping.”

¹⁴⁶ In one fell swoop; his seat was created, he ran for office in an election to fill six instead of the usual three senatorial seats at once, he was fortuitously positioned first on the ballot paper and he was allowed to use a suspiciously similar logo to the mainstream Liberal party. Melissa Davey, “Liberal Democratic Party Logo Failed to Meet AEC Guidelines,” *The Guardian*, May 11, 2017, sec. Australia news, <https://bit.ly/2Yd5Xfc>.

¹⁴⁷ Michael McGowan, “Sarah Hanson-Young Accuses David Leyonhjelm of Sexism at Defamation Trial,” *The Guardian*, April 30, 2019, sec. Australia news, <https://bit.ly/30Qy3i0>; Scott Shackford, “David Leyonhjelm Repeals Libertarianism Down Under,” *Reason.Com* (blog), March 11, 2019, <https://reason.com/2019/03/11/david-leyonhjelm-repeals-libertar/>.

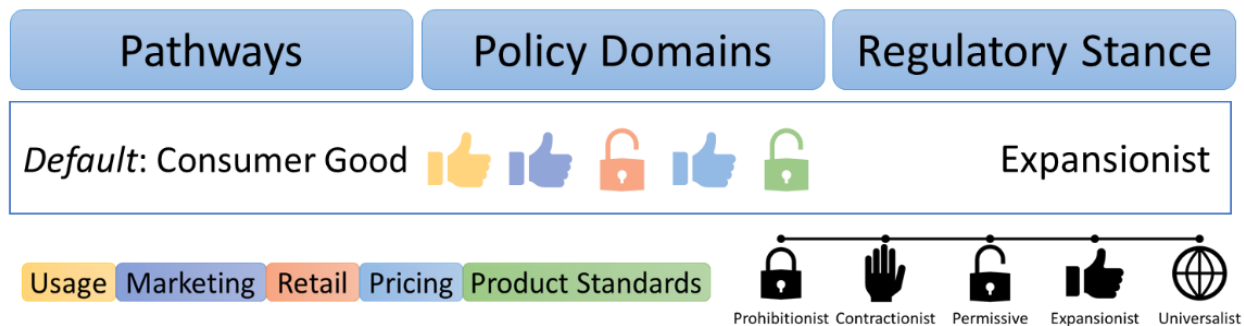
¹⁴⁸ AZ @ 19-20; He was described by an interviewee as, “a false populist saying things that will be published in the Murdoch press”.

¹⁴⁹ EM Greenhalgh et al., “10A.7 Mechanisms of Influence—Political Lobbying,” in *Tobacco in Australia: Facts and Issues*, by MM Scollo and MH Winstanley (Melbourne: Cancer Council Victoria, 2019), fig. 10A.7.1, <https://www.tobaccoinustralia.org.au/chapter-10-tobacco-industry/indepth-10a-strategies-for-influence/10a-7-the-mechanisms-of-influence-political-lobbyi>.

¹⁵⁰ AB @ 24; James Glenday, “Senate to Examine Drugs, Porn, Bike Helmets and Pools in ‘nanny State’ Inquiry,” Text, ABC News, September 11, 2015, <https://ab.co/2SvMFR0>.

This inquiry also marked the first time that e-cigarette regulation was mentioned in the Commonwealth Parliament. Leyonhjelm’s goal was to help overburdened tobacco companies undo the sales ban on e-cigarettes and other novel tobacco products. The inquiry’s results were handed down in February 2017 in a report on a private member’s bill, entitled the Vaporized Nicotine Products Bill 2017. The bill’s proposed regulatory framework (Figure 9) would have abolished the therapeutic pathway for nicotine-containing e-cigarettes and de-scheduled EU Tobacco Products Directive-compliant nicotine-containing e-cigarettes like tobacco cigarettes.¹⁵¹ The bill would have liberalized marketing of e-cigarettes and loosened controls on where the products could be used.¹⁵² It would continue exempting e-cigarettes from excise taxation. The bill was less clear on whether product standards that applied to tobacco products like limits on flavoring, graphic health warnings, age-of-sale restrictions, or plain packaging would be applied to the products.

Figure 9: Proposed Regulatory Framework for Nicotine-Containing E-Cigarettes in the Vaporized Nicotine Products Bill of 2017



The Senate committee charged with evaluating the bill reported out with a recommendation not to pass Leyonhjelm’s bill.¹⁵³ The Parliamentary Joint Committee on Human Rights noted that the proposed bill might infringe on Australian’s right to health because the risks of e-cigarettes were unknown.¹⁵⁴ As would become clearer over time, the Coalition government had little interest in advancing such a bill that would be easily framed by the opposition as acting in the best interest of the tobacco industry. The most significant outcome then, of the Nanny State Inquiry and the Vaporized Nicotine Products bill it fomented, was the decision to bring together THR advocates

¹⁵¹ Slade Brockman, *Vaporised Nicotine Products Bill 2017* (Canberra: Australia Parliament Senate, 2017), sec. 2.15, <https://bit.ly/2HfSmyb>; Brockman, sec. 2.26.

¹⁵² In places controlled by the Commonwealth government namely, airports.

¹⁵³ Brockman, *Vaporised Nicotine Products Bill 2017*.

¹⁵⁴ Brockman, sec. 1.8.

together for a hearing in Sydney in March 2016 where several policy advocates made the plan to push for legalization through a multitude of avenues that would be followed through in the next 24 months.¹⁵⁵

Leyonhjelm's interest in the policy and his close ties with the tobacco industry ended up backfiring on THR advocates. His leadership on the matter seems to have poisoned the well on future considerations over the country's regulatory stance towards e-cigarettes. The founder of ATHRA, Atilla Danko, recognized the error of partnering with Leyonhjelm and far-right wingers early on. In forum posts, he vented his frustration with the lack of focus in Australia on selling e-cigarettes as an innovative and disruptive technology idea to left-wing politicians.¹⁵⁶ Danko saw that the matter of e-cigarette regulations was being co-opted to push a libertarian point of view in policy, and was aware of the limited appeal that strategy would have with policy elites. The distrust of Leyonhjelm was not universal among THR advocates as Colin Mendelsohn, however, shared his frank communication with the Senator on a private message board for THR advocates which highlighted the pair's shared dislike for tobacco control advocate Simon Chapman.¹⁵⁷ Adopting an expansionist regulatory stance on e-cigarettes came to be characterized as being explicitly favorable to tobacco companies, a rather unappetizing position for mainstream Australian politicians and voters. If nothing politically could be gained from changing the regulatory stance by the Coalition government in power, then the chances of regulatory policy change had fallen substantially.

4.5 Failure to Couple the Streams

By 2016, on the matter of e-cigarettes, it would have been difficult to point to any of the three streams as being ripe for coupling that would lead to policy change. The policy stream was bifurcated between a well-established public health policy community that was skeptical of e-cigarettes and a THR advocate community that was relatively disempowered. The political stream was defined by a series of regional government actions made across all parties that consistently adopted strict regulations over the e-cigarette market. The problem stream was

¹⁵⁵ Chris Ketter, *Personal Choice and Community Impacts: Interim Report: The Sale and Use of Tobacco, Tobacco Products, Nicotine Products and e-Cigarettes (Term of Reference a)* (Canberra: Australian Senate Economics References Committee, 2016), 33.

¹⁵⁶ Atilla Danko, "Harm Reduction, State, and Utopia," Vaper Cafe Australia, March 16, 2016, <https://bit.ly/2yUduoW>; Urban, "Doctor Lobbies for 'life-Saving' Vaping."

¹⁵⁷ Mendelsohn and Leyonhjelm, "FW: Simon Chapman," June 21, 2017.

muddled as well. Skeptics' chosen framing of e-cigarettes as a poison that was threatening to both the health of children and the hard-won progress Australia had made fighting smoking dominated non-Murdoch outlets. The framing of e-cigarette regulations as an issue of nanny-state overreach in the Murdoch press was not making much headway.

THR advocates did not survey this landscape and choose to wait for the tide to change directions. They decided to try and repeal the lone Commonwealth policy keeping e-cigarettes out of Australia; by changing the TGA's classification of liquid nicotine as a scheduled poison. This decision cascaded into a series of reviews and inquiries that have carried on through the end of 2019 with little end in sight. Through it all, e-cigarette regulatory policy change has remained well out-of-reach of the THR advocates.

4.5.1 TGA De-Scheduling Application

In January 2016, THR advocates at Leyonhjelm's Nanny State hearing in Sydney, went out for dinner after their testimony had been given, and decided their next project would be to attempt to get liquid nicotine rescheduled from being a poison under the TGA's control.¹⁵⁸ By the end of June 2016, an application that had been prepared by Colin Mendelsohn was submitted to the TGA.¹⁵⁹ This effort continued a vein of the argument being made by THR advocates that the therapeutic pathway was inappropriate for e-cigarettes.¹⁶⁰ Instead, they suggested the TGA remove nicotine liquid for e-cigarettes from the poisons schedule if they met basic product safety standards: limits on nicotine concentration and size, sold in child-resistant containers and labeled with selected safety and consumer information.¹⁶¹ This would have created a similar regulatory framework to Leyonhjelm's proposal (See Figure 9).

The TGA already had established the country's regulatory framework for e-cigarettes by plugging the product into existing pathways (See Figure 8).¹⁶² Upon receipt of the de-scheduling application, the TGA was not immediately impressed with the case being made by THR

¹⁵⁸ AW @ 34

¹⁵⁹ "Scheduling Committees Meeting Dates and Decisions Timeframes," Therapeutic Goods Administration (TGA), November 9, 2016, <https://bit.ly/32EeKu5>.

¹⁶⁰ In the eyes of the government and e-cigarette skeptics, this was a huge weakness of their argument. It conflates appeals to anecdotal evidence, clinical trial research, and the lack of capital that e-cigarette companies must submit premarket applications that would meet government safety and efficacy standards.

¹⁶¹ Belinda Merhab, "Health Dept 'cautious' over e-Cigarettes," *AAP Bulletins*, October 19, 2016, <http://global.factiva.com/redir/default.aspx?P=sa&an=AAPBLT0020161019ecaj000dz&cat=a&ep=ASE>.

¹⁶² AJ @ 39

advocates. The application sought to de-schedule liquid nicotine on similar grounds that were used for nicotine replacement therapies, but the products would be used for the expressed purpose of “tobacco harm reduction” and not for the older product’s purpose of “smoking cessation”. Reviewers had no precedent to follow in this instance which immediately set up major roadblocks to the success of the proposal. Further, the application’s reviewers could not tell what the application was asking them to do once nicotine-containing e-liquid had been rescheduled; would it be an unscheduled therapeutic good, an ordinary consumer product, or an exempt tobacco product (like cigarettes)?¹⁶³

In February 2017, the interim decision on nicotine rescheduling was handed down. It confirmed that the committee thought the current scheduling of nicotine remained appropriate.¹⁶⁴ 54 submissions to the committee on the matter supported the change while 17 opposed the change.¹⁶⁵ The TGA cited the risk of nicotine dependence from the use of e-cigarettes and a lack of long-term safety data in its final decision on March 23, 2017.¹⁶⁶ The TGA decision anchored skeptics thereafter by providing an official reference point for their perspective above and beyond the NHMRC CEO Statements.¹⁶⁷

4.5.2 House Inquiry

One minute after the TGA’s final announcement that nicotine scheduling would not change, an inquiry into e-cigarettes to be led by the House’s Health, Aged Care and Sport Committee was announced to begin in May 2017.¹⁶⁸ A public relations group called Palin Communications helped THR advocates parlay their lost opportunity at the TGA into the inquiry by lobbying perceived friendly MPs.¹⁶⁹ The inquiry began with an apparent chance to result in legislative change because it was tasked with establishing the current law and evidence on e-cigarettes.¹⁷⁰

¹⁶³ Australian Committee on Medicines Scheduling, “Public Submissions on Scheduling Matters Referred to the ACMS #19, November 2016, Part 3,” Therapeutic Goods Administration (TGA), November 2016, <https://bit.ly/2TvefOS>.

¹⁶⁴ Australian Government Department of Health Therapeutic Goods Administration, “2.1 Nicotine.”

¹⁶⁵ 1 consultant, 2 peak health bodies, 3 academic groups, 6 business owners, 7 medical professionals and 35 consumers favored the proposed change in scheduling. 1 Academic group, 4 Non-governmental Organizations, 5 peak health bodies and 7 government health departments opposed the change.

¹⁶⁶ Australian Government Department of Health Therapeutic Goods Administration, “2.1 Nicotine.” See Note 35.

¹⁶⁷ AN2@ 4

¹⁶⁸ Joe Hildebrand, “Gone in 60 Seconds: Govt Backs Vaping Law Then Announces Inquiry One Minute Later,” NewsComAu, May 29, 2017, <http://bit.ly/2qwzFFv>.

¹⁶⁹ AW @ 37; Martin Palin, “Framing Issues in Healthcare,” *Palin Communications* (blog), February 12, 2018, <https://www.palin.com.au/palinblognew/framing-issues-in-healthcare>.

¹⁷⁰ Hildebrand, AQ@ 3

However, it never progressed beyond consideration of the evidence of e-cigarette safety and ended up favoring the forces of policy inertia. Health Minister Greg Hunt was perceived to be doing his due diligence by allowing inquiry, but eventually, it turned out that there was no crisis he needed to solve by changing policy, and a majority of the committee was able to point towards safety concerns as a reason not to change policy.¹⁷¹

The terms of reference for the House inquiry focused first on the safety of e-cigarettes and second on considerations of international and alternative regulatory frameworks. Legalization remained an ill-defined concept compared to the status quo policy, largely because skeptics preferred this and some bull politicians like Leyonhjelm were open to lax regulatory regimes. Several members of the Liberal Party who were former employees of a free-market think-tank called the Institute of Public Affairs, MPs Trent Zimmerman and Tim Wilson and Senator James Patterson, pushed for the House inquiry, all the while professing their belief in market solutions to social problems. In a mirrored reprisal to his role as public opponent number one to plain packaging during his time at the Institute of Public Affairs, Tim Wilson served as the most publicly vocal supportive inquiry member on the issue of e-cigarettes.¹⁷²

The inquiry held three public hearings, collected 352 submissions, and 45 exhibits from the public, conducted a fact-finding mission to New Zealand and received over a thousand form letters from the public.¹⁷³ The inquiry collected testimony from THR advocates and skeptics alike, even gathering a series of dueling submissions between local Australian experts and Public Health England, who sought to advise the Australians to adopt a regulatory framework similar to the United Kingdom. The Australian public health policy community did not take kindly to this advice fearing that Public Health England did not understand the local political context and the role that the Institute of Public Affairs alumni, and hence the tobacco industry, were playing in the inquiry.¹⁷⁴

The most consequential development for the house inquiry occurred in October 2017, when Health Minister Greg Hunt stated to the media that e-cigarettes would not be legalized on his

¹⁷¹ AJ @ 46, AZ @ 22

¹⁷² AH @ 22-23

¹⁷³ Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia* (Canberra: Commonwealth of Australia, 2018), sec. 1, <https://bit.ly/2GTRtK0>.

¹⁷⁴ AZ @ 30; AS @ 56

watch.¹⁷⁵ Hunt was described as someone who listened to his public servants, was properly briefed, motivated by a personal loss to tobacco caused-illness, and someone who believed there was no political advantage to the Coalition government to changing the e-cigarette regulatory framework.¹⁷⁶ Hunt was determined to keep the focus of the house inquiry on concerns around product safety and youth usage, and not on considering alternative regulatory frameworks because he had been convinced that absolute product safety concerns were reason enough to continue the status quo policy. From Hunt's public pronouncement on, it became clear that something would be done to prevent policy change. Therefore, unlike in Leyonhjelm's efforts, no concrete alternative regulatory framework for e-cigarettes ever crystallized within the committee's deliberations on the matter.

When the inquiry reported out in March 2018, the committee's reports split oddly. The committee chair, Trent Zimmerman wrote an unheard-of *dissenting minority* report joined by his fellow Institute of Public Affairs alumni Tim Wilson.¹⁷⁷ A further concurring dissenting report was authored by Liberal MP Andrew Laming read in whole, "Life is short and shorter for smokers. Just legalise vaping."¹⁷⁸ The chair's dissenting report claimed that Australia's smoking rates had stabilized and sought to use international lesson drawing, particularly from the experiences of the United States, United Kingdom, New Zealand, and Canada, as his uppermost reason to change Australian e-cigarette regulatory policy.¹⁷⁹ This was the highest-profile usage of THR advocates' health framing of the issue.

The majority report was written by all the Labor members on the committee and two Liberal members.¹⁸⁰ The majority agreed with the Department of Health's argument that the actions of other countries were not a sufficient justification for Australia to legalize nicotine-containing e-cigarettes and they claimed that smoking was still decreasing.¹⁸¹ The majority provided recommendations for further action; the NHRMC should continue funding research into e-

¹⁷⁵ "Health Minister Rules out Legalising E-Cigarettes," ABC, October 16, 2017, <https://ab.co/2yqVvHI>.

¹⁷⁶ AL @ 25; AH @ 50, AZ @ 19; AG2 @ 14

¹⁷⁷ AO@ 3; No interviewee could recall this happening before in the Australian Parliament. My further searches of the literature failed to turn up another example.

¹⁷⁸ Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, 19–20, 141.

¹⁷⁹ AQ @ 3-4; Standing Committee on Health, Aged Care and Sport, 141.

¹⁸⁰ Labour; Steve Georganas (Deputy Chair), Mike Freelander, Tony Zappia: Liberal; Lucy Wicks, Michelle Landry

¹⁸¹ Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, sec. 2.15.

cigarettes, the Department of Health should convene international consultations comparing e-cigarette regulatory frameworks, a national approach to regulate non-nicotine e-cigarettes and the flavorings in e-liquid should be devised, and the TGA should continue overseeing nicotine scheduling.

When e-cigarette liberalization could not find a majority on the committee, Coalition members derided the members of that majority as, “taking a political position, not a health-based decision”.¹⁸² They described their Labor opponents as being directed by their Shadow Minister for Health, Catherine King, to oppose changing regulatory policy, even if they privately had a different view.¹⁸³ The outcome could be partially attributed to well-documented Labor and Green Party discipline and THR advocates’ failure to successfully gain support across party lines.¹⁸⁴ Notwithstanding that, what seemed to tip the balance against the THR advocates was the failure to co-opt Coalition party elites like Minister Hunt and the failure to persuade anyone outside the right-wing of the Coalition that tobacco control was failing in Australia.

4.5.3 The Fight Continues

The House Inquiry concluded more research into e-cigarette safety, efficacy, and population effects was needed.¹⁸⁵ A spirited discussion of this “loose end” of a conclusion in the Coalition party room on September 18, 2018, began with Zimmerman, Paterson, Wilson, Andrew Laming, and Assistant Health Minister Bridget McKenzie pushing for another public inquiry into e-cigarettes.¹⁸⁶ The matter rose into a row of such consequence that party leadership, in the embodiment of Greg Hunt, protested by citing the position of US FDA commissioner, Scott Gottlieb, on the matter to push back.¹⁸⁷ Hunt felt that Zimmerman and allies wanted another chance to obtain the result they wanted from an inquiry, a recommendation for e-cigarette legalization.¹⁸⁸ Under pressure, Hunt offered a compromise wherein an independent evidence

¹⁸² AQ@ 10

¹⁸³ AQ@ 10

¹⁸⁴ Christopher J. Kam, *Party Discipline and Parliamentary Politics* (Cambridge: Cambridge Univ. Press, 2009). AW @ 35

¹⁸⁵ Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, sec. 3.145.

¹⁸⁶ The day prior, the topic had been broached by Senator Eric Abetz on the Senate floor in the context of the Tobacco Plain Packaging Amendment Bill. AO@ 18; AN@ 21; Eric Abetz, “BILLS - Tobacco Plain Packaging Amendment Bill 2018 - Second Reading,” text, Australian Senate Hansard, September 17, 2018, <https://bit.ly/2K4fVLV>.

¹⁸⁷ Murphy, “Vaping Inquiry.”

¹⁸⁸ AZ @ 25

review which would be ordered from the Australian National University.¹⁸⁹ Ministers in related departments continued to toe the party elite line that Australia intends to utilize the inquiry to support its precautionary policy approach as it sought to learn from the experiences of other countries.¹⁹⁰

In April 2019, the 45th Parliament of Australia was dissolved, and an election campaign began with the Labor party in prime position to retake power.¹⁹¹ The Coalition government had been significantly weakened by the “World’s Most Ridiculous Constitutional Crisis” which rocked the Parliament causing fifteen parliamentarians to be ruled ineligible to sit in parliament because they were found to be dual citizens of another country besides Australia.¹⁹² E-cigarette regulation was not mentioned among issues under consideration by the voters during the campaign. Growing public dislike of Labor’s leader Bill Shorten and a preference for the Coalition’s policies on the economy and immigration swung public opinion against Labor over the course of the campaign.¹⁹³ In May 2019, the Coalition government scored a surprise election victory over Labor, setting the stage for a continued political shift in Australia towards the right.¹⁹⁴

It remains uncertain whether the newly empowered Commonwealth Coalition government will shift its regulatory stance towards e-cigarettes. As of July 2019, the Australian National University inquiry was still being conducted and its terms of reference were not yet public.¹⁹⁵ There is no indication that Labor’s election loss has softened its position against considering the

¹⁸⁹ Hunt was reappointed to the post of Health Minister the prior month after losing the position once Scott Morrison became PM. Hunt had voted to support Peter Dutton, the challenger for PM from the hard right, as he was tapped to be Dutton’s deputy had Dutton won the leadership fight. John Wanna, “Commonwealth of Australia,” *Australian Journal of Politics & History* 65, no. 2 (2019): 295–300, <https://doi.org/10.1111/ajph.12576>.

¹⁹⁰ David Leyonhjelm and Nigel Scullion, “QUESTIONS WITHOUT NOTICE - E-Cigarettes,” text, Australian Senate Hansard, November 28, 2018, <https://bit.ly/3327Z5c>.

¹⁹¹ Michael McGowan, “The Australian Election 2019 Has (Finally) Been Called: Here Is Everything You Need to Know,” *The Guardian*, April 10, 2019, sec. Australia news, <https://www.theguardian.com/australia-news/2019/apr/11/the-australian-election-2019-has-finally-been-called-heres-what-you-need-to-know>.

¹⁹² The dual citizenships in question were with respect to the United Kingdom, Canada, and New Zealand. David Fickling, “The World’s Most Ridiculous Constitutional Crisis,” *Bloomberg.Com*, August 16, 2017, <https://www.bloomberg.com/opinion/articles/2017-08-16/australia-faces-the-world-s-most-ridiculous-constitutional-crisis>; “Fact File: The Dual Citizenship Crisis,” Text, ABC News, December 6, 2017, <https://www.abc.net.au/news/2017-12-06/fact-file-the-dual-citizenship-scandal/9147418>.

¹⁹³ Sarah Cameron and Ian McAllister, “The 2019 Australian Federal Election: Results from the Australian Election Study” (Canberra: The Australian National University, December 2019), <https://australianelectionstudy.org/wp-content/uploads/The-2019-Australian-Federal-Election-Results-from-the-Australian-Election-Study.pdf>.

¹⁹⁴ Marija Taflaga, “Morrison Has Led the Coalition to a ‘miracle’ Win, but How Do They Govern from Here?,” *The Conversation*, May 19, 2019, <https://bit.ly/2KNOK78>.

¹⁹⁵ Cory Bernardi and Michaela Cash, “QUESTIONS WITHOUT NOTICE - Health,” text, Australian Senate Hansard, July 31, 2019, <https://bit.ly/2TubWvd>.

legalization of e-cigarettes.¹⁹⁶ We can conclude that the Coalition's choice to not pursue e-cigarette regulatory policy change did not harm their electoral prospects, as the upset victory seemed a handsome payoff for policy caution, at least in this one area of policy.

4.6 Conclusion

Australia's regulatory framework towards nicotine-containing e-cigarettes has remained stable over time. Regional level policies served to cement the prohibitionist regulatory stance taken under commonwealth poisons regulations. Efforts to change the policy were blocked because policy entrepreneurs were unable to create the conditions to open a policy window. Inadequate ripening of the problem stream could not overwhelm the preferences of expertise-based policymaking institutions to maintain the status-quo policy. Above all, policy entrepreneurs failed to persuasively define a problem that e-cigarettes would solve. Divided THR advocates failed to entertain policy solutions that were acceptable to the values of a winning political coalition. Entrepreneurs hawked a solution that did not have value acceptability with an elite policymaker consensus. THR advocates hamstrung their proposal from being considered by all but the fringe of right-wing Australian politics and thus failed to change the regulatory framework.

Australia is a useful case of regulatory framework stasis. The country's experience with e-cigarettes demonstrates the value of constructing a consensus position within a policy community. Skeptics had a consensus and THR advocates did not. Further, a consensus position is made stronger if it favors a policy solution that either has value acceptability to policymakers or it represents the status quo. Skeptics' position satisfied both criteria, while THR advocates non-consensus views satisfied neither. If one is pursuing a change in a regulatory framework, it is advisable to cover these bases before setting out on a campaign. If one is trying to prevent a change in a regulatory framework, then stifling the process of problem definition could be an effective first-line strategy.

¹⁹⁶ See further evidence of this in the aftermath of the EVALI outbreak in section 7.3.3 on page 227.

Chapter 5 Canada

From Unregulated to Business-Friendly Harm Reduction

In January 2014 when Mitch Tarala, owner and proprietor of Vapor Jedi an e-cigarette retail shop in Saskatoon, Saskatchewan, received a cease-and-desist letter from Health Canada's Prairie Region and Programs Branch, the federal omnibus health regulator, that he cease selling nicotine-containing e-cigarettes out of his store.¹ Mr. Tarala reacted peculiarly to the regulator's request. He framed the letter, hung it up for his customers to see in his shop, and carried on selling e-cigarettes². He claimed that the regulators were incorrectly interpreting federal law and that his products were exempt from their regulatory authority because they did not provide enough nicotine to users to qualify as drug delivery devices.³ Instead, of immediately serving Mr. Tarala with a notice to appear in court, regulators and enforcement officers did not follow up their letter with further action. In the interim, Mr. Tarala ended up participating in public consultations on the use of e-cigarettes in public spaces in his city, and his store was burgled and the crime was reported on the local news.⁴ But in 2019, after the e-cigarette market in Canada had been deemed legal, Mr. Tarala's business folded due to business factors, like competition with the products of transnational tobacco companies, that had little to do with the cease-and-desist letter he had received in 2014.⁵

Mr. Tarala's journey was not unique. His story is emblematic of the changing regulatory landscape of the Canadian e-cigarette market. Questionably legal retailers eventually became straightforwardly legal. Then, they suffered the consequences of competing in a legal market.

¹ Mitch Tarala, "R/Electronic_cigarette - Health Canada Asks Vapor Jedi To Shut Down!!," reddit, January 20, 2014, <https://bit.ly/2LVtoX5>.

² Andrea Hill, "Vapour Shops Defy Ottawa's Warning Letters over e-Cigarettes," *Vancouver Sun*, April 25, 2014, sec. Canada & World, NexisUni.

³ John Overall, "Health Canada Claims E-Juice with Nicotine Is a Drug," Northern Vapers Victoria BC, November 27, 2013, <https://bit.ly/2toNC58>.

⁴ "Surveillance Camera Catches Thief Filling Bag at Vapor Jedi," CBC, February 4, 2016, <https://www.cbc.ca/news/canada/saskatoon/surveillance-camera-catches-thief-filling-bag-vapor-jedi-1.3432885>; Leena Latafat, "Council Votes to Ban E-Cigarettes on Outdoor City Property," Global News, November 24, 2015, <https://globalnews.ca/news/2359391/council-votes-to-ban-e-cigarettes-on-outdoor-city-property/>.

⁵ Mitch Tarala, "RIP Vapor Jedi, 2013-2019," Vapor Jedi, 2019, <https://www.vaporjedi.com/>.

This chapter utilizes Kingdon's Multiple Streams approach to explain how and why e-cigarette regulation changed in Canada.

5.1.1 Governing Legislation

E-cigarette regulation in Canada is governed by 3 primary pieces of legislation, the *Food and Drugs Act*, the *Consumer Product Safety Act*, and the *Tobacco Products Act*.⁶ These pieces of legislation work together to establish the regulatory stance of the Canadian government towards e-cigarettes.

First passed in 1920, the *Food and Drugs Act* of Canada has evolved to empower the Canadian federal government with regulatory jurisdiction over most of the products that Canadians put into their bodies.⁷ The process for gaining premarket authorization for drugs began with a 1951 requirement that manufacturers notify the Food and Drugs Directorate within Health Canada that they were releasing a product onto the market.⁸ In the aftermath of the thalidomide tragedy, further regulations were passed requiring manufacturers to prove the efficacy and safety of drugs before market entry.⁹ The *Food and Drugs Act* imbues regulators with gatekeeping authority over market entry for new drugs and it sets the standards for what chemicals Canadians can ingest as a food or a drug.

The *Canada Consumer Product Safety Act* was passed into law in December 2010 by the Conservative Harper government.¹⁰ The *Consumer Product Safety Act* was designed to more effectively police commerce in consumer goods previously covered under the country's *Hazardous Products Act* in response to an escalating rash of recalls of products found to be hazardous to children. The *Consumer Product Safety Act* governs all products without therapeutic claims and sets product standards governing the contents of consumer goods. Under the *Consumer Product Safety Act*, the Consumer Product Safety Directorate within Health

⁶ Since May 2018, the *Tobacco and Vaping Products Act*. Health Canada, "Tobacco and Vaping Products Act," guidance - legislative, aem, June 26, 2018, <https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/legislation/federal-laws/tobacco-act.html>.

⁷ Neal D. Fortin and Bernd van der Meulen, "Development of Food Legislation Around the World," in *Ensuring Global Food Safety*, ed. Christine E. Boisrobert et al. (San Diego: Academic Press, 2010), sec. 2.7.4.1, <https://doi.org/10.1016/B978-0-12-374845-4.00002-3>.

⁸ Joel Lexchin, *Private Profits versus Public Policy: The Pharmaceutical Industry and the Canadian State* (University of Toronto Press, 2016), 55.

⁹ M. Herder et al., "Regulating Prescription Drugs for Patient Safety: Does Bill C-17 Go Far Enough?," *Canadian Medical Association Journal* 186, no. 8 (May 13, 2014): E287–92, <https://doi.org/10.1503/cmaj.131850>.

¹⁰ "Consumer Safety Bill Passes Parliament," CBC, December 14, 2010, <https://www.cbc.ca/news/consumer-safety-bill-passes-parliament-1.927400>.

Canada gained authority to deem which products are safe for consumption and can recall products found to be unsafe.¹¹

Canada's history of regulating novel products is uneven and littered with examples where politics and economic interests shaped what was purported to be science-based regulation. The regulatory history of margarine in Canada, for example, is littered with prohibitionist and contractionist regulatory stances adopted at the behest of protecting the country's dairy interests that were intent on crushing the market for butter substitutes.¹² For health reasons, Canada has also prohibited the sale of baby-walkers and the use of Bisphenol A, a component of resins and plastics that are used elsewhere in baby bottles.¹³ However, Canada has adopted an expansionist regulatory stance towards genetically modified foods.¹⁴ The reasons for adopting these varied policies are not self-evidently consistent across different markets as foreign jurisdictions have adopted regulatory stances based on reasons that at times align with Canada's reasoning and at times oppose their logic.¹⁵

The main statute used to advance Canada's tobacco control policy interests is the *Tobacco Products Act*, which governs the regulation of tobacco products in a functionally different manner than other substances that are ingested into the body (food, drugs, etc.). In terms of tobacco regulation, Canada has often been a global leader, eventually creating what is now a strongly contractionist framework for cigarettes. Liberal and New Democratic Party (NDP) lawmakers (respectively, the country's center-left and left-wing political parties) from ridings outside the country's tobacco producing regions steadily advanced policies intended to control cigarette smoking rates in the country through the 1960s and 1970, culminating in the passage of

¹¹ Claudia Irigoyen, "The Canada Consumer Product Safety Act (CCPSA)," Case Study (Arlington, VA: Centre for Public Impact, June 13, 2017), <https://www.centreforpublicimpact.org/case-study/canadian-consumer-product-safety-act-ccpsa/>.

¹² Charlene Elliott, "Canada's Great Butter Caper," *Food, Culture & Society* 12, no. 3 (September 1, 2009): 379–96, <https://doi.org/10.2752/175174409X432049>.

¹³ Sara Edge and John Eyles, "Message in a Bottle: Claims Disputes and the Reconciliation of Precaution and Weight-of-Evidence in the Regulation of Risks from Bisphenol A in Canada," *Health, Risk & Society* 15, no. 5 (August 1, 2013): 432–48, <https://doi.org/10.1080/13698575.2013.802293>; A. Murphy and A. J. Nicholson, "Baby Walkers in Europe--Time to Consider a Ban," *Irish Medical Journal* 104, no. 3 (March 2011): 69.

¹⁴ Stuart J. Smyth and Alan McHughen, "Regulation of Genetically Modified Crops in USA and Canada: Canadian Overview," in *Regulation of Agricultural Biotechnology: The United States and Canada*, ed. Chris A. Wozniak and Alan McHughen (Dordrecht: Springer Netherlands, 2012), 15–34, https://doi.org/10.1007/978-94-007-2156-2_2.

¹⁵ For example, the US allows the sale of Bisphenol A and baby walkers and promotes the sale of genetically modified food on the grounds that none of these substances have been found by its regulatory agencies to be injurious to health. The European Union allows the sale of Bisphenol A and baby walkers but prohibits the sale of genetically modified foods for similar reasons. "Bisphenol A," European Food Safety Authority, 2018, <https://www.efsa.europa.eu/en/topics/topic/bisphenol>; Paarlberg, *The Politics of Precaution*.

the *Tobacco Products Control Act* of 1988 under a federal Conservative government.¹⁶ These efforts were pushed forward by public health activist groups led by the Canadian Cancer Society, the Non-Smokers Rights Association, Physicians for a Smoke-Free Canada, and the Heart and Stroke Foundation.¹⁷ The 1988 law restricted tobacco advertising, sponsorship, and promotion and introduced the country's first mandatory cigarette package health warnings. Through the early 1990s, Canada strengthened its tobacco control policy by increasing tobacco taxes, increasing its minimum age of sale of tobacco products to 18, and removing some cigarette vending machines.¹⁸

However, Canadian federal policy has not proceeded monotonically towards tighter restrictions on tobacco products. In 1995, tobacco control advocates suffered several setbacks in the form of a Supreme Court ruling that overturned some of the provisions restricting the use of trademarks and advertising in the 1988 *Tobacco Products Control Act* and a rollback of tobacco tax levels in the face of persistent smuggling efforts from First Nations reservations and the United States.¹⁹ The Tobacco Control Programme (today, Directorate) within Health Canada led a revision of the *Tobacco Products Act* that responded to the high court's decision that was passed into law in 1997 by a Liberal government and restored much of the 1988 *Act* in slightly adulterated and diminished form.²⁰ These setbacks in policy were also accompanied by setbacks in the declining rate of smoking, particularly as surveys began to find that young adult smoking began to climb from a low of 28.3% in that age group to 1993 back to 32.3% in 1997.²¹

Through the first half of the 2000s, Canada became a global tobacco control policy innovator. The country debuted the world's first graphic health warnings on cigarette packages in 2000 and

¹⁶ Rob Cunningham and Centre de recherches pour le développement international (Canada), *Smoke & Mirrors the Canadian Tobacco War* (Ottawa, Ont: International Development Research Centre, 1996), chap. 6,7, <http://accessbib.uqam.ca/cgi-bin/bduqam/transit.pl?&noMan=25205319>.

¹⁷ Studlar, *Tobacco Control*, chap. 5.

¹⁸ Studlar, chap. 3.

¹⁹ Max H. Kelton and Michael S. Givel, "Public Policy Implications of Tobacco Industry Smuggling through Native American Reservations into Canada," *International Journal of Health Services* 38, no. 3 (July 1, 2008): 471–87, <https://doi.org/10.2190/HS.38.3.f>; Christopher P. Manfredi, "Expressive Freedom and Tobacco Advertising: A Canadian Perspective," *American Journal of Public Health* 92, no. 3 (March 2002): 360–62.

²⁰ C. Callard, "The Canadian Set-Back: Tobacco Use in Canada, 1986–97," in *Tobacco: The Growing Epidemic*, ed. Rushan Lu et al. (London: Springer London, 2000), 610–15, https://doi.org/10.1007/978-1-4471-0769-9_261.

²¹ Steering Committee of a National Strategy to reduce tobacco use in Canada and Advisory Committee on Population Health, *New Directions for Tobacco Control in Canada: A National Strategy* (Ontario: Health Canada, 1999), <http://publications.gc.ca/site/eng/9.661567/publication.html>.

played a leading role pushing the ratification of the WHO FCTC.²² By the end of the decade, Canadian policymakers had eliminated smoking from virtually all public places, with increasing assistance being provided by parties across the entire ideological spectrum.²³ Dramatic reductions in smoking prevalence have followed, and have placed Canada among the world's most effective countries in the implementation of a comprehensive tobacco control policy regime.²⁴ These efforts have created a strongly contractionist regulatory framework for the tobacco cigarette market.

5.1.2 Multiple Streams and Policy Change

The fit of nicotine-containing e-cigarettes under each of these pieces of regulatory legislation has never been straightforward. Conditions eventually aligned, in the sense that Kingdon's multiple streams eventually coupled, to bring forward legislation that clarified the place of e-cigarettes under the *Food and Drugs Act*, the *Consumer Product Safety Act*, and even the *Tobacco Products Act*, which would have to change its name to reflect the importance of e-cigarettes to the Canadian regulatory strategy. In 2018, Canada passed the *Tobacco and Vaping Products Act* (formerly bill S-5) as the Federal government's primary regulatory response to the development of widespread demand for e-cigarettes.²⁵

This change in the regulatory stance can be explained by three factors that are well-represented by Kingdon's Multiple Streams Approach.²⁶ The sequential attainment of readiness in the problem, policy, and politics streams in Canada over the course of several years opened a policy window which resulted in the passage of a new federal e-cigarette regulatory framework in May 2018. The e-cigarette market in Canada came to be framed by actors in the media and the provinces as unregulated and needing a revised federal regulatory approach. A strong policy

²² Jidong Huang, Frank J. Chaloupka, and Geoffrey T. Fong, "Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis," *Tobacco Control* 23, no. suppl 1 (March 1, 2014): i7–12, <https://doi.org/10.1136/tobaccocontrol-2013-051170>; Donley T. Studlar, "Ideas, Institutions and Diffusion: What Explains Tobacco Control Policy in Australia, Canada and New Zealand?," *Commonwealth & Comparative Politics* 45, no. 2 (April 1, 2007): 164–84, <https://doi.org/10.1080/14662040701317493>.

²³ Cathy A. Sabiston, "Canada: Second (Five Year) Implementation Report," Framework Convention on Tobacco Control (World Health Organization, March 10, 2010), http://www.who.int/fctc/reporting/Canada_5y_report_v2_final.pdf.

²⁴ Jeffrey Drope et al., *The Tobacco Atlas*, 6th ed. (Atlanta, GA: American Cancer Society and Vital Strategies, 2018); JL Reid et al., "Tobacco Use in Canada: Patterns and Trends, 2017 Edition" (Propel Centre for Population Health Impact, University of Waterloo, 2017), https://uwaterloo.ca/tobacco-use-canada/sites/ca.tobacco-use-canada/files/uploads/files/2017_tobaccouseincanada_final_0.pdf.

²⁵ Harder, An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts.

²⁶ Kingdon, *Agendas, Alternatives, and Public Policies*.

preference for revising the e-cigarette regulatory framework to permit or encourage the expansion of the e-cigarette market was advanced by public health and consumer groups developed in the wake of a study in the House of Commons. Strong opposition to such policy changes never emerged from tobacco companies, as they stood to profit from the adoption of such a regulatory framework. Finally, the election of the Trudeau Liberal government in 2015 solidified political momentum towards the application of a harm reductionist philosophy to this public health problem. A particularly business-friendly form of harm reduction policy was applied to e-cigarettes in the form of an expansionist regulatory stance.

5.2 Regulatory Stances Towards E-Cigarettes

Bill S-5 enabled federal regulators in the Tobacco Control Directorate of Health Canada to create product standards that were much more favorable to e-cigarettes than tobacco cigarettes. This represented a significant change from the prior prohibitionist regulatory stance of the Canadian government towards e-cigarettes. The details of the policies that comprised the regulatory stance are described in this section.

5.2.1 Before Bill S-5

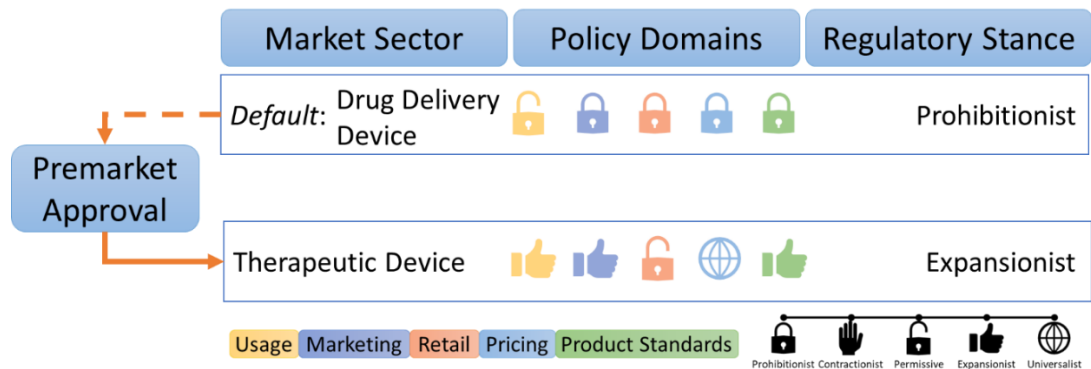
When e-cigarettes began to enter the Canadian market, between 2007 and 2009, they were classified by Health Canada's Therapeutic Products Directorate as 'drug delivery devices' if they contained nicotine or if marketers made a therapeutic claim about the products.²⁷ A drug delivery device that did not receive premarket approval from the Therapeutic Products Directorate could not be legally sold, as it would be classified as a new drug.²⁸ In effect, if a company wanted to sell a nicotine-containing e-cigarette, and they submitted the product for premarket approval, that product would have been subject to an expansionist regulatory stance (Figure 10) that granted marketing, retailing, subsidy, and product standards that would have placed the product at a competitive advantage over tobacco cigarettes. Such a product would have been granted pricing advantages such as being subject to provincial pharmaceutical reimbursement schemes, being

²⁷ Devices that did not contain nicotine were not delivering a drug that was regulated under the *Food and Drugs Act*. The same devices that could process e-liquid for consumption without nicotine could process nicotine-containing liquid just as easily. Matthew B. Stanbrook, "Regulate E-Cigarettes as Drug-Delivery Devices," *CMAJ* 185, no. 16 (November 5, 2013): 1379–1379, <https://doi.org/10.1503/cmaj.131469>.

²⁸ E. Somers, M. Carman Kasperek, and J. Pound, "Drug Regulation—The Canadian Approach," *Regulatory Toxicology and Pharmacology* 12, no. 3, Part 1 (December 1, 1990): 214–23, [https://doi.org/10.1016/S0273-2300\(05\)80059-5](https://doi.org/10.1016/S0273-2300(05)80059-5).

exempt from bans on use in public places, and being subject to relatively lax marketing regulation.²⁹

Figure 10: Canada's Regulatory Stance Towards Nicotine-Containing E-Cigarettes Before Bill S-5



The regulatory stance of the Canadian federal government towards the nicotine-containing e-cigarette market that had not gone through premarket approval processes was officially prohibitionist, but in effect, e-cigarettes were rapidly proliferating across the country. Ever use of e-cigarettes among adult smokers quintupled from 2010 to 2013, e-cigarette sales grew to over US \$100 million by 2014, and the number of people using e-cigarettes in the country approached 800,000 by 2016.³⁰

In contrast to the federal government's approach that did not acknowledge the legality of the market in any way, the regulatory choices made by the provinces added to the confusion about Canadian law.³¹ As some provinces passed their own legislation designating certain public spaces as being unacceptable for use of e-cigarettes, e-cigarette users began to assume that other public spaces were legitimate places where e-cigarettes could be used.³²

As time passed and no nicotine-containing e-cigarette received premarket approval from the Therapeutic Products Directorate, e-cigarette retailers repeatedly and brazenly flouted the

²⁹ David M. Gardner, Barbara Mintzes, and Aleck Ostry, "Direct-to-Consumer Prescription Drug Advertising in Canada: Permission by Default?," *CMAJ: Canadian Medical Association Journal* 169, no. 5 (September 2, 2003): 425–27.

³⁰ David Attwood and Daniel Irwin-Brown, "In Depth: Canadian e-Cigarette Market, December 2014," *ECigIntelligence* (blog), December 5, 2014, <https://ecigintelligence.com/in-depth-canada-e-cigarette-market-analysis-december-2014/>; Barnaby Page, "Sharp Increase in Canadian Vaper Numbers and Sales," *ECigIntelligence* (blog), June 27, 2016, <https://ecigintelligence.com/sharp-increase-in-canadian-vaper-numbers-and-sales/>.

³¹ "What Does The Law Say? | A Canadian Guide to Electronic Cigarettes and Related Canadian Law," February 28, 2014, <https://web.archive.org/web/20140228183349/http://whatdoesthelawsay.ca/>.

³² CG @ 3; Angela Mulholland, "E-Cigarettes in Regulatory Grey Zone: Are They Banned or Aren't They?," CTV News, April 22, 2014, <https://bit.ly/2SRpliF>.

prohibitionist regulatory stance in public spaces by setting up shops, marketing their products, and conducting normal business.³³ A 2014 secret shopper investigation conducted by the Office of Research and Surveillance within the Tobacco Directorate found that 90% of retailers who refused to sell a minor a cigarette also refused to sell the same youths an e-cigarette, even though such a sale was *not* expressly prohibited under federal or provincial law.³⁴ The behavior of retailers regarding youth access via retail to e-cigarettes reflected the vaguely defined legal position around whether anyone was allowed to buy these products.

5.2.2 After Bill S-5

Health Canada, led by its Tobacco Control Directorate, in conjunction with Parliament, sought to adopt an on-balance expansionist regulatory stance by providing the e-cigarette market with certain competitive advantages over the substitute cigarette market, even as they have sought greater control over both markets. The bill contains permissive elements that put e-cigarettes on parity with substitute products, namely including them in smoke-free policies and prohibiting sales to persons under 18 years old nationwide. Other measures were expansionist, such as allowing a limited amount of e-cigarette marketing activities, albeit through materials that make no health claims, allowing the sale of certain flavors that are deemed not to be appealing to children, and exempting e-cigarettes from the plain packaging regulations that apply to other tobacco products.³⁵ The net effect of the policy is likely to be expansionist, but the bill empowers federal regulators, should they choose, to change that regulatory stance.

The affirmative product standards that nicotine-containing e-cigarettes sold in Canada must follow mostly stem from requirements in the *Consumer Product Safety Act* that devices containing toxic liquid must be childproof.³⁶ S-5 allows the sale of flavored products, with only a few exceptions (see note 128), but federal (and even provincial) regulators can narrow this

³³ Melodie L. Tilson, “Regulating E-Cigarettes as Drugs Is Not the Best Solution,” *CMAJ: Canadian Medical Association Journal* 186, no. 2 (February 4, 2014): 137–38, <https://doi.org/10.1503/cmaj.114-0007>.

³⁴ 33% of all retailers in the country were found to display e-cigarettes in view of the point of sale, a practice that was prohibited under Federal law for cigarettes, but not e-cigarettes. A further third of these retailers kept the display of e-cigarettes within reach of youth. Health Canada, “Evaluation of Retailers’ Behaviour towards Certain Youth Access-to-Tobacco Restrictions – 2014,” research, aem, June 15, 2015, <https://www.canada.ca/en/health-canada/services/key-results-surveys-tobacco-retailers/evaluation-retailers-behaviour-towards-certain-youth-access-tobacco-restrictions-2014.html>.

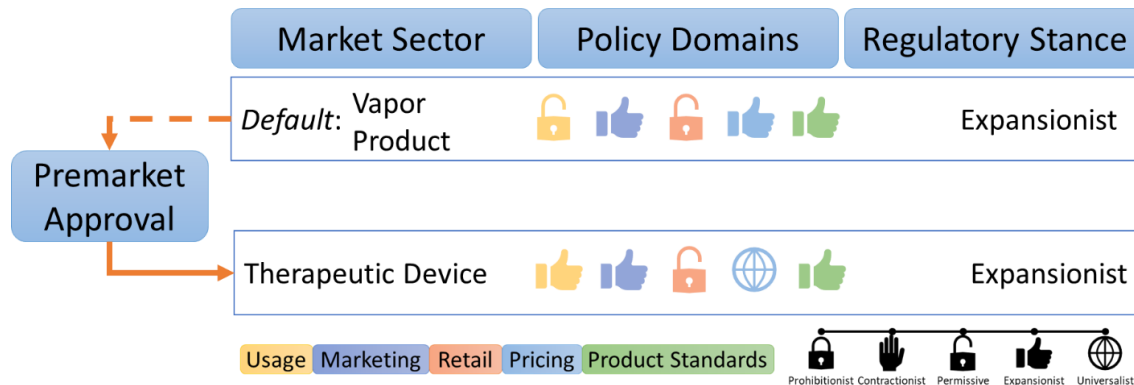
³⁵ The Tobacco Control Directorate within Health Canada has the responsibility to interpret this language because the statute can be read to prohibit almost all e-cigarette flavors. If that were the case, then the provision would certainly be contractionist as unflavored nicotine liquid has an unpleasant taste.

³⁶ Public Works and Government Services Canada Government of Canada, “Vaping Products Labelling and Packaging Regulations,” *Canada Gazette Part I* 153, no. 25 (June 22, 2019): 3089–3131.

provision going forward.³⁷ E-cigarettes are exempt from displaying a graphic health warning, being sold in plain packing like tobacco products, or even in the standardized packaging in which cannabis products must be sold. In contrast to the European Union, e-cigarettes may be sold in Canada at high nicotine concentrations and in large volume containers.³⁸

The agency ruled soon after S-5’s implementation that nicotine liquid with a concentration above 6.6% would be classified as “very toxic” under the *Consumer Product Safety Act* and would be prohibited from being manufactured, imported, marketed, or sold in the country.³⁹ Bill S-5 designated all nicotine-containing e-cigarettes below that very toxic threshold as “vaping products” by default, and could be submitted for premarket approval as therapeutic devices, as had been possible before the passage of Bill S-5. The default regulatory pathway effectively changed from being that of a new drug that required premarket approval to be legally sold to a vaping product which only required manufacturers to meet certain product standards before a product’s release on the market (See Figure 11⁴⁰). Premarket approval went from being obligatory to obtain access to a legal market to entirely optional, even obsolete.

Figure 11: Canada’s Regulatory Stance Towards Nicotine-Containing E-Cigarettes After Bill S-5



Bill S-5 aligned regulations on e-cigarette usage in areas controlled by the federal government to be equivalent to restrictions on tobacco cigarettes. Provincial restrictions have been similarly

³⁷ Health Canada, “Reducing Youth Access and Appeal of Vaping Products: Potential Regulatory Measures,” consultations, aem, April 11, 2019, <https://www.canada.ca/en/health-canada/programs/consultation-reducing-youth-access-appeal-vaping-products-potential-regulatory-measures/document.html>; John McPhee, “Nova Scotia to Ban Flavoured Vaping Products as of April 1,” *The Chronicle Herald*, December 5, 2019, <http://www.thechronicleherald.ca/news/local/nova-scotia-to-ban-flavoured-vaping-products-as-of-april-1-384666/>.

³⁸ Hasselbalch, “Professional Disruption in Health Regulation.”

³⁹ Health Canada, “Guidance on Vaping Products Not Marketed for a Therapeutic Use,” guidance, aem, July 12, 2018, <https://www.canada.ca/en/health-canada/services/publications/product-safety/vaping-not-marketed-therapeutic-use.html>.

⁴⁰ Only applies to those products with a nicotine concentration under 6.6%.

equivalent to tobacco cigarettes as each has come into effect. Additional permissive retail policies were adopted, as only persons who were of the minimum age to legally purchase cigarettes were permitted to purchase e-cigarettes. Additional regulations on the retail environment are permitted at the provincial level and while some provinces like Quebec and New Brunswick have attempted to create regulations that were on par with tobacco product retailing, others like Newfoundland and Ontario have exempted e-cigarettes from some retail regulations that apply to tobacco products.⁴¹

Canada is regarded as a ‘dark market’ for tobacco product marketing, wherein the channels available to market those products are extremely limited.⁴² The only legal forms of marketing left for tobacco products are direct mail and brand-information-only ads in adult-only facilities. S-5 originally only was written to allow e-cigarettes to be marketed using lifestyle advertising (see Note 183), but after a round of lobbying from public health groups, that provision was diluted to only allow brand-preference advertising. E-cigarettes ended up being subject to fewer restrictions on advertising than tobacco cigarettes.⁴³

Pricing policy remains unchanged at the federal level as the budgets offered by the federal Liberal government since the passage of S-5 have not levied an excise tax on e-cigarettes.⁴⁴ The task of establishing excise tax policy remains reserved for the provinces and the federal Ministry of Finance.⁴⁵ Before the passage of Bill S-5, several provinces wanted to set up an excise tax framework for e-cigarettes, but if the products were not yet designated as legal by federal law, no such framework could be put into place.⁴⁶ Bill S-5, itself, avoided the subject of tax policy by

⁴¹ From, Millar, and Phillips, “Vaping and the Law: Comparing Legislation Across Canada.”

⁴² CIG @ 27-28; Timothy Dewhirst, “Price and Tobacco Marketing Strategy: Lessons from ‘Dark’ Markets and Implications for the WHO Framework Convention on Tobacco Control,” *Tobacco Control* 21, no. 6 (November 1, 2012): 519–23, <https://doi.org/10.1136/tobaccocontrol-2012-050693>.

⁴³ However, the degree of difference between these restrictions is decreasing over time. By 2021, e-cigarette marketing rules will be nearly as strict as tobacco products with the sole exception being increased point-of-sale marketing opportunities. Public Works and Government Services Canada Government of Canada, “Vaping Products Promotion Regulations,” *Canada Gazette Part I* 153, no. 51 (December 21, 2019): 4463–4514.

⁴⁴ The 2018 budget introduces an excise tax regime for cannabis and reforms the tobacco products excise tax regime by increasing the level and adding inflationary adjustments to the rates thereafter. Because the budget was introduced in February of that year and cannabis legalization did not receive Royal Assent until June 2018, it is curious that vaping products were not included in the 2018 or even the 2019 Budget. Canada Revenue Agency, “EDRATES Excise Duty Rates,” aem, May 1, 2019, <https://www.canada.ca/en/revenue-agency/services/forms-publications/publications/edrates/excise-duty-rates.html>; Department of Finance Government of Canada, “Budget 2018,” Government of Canada, February 27, 2018, <https://www.budget.gc.ca/2018/docs/tm-mf/si-rs-en.html#Toc507170873>.

⁴⁵ CE @ 28; Health Canada, “Health Canada and Fontem Ventures Meeting: Proposed Vaping Products Regulations – June 15, 2018,” decisions, aem, May 8, 2019, <https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/meeting-summaries-tobacco-vaping-industry/june-15-2018.html>.

⁴⁶ CG @ 4-5

starting its legislative journey in the Senate, the chamber without revenue-raising powers in the Canadian system.⁴⁷ Interest in imposing such excise taxes on e-cigarettes does seem to be gestating as both the Conservative Alberta government and the Liberal British Columbia government are likely to be among the first Canadian jurisdictions to impose such a tax in 2020.⁴⁸

Fundamentally, bill S-5 clarified the regulatory pathway for e-cigarettes to ensure that the presence of nicotine-containing e-cigarettes on the Canadian market was legal. Determining whether the e-cigarette market would be a commercial success, or a failure, was never the point of codifying federal regulatory authority.⁴⁹ The legislation empowered Health Canada staff to flexibly regulate the industry without proscribing regulatory outcomes. Instead, the bill allowed the regulatory agency to change the regulatory stance of the country to the market over a wide latitude while respecting the regulatory powers that have been reserved for the provinces. The statute allowed the agency to determine what it thought the appropriate regulatory stance towards the market would be. But that stance would not remain stable over time.⁵⁰

5.3 The Problem Stream

In Canada, e-cigarettes were framed in the media, by bureaucrats, and by policymakers as an unregulated market that potentially could harm the public and were not being properly regulated. That is, the market was not subject to specialized provincial or federal laws ensuring the products were safe or of sufficient quality. To the market's assumed federal regulators, most notably the Therapeutic Products Directorate and the Tobacco Control Directorate of Health Canada, the early Canadian e-cigarette market came to be defined by the label "unregulated". This group of officials and their compatriots at the local and provincial levels tended to emphasize the threat posed by unregulated e-cigarette use and sales in their communication with the media. Official

⁴⁷ Henry S. Albinski, "The Canadian Senate: Politics and the Constitution," *The American Political Science Review* 57, no. 2 (1963): 382, <https://doi.org/10.2307/1952829>.

⁴⁸ Vaping Industry Trade Association, "Alberta Government Proposes First Vaping Tax in Budget," [markets.businessinsider.com](https://markets.businessinsider.com/news/stocks/alberta-government-proposes-first-vaping-tax-in-budget-1028632186), October 25, 2019, <https://markets.businessinsider.com/news/stocks/alberta-government-proposes-first-vaping-tax-in-budget-1028632186>; Rob Shaw, "B.C. to Hike Taxes on Vaping Products but Not Ban Flavours," *Vancouver Sun* (blog), November 15, 2019, <https://vancouversun.com/news/politics/b-c-to-hike-taxes-on-vaping-products-but-not-ban-flavours>. *The position of the Alberta Conservatives appears to have evolved since March 2019 when they claimed they had no plans to introduce a tax on e-cigarettes.* Stephanie Dubois, "Here's What Alberta's Major Political Parties Say about a Tax on e-Cigarettes," CBC, March 29, 2019, <https://www.cbc.ca/news/canada/edmonton/alberta-vaping-products-tax-1.5076279>.

⁴⁹ CH @ 48

⁵⁰ In the immediate period after S-5 became law, Health Canada was poised to write an expansionist regulatory stance towards e-cigarettes into policy. More contractionist policies would soon follow. See Section 7.3.1 on page 224.

efforts to corral the growth of this market by enforcing a prohibition against the sale of nicotine-containing e-cigarettes eventually became little more than bluster rather than a concerted effort to stamp out the e-cigarette market. As officials became convinced that enforcement efforts were better spent on enforcing policies against more dangerous products, they turned their actual enforcement efforts elsewhere.⁵¹

In this case, the Canadian problem stream became defined more by the actions of bureaucrats than the media as the stream neared maturation. Federal regulators and provincial government officials came to agree that the federal regulatory framework for e-cigarettes was thoroughly lacking and that reform was necessary. E-cigarette retailers routinely violated the *Food and Drugs Act*. Health Canada's leaders and their counterparts in the provinces, eventually concluded the remedy for this lack of regulation was to implore policymakers to alter the regulatory framework, so that more products flowed through the product pathways that regulators had intended them to. In effect, Canadian policymakers would address the problem of an illegal market by making that same market legal.⁵² The maturation of the problem stream reached its peak when provincial ministers of health persuaded the federal minister of health to form a committee tasked with studying the issue and determining the way forward for a federal regulatory framework for e-cigarettes.

5.3.1 An Unregulated Market

E-cigarettes first arrived in Canada in 2007.⁵³ When they first gained attention in the media, the products were touted as a legal loophole for smokers to get their nicotine in public venues covered by smoking bans.⁵⁴ The fact that the products contained no tobacco exempted their use from provincial smoking bans.⁵⁵ While federal, provincial, and municipal health authorities were

⁵¹ Efforts tended to focus on ensuring that drugs were produced in sterile environments or that blood products were being extracted and distributed with proper care. These activities were deemed of sufficient risk to the health and safety of Canadians to merit the attention of Health Canada inspectors. Health Canada, "Inspectorate Program Annual Inspection Summary Report 2012-2013," transparency - other, aem, March 25, 2014, <https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/compliance-enforcement/inspectorate-program-annual-inspection-summary-report-2012-2013.html#a11>.

⁵² CB @ 13

⁵³ HESA Committee, "Vaping: Toward a Regulatory Framework for E-Cigarettes."

⁵⁴ Misty Harris, "E-Cigarettes Skirt Ban on Smoking; Nicotine Release Device Has No Smoke and No Tobacco," *The Calgary Herald*, June 13, 2008, Final edition, sec. News, NexisUni; Nancy J. White, "Electric Stick Delivers Nicotine Hit, Has No Tobacco or Tar, Can Be Lit up inside and Ignites Controversy," *Toronto Star*, March 12, 2009, sec. News.

⁵⁵ Dalson Chen, "Light up with E-Cigarettes," *The Calgary Herald*, March 13, 2009, sec. News, NexisUni; Jenny Yuen, "E-Cig Users Don't Have to Fear Smoking Police: Province," *Ottawa Sun* (blog), July 5, 2015, <https://ottawasun.com/2015/07/05/e-cig-users-dont-have-to-fear-smoking-police-province/wcm/bf0645c3-2e01-46ac-ac36-5924429d4c00>.

not pleased with this situation, they often accepted this as the plain meaning of the indoor smoking ban statutes.⁵⁶

Health Canada spokespeople said in official statements that the agency was "determining whether or not these products can be covered under existing legislation" to clear up the confusion about regulatory jurisdiction over e-cigarettes.⁵⁷ These early media mentions were shot through with confusion and uncertainty. E-cigarettes were deemed to be "not a safe alternative to tobacco" and described as containing "a number of chemical additives in the product which could be very toxic".⁵⁸ Newspaper accounts vacillated between the hazard narrative and a narrative that the products were harmless.⁵⁹ Few journalists were assigned to cover the e-cigarette issue on a repeat basis, possibly making their accounts of the issues at hand more susceptible to the framing provided by their sources. Reports soon followed that other countries were considering banning the sale of e-cigarettes until their safety could be verified.⁶⁰

In March 2009, the Therapeutic Products Directorate within Health Canada determined that e-cigarettes containing nicotine needed to be approved for sale by the agency before they could be legally sold in the country as they were determined to be drug delivery devices under the country's *Food and Drugs Act*.⁶¹ Federal regulators were attempting to exercise their gatekeeping power to limit which products could be sold on the internal Canadian market.⁶² Additional concern by the health regulator pointed to the practice of e-cigarettes being marketed with a health claim particularly; a) that they were safe to use and b) that they were smoking cessation aids.⁶³ The Therapeutic Products Directorate roundly disapproved of such conduct.⁶⁴

⁵⁶ Keith Gerein, "The Rise of Electronic Cigarettes Is Posing Unfamiliar Challenges for Regulators," *Edmonton Journal*, February 3, 2014, Early edition, sec. City & Region, PressReader.

⁵⁷ Harris, "E-Cigarettes Skirt Ban on Smoking; Nicotine Release Device Has No Smoke and No Tobacco."

⁵⁸ CBC News, "Electronic Cigarettes No Safe Alternative to Tobacco, WHO Warns," *CBC News*, September 19, 2008, Lexis Nexis Academic.

⁵⁹ E.g. They contained, "a microchip and a harmless liquid". Diana Zlomislac, "Blowing Faux Smoke," *The Toronto Star*, June 27, 2008, sec. Life, Lexis Nexis Academic.

⁶⁰ CBC News, "U.S. Senator Seeks to Ban Electronic Cigarettes Pending More Research" (CBC News, March 24, 2009), Lexis Nexis Academic.

⁶¹ Health Canada, "Notice - To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada."

⁶² Carpenter, *Reputation and Power*, chap. 2.

⁶³ Geller et al., Evidence on E-Cigarettes.

⁶⁴ Don Butler, "Health Canada Moves to Get Read on E-Cigarette Use," *Ottawa Citizen*, March 18, 2014, sec. City.

The decision was interpreted by the media as the regulator signaling that the products were untrustworthy and likely dangerous.⁶⁵

Media articles in the following years vacillated from reminding readers that e-cigarettes were being sold illegally and should be avoided to agitations for regulatory liberalization.⁶⁶ E-cigarette users consistently told media outlets they were hopeful that evidence supporting their assertions that e-cigarettes were smoking cessation devices would surface in the coming years and pave the way for the approval of their sale as legal therapeutic products.⁶⁷

E-cigarette retailers did not heed the Regulatory Operations and Enforcement Branch's order to seek the regulators' approval to sell their wares and carried on growing with little regard for federal regulations, expanding dramatically into a thriving gray market.⁶⁸ These retailers did not help build their case for being responsible businesses when they routinely violated health marketing prohibitions. Notably, during the 2009 H1N1 influenza epidemic, retailers parroted a Texas-based e-cigarette brand's press release claiming that vaping was "more effective than swine flu vaccine" citing a study from the 1940s that identified a protective effect of propylene glycol.⁶⁹

This e-cigarette market was officially illegal, but it conducted business in brick-and-mortar storefronts across the country.⁷⁰ The density of e-cigarette retailers was high, with some

⁶⁵ The Canadian Press, "Health Canada Warns against Use of Smoking 'Gadgets,'" *The Times & Transcript*, March 30, 2009, sec. Life, NexisUni; Corrinna Pole, "Butting Out Electronic Cigarettes," *Sherbrooke Record*, March 30, 2009, sec. News, NexisUni; Herald News Services, "WHO Rejects Smoking Cessation Tube," *The Calgary Herald*, September 20, 2008, Final edition, sec. World in Brief, NexisUni.

⁶⁶ CBC News, "Electronic Cigarettes Face Regulatory Wrath," NexisUni, September 9, 2010; Kerri McCraig, "E-Cigarettes Not Approved in Canada," *Prince George Citizen*, January 20, 2010, sec. Opinion, NexisUni; Tara Carman, "Breaking the Law to Quit Smoking," *Vancouver Sun*, December 26, 2012, sec. West Coast News; Jesse Kline, "Not Your Father's Cigarettes," *The National Post*, February 4, 2013, National edition, sec. Editorials, NexisUni.

⁶⁷ Carman, "Breaking the Law to Quit Smoking."

⁶⁸ CG @ 2; CBC News, "E-Cigarette Seller Told to Stop by Health Canada," CBC, December 3, 2013, <https://www.cbc.ca/news/canada/nova-scotia/e-cigarette-seller-told-to-stop-by-health-canada-1.2449127>.

⁶⁹ Pat Hewitt, "Experts Say Don't Fall for H1N1 'cures' or Myths, Stick with Flu Shot," *Metro US*, November 8, 2009, <https://www.metro.us/news/experts-say-don-t-fall-for-h1n1-cures-or-myths-stick-with-flu-shot/tmWikh---115mEhkq228S6>; No.7 E Cigarettes, "E Cigarettes May Be More Effective Than Swine Flu Vaccine," Reuters, November 31, 2009, <https://web.archive.org/web/20100317122026/http://www.reuters.com/article/idUS91433+03-Nov-2009+PRN20091103>. *The study being referenced:* O. H. Robertson et al., "The Protection of Mice against Infection with Air-Borne Influenza Virus by Means of Propylene Glycol Vapor.," *Science (Washington)*, 1941, 612–13.

⁷⁰ CBC News, "Banned E-Cigarettes on Sale in Regina Stores," CBC, September 5, 2011, <https://www.cbc.ca/news/canada/saskatchewan/banned-e-cigarettes-on-sale-in-regina-stores-1.1084264>; Armina Ligaya, "How E-Cigarettes Have Become a 'Very Wild West' Industry in Canada," *Financial Post*, November 16, 2013, <http://financialpost.com/news/how-e-cigarettes-have-become-a-very-wild-west-industry-in-canada>.

observers estimating there were more vape shops than libraries or post offices in some cities.⁷¹ Health Canada's Border Integrity and Emergency Preparedness Unit, the Royal Canadian Mounted Police, and the Canadian Border Services Agency enforced some order by refusing entry to shipments of e-cigarette parts into the country at its border.⁷² Products without premarket authorization could be (and often were) refused entry by customs officials under Health Canada's Import and Export Policy.⁷³ Heavy reliance on internet sales enabled e-cigarette users to obtain constant supplies of nicotine-containing liquid, despite the efforts of Health Canada and the Royal Canadian Mounted Police to shut down online retailers by asking third-party payment providers to not work with e-cigarette retailers.⁷⁴

Through the early 2010s, e-cigarette sales growth did not slow down, a condition attributable to Health Canada's choice to not actively shut down e-cigarette businesses.⁷⁵ In one of the few instances where federal regulatory authority was tested in this matter, Zen E-cigarettes, an online e-cigarette retailer based in Quebec, sued Health Canada after the regulator refused to allow the retailer to import a package of 200 nicotine-containing e-cigarettes in 2011.⁷⁶ Zen's case, which was echoed by many other e-cigarette retailers, was that e-cigarettes should not be considered a drug under the *Food and Drugs Act* because they did not provide enough nicotine to the user.⁷⁷ Health Canada's legal team countered that because the dosage of a regulated drug was written on the package,⁷⁸ it was implied that a drug was being sold, and the product was, therefore, subject

⁷¹ CJ @ 1; David Hammond et al., "Retail Availability and Marketing of Electronic Cigarettes in Canada," *Canadian Journal of Public Health* 106, no. 6 (October 9, 2015): e408-412, <https://doi.org/10.17269/cjph.106.5105>.

⁷² Geller et al., Evidence on E-Cigarettes, 4; Nick Waddell, "Ecig Battle: Canada's Showdown with Vaping Is about to Reach High Noon," Cantech Letter, May 13, 2015, <https://www.cantechletter.com/2015/05/canadas-showdown-with-vaping-is-about-to-reach-high-noon/>.

⁷³ Ranish Raveendrabose, "TO VAPE, OR NOT TO VAPE: Electronic Cigarettes and the Ambiguous State of Their Legality in Canada.," *Manitoba Law Journal* 40, no. 2 (2017): 322-23; Health Canada, "Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and Its Regulations (GUI-0084)," guidance, aem, June 1, 2010, <https://bit.ly/2s0UGo1>.

⁷⁴ For example, PayPal and certain credit card providers were pressured by Health Canada's Regulatory Operations and Enforcement Branch to adopt policies stating they would not work with e-cigarette retailers based in Canada. CE @ 19; Jesse Kline, "E-Smoke 'em If You Got 'em," *National Post*, January 2, 2012, National edition, sec. Editorials; Tom Blackwell, "Ban on Nicotine-Loaded e-Cigarettes Aggressively Enforced While Some Anti-Smoking Advocates Call for Legalization," *National Post* (blog), January 21, 2014, <https://nationalpost.com/news/canada/ban-on-nicotine-loaded-e-cigarettes-aggressively-enforced-while-some-anti-smoking-advocates-call-for-legalization>.

⁷⁵ Kline, "Jesse Kline"; Barnaby Page, "In Depth: Canada Regulatory and Legal Analysis, October 2014," *ECigIntelligence* (blog), November 4, 2014, <https://ecigintelligence.com/in-depth-canada-regulatory-and-legal-analysis-october-2014/>.

⁷⁶ André F.J. Scott, *Zen Cigarette Inc v. Canada (Health)*, 2012 FC 1465 (Federal Court 2012).

⁷⁷ Overall, "Health Canada Claims E-Juice with Nicotine Is a Drug"; Scott, *Zen Cigarette Inc v. Canada (Health)*, 2012 FC paragraph 20.

⁷⁸ In this case, the e-cigarettes that had been refused entry claimed they contained a 1.8% nicotine concentration on their packaging.

to their jurisdiction.⁷⁹ The agency submitted evidence to the court alleging that the e-cigarettes in question delivered more nicotine per inhalation than the regulated and approved-for-sale Nicorette inhaler.⁸⁰ The court sided with Health Canada and Zen's operations were moved to Maine before their going-out-of-business in July 2014.⁸¹

Over several years of site visits, Health Canada's Regulatory Operations and Enforcement Branch seized several thousand units of products it deemed non-compliant with the *Food and Drugs Act*, but after 2012, these confiscations ceased.⁸² By late 2014, the Regulatory Operations and Enforcement Branch had undertaken at least 250 enforcement actions (written cease-and-desist letters) against e-cigarette retailers, and most retailers ignored the agency's demand.⁸³ Similar to the argument made by Zen E-cigarettes, the retailers argued that e-cigarettes should be exempt from the *Food and Drugs Act* because they did not provide sufficient quantities of nicotine to users, but they did not heed the court's conclusion.⁸⁴ But, by August 2014, 123 brick and mortar stores and 31 websites who had received cease-and-desist letters had not stopped selling non-compliant e-cigarettes.⁸⁵ Tellingly, federal regulators never backed up these letters by laying charges against the retailers.⁸⁶

Health Canada's enforcement program run from its Regulatory Operations and Enforcement Branch was described as "complaint-driven and risk-based", and it was eventually toned down for e-cigarettes based on a calculation that the products were not high-risk and complaints were

⁷⁹ Scott, *Zen Cigarette Inc v. Canada (Health)*, 2012 FC paragraph 25.

⁸⁰ Scott, 2012 FC paragraphs 33–34.

⁸¹ Benoit Moulin, *Deblois c. Attorney General of Canada*, 2017 QCCS 4855 (Quebec Superior court 2017); Ligaya, "How E-Cigarettes Have Become a 'Very Wild West' Industry in Canada."

⁸² Geller et al., *Evidence on E-Cigarettes*.

⁸³ Nick Wenbourne, "In Depth: Canada Regulatory and Legal Analysis, October 2014," *ECigIntelligence*, November 4, 2014, <https://ecigintelligence.com/in-depth-canada-regulatory-and-legal-analysis-october-2014/>.

⁸⁴ The statutory definition they pointed to was that nicotine was exempted from being covered as a drug if administered, "in a form to be administered orally by means of an inhalation device delivering 4 milligrams or less of nicotine per dosage unit". In a typical day, a user of freebase nicotine liquid might consume nicotine liquid containing 42 milligrams of nicotine (3.5 milliliters of 12 milligram per milliliter liquid). Even tests of liquids labelled to be "nicotine-free" conducted by Health Canada found that 46% did in fact contain nicotine. Hill, "Vapour Shops Defy Ottawa's Warning Letters over e-Cigarettes"; Carly Souther, "Canada's e-Cig Regulation a Three-Tiered Tangle," *ECigIntelligence*, March 29, 2016, <https://ecigintelligence.com/canadas-e-cig-regulation-a-three-tiered-tangle/>; Liber, Drope, and Stoklosa, "Combustible Cigarettes Cost Less to Use than E-Cigarettes"; Sarah Petrescu, "E-Cigarette Seller Fights Health Canada Warning," *Times Colonist*, December 18, 2013, <https://www.timescolonist.com/news/local/e-cigarette-seller-fights-health-canada-warning-1.764804>; Geller et al., *Evidence on E-Cigarettes*.

⁸⁵ Geller et al., *Evidence on E-Cigarettes*.

⁸⁶ Blackwell, "Ban on Nicotine-Loaded e-Cigarettes Aggressively Enforced While Some Anti-Smoking Advocates Call for Legalization."

not streaming in.⁸⁷ The regulator believed that cracking down on e-cigarette retailers would be either counterproductive or useless in their hierarchy of assigned enforcement activities.⁸⁸ This decision reflected a risk management approach adopted by the agency in the 1990s.⁸⁹ As far as enforcement officers could see, e-cigarettes were not yet responsible for anyone's death, and few serious injuries could be traced to the products.⁹⁰ No one in Canada was seeking to ban the use of nicotine-containing e-cigarettes, like injected illicit drugs.⁹¹ No one intended that all Canadians should be forever blocked from accessing nicotine-containing e-cigarettes. Officers within the Regulatory Operations and Enforcement Branch decided that finite resources were better spent enforcing other issues under the *Food and Drugs Act*.⁹²

This state of *de jure* illegality and *de facto* availability cemented a reality where e-cigarette retailers were not incentivized to put their products through proper regulatory channels when their competitors would not do the same.⁹³ The e-cigarette continued to grow as small businesses that were essentially left alone by federal regulators proliferated. In the end, the most significant consequence of this policy was that transnational tobacco companies stayed completely out of the e-cigarette market and that pressure to create a legal federal regulatory framework continued to build.

5.3.2 Provinces Build Pressure for Federal Action

The federal government was the last level of the Canadian government to create e-cigarette regulations. In 2013, provincial ministers of health worried that e-cigarettes could cause a backslide in the country's progress in the fight to control smoking.⁹⁴ Some provincial ministers

⁸⁷ Geller et al., Evidence on E-Cigarettes.

⁸⁸ Geller et al.; CB @ 12

⁸⁹ Health Canada, "Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks," transparency - other, aem, August 1, 2000, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html>.

⁹⁰ Explosions of e-cigarettes started cropping up as a problem through 2016 and ended up building support among e-cigarette manufacturers for the introduction of product quality control measures in legislation. Testimony given to HESA Committee in 2014 explicitly mentioned that it wasn't an issue in the country at the time. Cotter, "Exploding E-Cigarette 'lit My Kid's Face on Fire' Warns Alberta Father"; Geller et al., Evidence on E-Cigarettes.

⁹¹ Raveendrabose, "To Vape, Or Not To Vape," 347-48.

⁹² CJ @ 9; Geller et al., Evidence on E-Cigarettes; Health Canada, "Compliance and Enforcement Policy for Health Products (POL-0001)," policies, aem, December 21, 2018, sec. 5b, <https://bit.ly/2sAL97l>.

⁹³ Liam H M O'Reilly, "A Harm Reduction Tool or Cigarettes 2.0: E-cigarette Regulation and Charter Justification of Advertising Bans" (CanLII Connects, November 30, 2015), 13, https://s3.eu-west-1.amazonaws.com/canliiconnects-production/uploads/opinion/file/42319/E-cigaress_final.pdf.

⁹⁴ CBC News, "E-Cigarette Laws Coming in Nova Scotia," CBC, November 26, 2013, <https://www.cbc.ca/news/canada/nova-scotia/e-cigarette-laws-coming-in-nova-scotia-1.2440285>; CBC News, "E-Cigarettes Doing Strong Business in New Glasgow,"

of health began declaring they would advance legislation to regulate e-cigarettes if the federal government did not begin to act to regulate the e-cigarette market.⁹⁵ The provinces held the power to respond to these issues of public use, and the lack of federal action on the matter of product regulation did not stand in their way to create their own regulations.⁹⁶

Led by Dr. Robert Strang, the chief medical officer of Nova Scotia, who was serving as the chair of the Council of Chief Medical Officers of Health (CCMOH) at the time, on November 26, 2013, the Federal/Provincial/Territorial Deputy Ministers of Health asked the CCMOH to provide advice to the federal government on how best to construct a regulatory approach for e-cigarettes.⁹⁷ The CCMOH is a mechanism to coordinate between the various Chief Medical Officers of Health of each province and senior federal public health officers on topics of mutual interest.⁹⁸ The role of the provincial Chief Medical Officer is split between serving as an advisor to provincial governments on matters of health and as communicators with the public on matters of health of general concern.⁹⁹ The topic of e-cigarette use and regulation was regarded as an appropriate topic for the CCMOH to advise upon.¹⁰⁰

Municipalities were the first mover jurisdictions pass regulations on e-cigarette use and retailing, as Red Deer, Alberta, and Hamilton, Ontario began to adopt policies to treat e-cigarette use like cigarette smoking in public places in mid-2014.¹⁰¹ Provinces followed and began discussing their regulatory frameworks for controlling the sale and use of e-cigarettes.¹⁰² By late 2014, the Liberal government of Nova Scotia led the country to include e-cigarettes in its smoke-free policies and banned sales to persons under 19 years of age.¹⁰³

CBC, November 22, 2013, <https://www.cbc.ca/news/canada/nova-scotia/e-cigarettes-doing-strong-business-in-new-glasgow-1.2436070>.

⁹⁵ Jeff Nagel, "Province Pledges E-Cigarette Regulation If Feds Won't Act," *Barriere Star Journal*, September 29, 2014, <https://www.barrierestartjournal.com/news/province-pledges-e-cigarette-regulation-if-feds-wont-act/amp/>.

⁹⁶ Raveendrabose, "To Vape, Or Not To Vape," 350.

⁹⁷ Strang et al., "Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems."

⁹⁸ CA @ 4; PHN, "The Council of Chief Medical Officers of Health Supports Position Statement on Active Outdoor Play," Pan-Canadian Public Health Network, May 29, 2018, <http://www.phn-rsp.ca/aop.php>.

⁹⁹ Patrick Fafard et al., "Contested Roles of Canada's Chief Medical Officers of Health," *Canadian Journal of Public Health* 109, no. 4 (August 1, 2018): 585–89, <https://doi.org/10.17269/s41997-018-0080-3>.

¹⁰⁰ CC @ 17; CA @ 14

¹⁰¹ Amanda Connolly, "Central Alberta City Bans E-Cigarettes under Local Smoking Bylaw," CBC, June 27, 2014, <https://www.cbc.ca/news/canada/calgary/red-deer-bans-e-cigarettes-under-local-smoking-bylaw-1.2689294>.

¹⁰² CBC News, "E-Cigarette Laws Coming in Nova Scotia."

¹⁰³ From, Millar, and Phillips, "Vaping and the Law: Comparing Legislation Across Canada."

In June 2014, the CCMOH held a virtual symposium which solicited input from public health experts representing widely varying policy preferences from the contractionist regulations preferred by advocates of policy informed by the precautionary principle, Dr. Stanton Glantz, to the expansionist regulations advanced by tobacco harm reductionists, Dr. Peter Selby, to preferences somewhere in between, from figures like Dr. David Hammond.¹⁰⁴ At the symposium, these experts were asked to present their view on the harms or benefits of e-cigarettes, the policy goals of e-cigarette regulation, and the regulations they would recommend Canada put into practice.

The CCMOH symposium coalesced into a consensus position statement from the officers that aimed to provide “common and consistent policy advice” to deputy ministers of health across the country.¹⁰⁵ The position statement called for a “balanced approach” between allowing smokers to have access to a safer form of nicotine and preventing the creation of more nicotine dependence in the population at large, especially among youth. The medical officers wanted provinces and territories to pass legislation making sales to minors illegal, restrict advertising and promotion, and point of sale display, and extend clean indoor air policies to cover e-cigarettes. The medical officers also called for the federal government to pass legislation to give Health Canada regulatory authority over the products and a mandate to ensure the products were used to improve public health. Even e-cigarette manufacturers complained that operating in a market devoid of government oversight meant that, “anybody and their dog can make this stuff”.¹⁰⁶ From the perspective of all stakeholders, the situation was unsustainable.

The provincial and territorial health ministers, led by Nova Scotia’s, used a meeting with Federal Minister of Health, Rona Ambrose, in September 2014 to call for the federal government to develop the regulatory framework for e-cigarettes in partnership with the provinces and territories their position statement had called for.¹⁰⁷ A week later, the ruling Federal Conservatives formed an inquiry into creating a federal regulatory framework for e-cigarettes in

¹⁰⁴ CA @ 21; Strang et al., “Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems.”

¹⁰⁵ CA @ 18; Geller et al., Evidence on E-Cigarettes.

¹⁰⁶ Reid Southwick, “‘Anybody Can Make’ e-Cig Liquids; Manufacturers Needs Regulation, Retailer Warns,” *The Calgary Herald*, October 2, 2014, sec. City & Region, NexisUni.

¹⁰⁷ CICS, “News Release - Provinces and Territories Talk Health Care” (Canadian Intergovernmental Conference Secretariat, September 30, 2014), <http://www.scics.ca/en/product-produit/news-release-provinces-and-territories-talk-health-care/>; Vogel, “Provinces Press for E-Cigarette Crackdown”; Geller et al., Evidence on E-Cigarettes, 11.

the Standing Committee on Health (HESA) in the House of Commons.¹⁰⁸ This call-and-response between provincial and federal ministers of health represented the focusing event that opened a policy window that managed to stay open for nearly four years until changes to the federal e-cigarette regulatory framework could be passed into law.

In May 2015 the Liberal government in Ontario, Canada's largest province, passed rules regulating the sale and use of e-cigarettes by a vote of 99-1 as a portion of an omnibus health bill.¹⁰⁹ By November 2015, a Liberal-led Quebec government passed even stricter regulations on e-cigarettes, particularly limiting out almost all marketing activity.¹¹⁰ Across the country, using an e-cigarette in public had become recognized as a problem behavior as such behavior was seen to undermine the spirit of indoor smoking bans,¹¹¹ and requisite rule changes to control such activity followed. Except for a few notable setbacks, like a decision to delay the implementation of a ban on using e-cigarettes in public spaces in Ontario, e-cigarette regulation proliferated across Canada at the sub-federal level with the approval of almost every political party.¹¹² Analyses conducted years later found that youth in provinces without bans on sales of e-cigarettes to minors reported having much easier access to the products than those young people in provinces with such restrictions.¹¹³

Provincial-level actions that regulated the retailing, marketing, and use of e-cigarettes created a policy vacuum at the federal level. The provinces acted to regulate the aspects of the e-cigarette

¹⁰⁸ Vogel, "Health Canada E-Cigarette Response Delayed."

¹⁰⁹ Jake Bleiberg, "Vapers Take Note: Ontario Becomes First Canadian Province to Regulate E-Cigarettes," *Vice News* (blog), May 27, 2015, https://news.vice.com/en_us/article/wjaq4w/vapers-take-note-ontario-becomes-first-canadian-province-to-regulate-e-cigarettes. *The title of the piece is inaccurate, as Nova Scotia was the first province to regulate e-cigarettes.* The lone dissenting vote in Ontario came from Conservative MPP, Randy Hillier, who based his opposition on his belief that e-cigarettes had help him quit smoking and he earned the nickname "Vape Dad" for his troubles. Jessica Smith Cross, "'Vape Dad' MPP Booted from the House during Marijuana Bill Debate," *QP Briefing* (blog), November 21, 2017, <https://www.qpbriefing.com/2017/11/21/vape-dad-mpp-booted-house-marijuana-bill-debate/>.

¹¹⁰ CBC News, "Quebec Cracks down on E-Cigarettes, Bans Patio Smoking," CBC, November 27, 2015, <https://www.cbc.ca/news/canada/montreal/quebec-new-law-tobacco-e-cigarettes-patio-1.3339479>.

¹¹¹ Helen Branswell, "Health Canada Slow to Regulate E-Cigarettes," *Global News*, May 13, 2015, <https://globalnews.ca/news/1994306/health-canada-slow-to-regulate-e-cigarettes/>.

¹¹² *Although, all regulatory efforts were started by left-of-center governments prior to 2017.* CBC News, "P.E.I. e-Cigarette, Vaping Restrictions Begin Sept. 1," CBC, August 26, 2015, <https://www.cbc.ca/news/canada/prince-edward-island/p-e-i-e-cigarette-vaping-restrictions-begin-sept-1-1.3203857>; CBC News, "Calgary Expands Public Smoking Ban to E-Cigarettes," CBC, June 30, 2015, <https://www.cbc.ca/news/canada/calgary/e-cigarettes-now-included-in-calgary-s-public-smoking-ban-1.3132779>; Kevin Bissett, "N.B. Government Bans Smoking on Patios, Sports Fields and Beaches," *Global News*, May 27, 2015, <https://globalnews.ca/news/2020017/new-brunswick-to-reduce-places-to-smoke/>; "Province Delays Ban on Vaping in Public," CBC, December 16, 2015, <https://www.cbc.ca/news/canada/toronto/vaping-ban-ontario-1.3368613>.

¹¹³ Hai V. Nguyen, "Association of Canada's Provincial Bans on Electronic Cigarette Sales to Minors With Electronic Cigarette Use Among Youths," *JAMA Pediatrics*, November 4, 2019, e193912–e193912, <https://doi.org/10.1001/jamapediatrics.2019.3912>.

market that were within their spheres of control as enumerated under Section 92 of the *Constitution Act*, those matters that solely affected the province.¹¹⁴ But, the federal government was foremost in charge of regulating what products could enter the internal Canadian market.¹¹⁵ As the source of e-cigarettes was almost exclusively international in nature, the Constitution placed the duty to decide which products were admissible into the country in the hands of the federal bureaucrats.¹¹⁶

5.4 The Policy Stream

The fall of 2014 was characterized by a widespread sense of dissatisfaction with the current regulatory framework for e-cigarettes. Officers of the Regulatory Operations and Enforcement Branch could not justify strictly enforcing the prohibitionist stance implied by current law. Provinces were looking to the federal government and its bureaucrats for direction on how they should regulate the market.

The primordial soup of policy ideas for regulating e-cigarettes contained two basic camps at the time, and each is well characterized by their position on the range of regulatory stances. To those who were favorably disposed to expanding the e-cigarette market, a group led by THR advocates like David Sweanor, e-cigarette users, and e-cigarette retailers preferred to emphasize the potential health benefits of such a product.¹¹⁷ To some in this group, tobacco smoking was an ongoing public health crisis that required novel solutions to be adequately addressed. They did not perceive the current unregulated state of the e-cigarette market as a serious problem. Instead, they saw the e-cigarette as a vehicle to help Canada achieve its tobacco usage reduction goals. Tobacco harm reduction was a belief in the idea that regulation, especially of product standards, could raise the perceived quality of regulated products relative to unregulated products, and shift consumption into legal channels. One large portion of this philosophy in action is to regulate products in proportion to their risk.¹¹⁸ This group wanted federal regulators to adopt an

¹¹⁴ CK @ 4

¹¹⁵ Dara Lithwick, "A Pas de Deux: The Division of Federal and Provincial Legislative Powers in Sections 91 and 92 of the Constitution Act, 1867," Parliament of Canada, December 8, 2015, https://lop.parl.ca/sites/PublicWebsite/default/en_CA/ResearchPublications/2015128E.

¹¹⁶ Josh Horwitz, "China's Tobacco Monopoly Means Big Risks for e-Cigarette Startups," *Reuters*, November 7, 2019, <https://www.reuters.com/article/us-china-ecigarettes-insight-idUSKBN1XHOLW>.

¹¹⁷ David Sweanor and Adam R. Houston, "Rethinking Nicotine: The Role of Public Health Law in Ending an Epidemic," *Ottawa Law Review* 47 (2016 2015): 419.

¹¹⁸ CB @ 42

aggressively expansionist regulatory stance and direct the kinetic energy the e-cigarette market represented into solving a major public health problem.

Public health groups did not uniformly agree with the harm reduction advocates. These groups primarily wanted the country to adopt a regulatory framework that suppressed the downsides of an expanded e-cigarette market to be balanced with a measured approach to reaping the upside benefits of growth.¹¹⁹ No public health group would defend the status quo, but there was a range of positions expressed from those who wanted to treat e-cigarettes just like tobacco cigarettes to those who wanted to give the market key advantages over tobacco cigarettes to direct newer, safer products to cannibalize the older, more dangerous products' market share. Public health groups saw the continued existence of an unregulated e-cigarette market as the problem that regulation would address.¹²⁰ They were open to using e-cigarettes as a potential solution to cigarette smoking and wanted to preserve some of the market's potential to displace tobacco cigarette sales. But they were willing to sacrifice some of that disruptive energy to protect people who did not already use tobacco products from the harms posed by e-cigarette use. The belief that establishing a well-regulated market for e-cigarettes could address both these problems in one fell swoop came to dominate the discussion around the creation of the bill put forward to solve these matters.

5.4.1 HESA Committee

As had been called for a month earlier by Minister Ambrose, in October 2014 the HESA Committee, led by Conservative MP Ben Lobb, began calling fact witnesses in the committee's inquiry into the benefits and challenges posed by e-cigarettes, the international regulatory approaches towards e-cigarettes, and the potential regulations the federal government could adopt for e-cigarettes.¹²¹ These areas of focus for the inquiry mirrored those of the CCMOH efforts undertaken the previous year. The HESA Committee questioned witnesses representing all sides of the e-cigarette market, regulatory apparatus, and health advocacy community. Members of all political parties joined in on questioning the witnesses who mostly coalesced

¹¹⁹ Strang et al., "Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems"; Carly Weeks, "Heart and Stroke Foundation Wants Federal Regulation on E-Cigarettes," *The Globe and Mail*, October 2, 2014, <https://www.theglobeandmail.com/life/health-and-fitness/health/heart-and-stroke-foundation-wants-federal-regulation-on-e-cigarettes/article20885830/>.

¹²⁰ Southwick, "Anybody Can Make' e-Cig Liquids; Manufacturers Needs Regulation, Retailer Warns."

¹²¹ HESA Committee, "Vaping: Toward a Regulatory Framework for E-Cigarettes," 138.

around the idea that, relative to the status quo, federal regulation would improve product quality, safety, and health outcomes of the e-cigarette market.¹²²

Ideas floated during these committee hearings included a legally questionable ban on tobacco company participation in the e-cigarette market.¹²³ Nicotine concentration limits like those used in the European Union Tobacco Products Directive were also considered but never codified in recommendations.¹²⁴ After eight meetings, where the committee interviewed 33 witnesses, the HESA committee produced a unanimous report entitled “*Vaping: Towards a Regulatory Framework*” in March 2015.¹²⁵ Minister Ambrose reiterated months after that her government took the report seriously was proceeding with ordering a draft bill, as she was the one who asked for its production.¹²⁶ The recommendations of the HESA report (see Table 6) were less prescriptive and more normative in nature. They suggested the outlines of a regulatory framework that would empower regulators to fill in details over time.

Table 6: HESA Vaping Report vs Bill S-5

#	Recommendation	S-5 Section
1	Health Canada financially supports research into health effects, youth impacts of e-cigarettes	-
2	The government would develop a new legislative framework for regulating e-cigarettes	Bill S-5
3	Federal government consults with provinces with an eye on protecting the health of Canadians	3
4	Framework will cover e-cigarettes with and without nicotine	3(3)(d)
5	Framework should require that e-cigarettes look visually distinct from other tobacco products	7.8(a)
6	Framework should establish maximum levels of nicotine in liquid or vapor	Excluded ¹²⁷
7a	Establish safety standards for e-cigarette components	6
7b	Require manufacturers and importers to disclose ingredients	11(3)c
8a	Require all components be sold in child-resistant packaging	7.8(a)
8b	Require all products to display appropriate safety warnings	15(2)1.1
8c	Require all products to display nicotine content	15(1)
9	Prohibit manufacturers from making unproven health claims	20(2)
10	Prohibit sales to persons under 18 years of age	8(1)
11	Prohibit use in federally regulated places	82
12	Restrict advertising and promotion of these products	44
13	Prohibit cross-branding practices	23

¹²² The lack of clarity in federal and provincial regulations around the products was repeatedly raised as a reason for bringing forth a policy change. The line between what rules applied to e-cigarettes containing nicotine and what rules applied to those that did not contain nicotine was hard to define and required legislation to draw clear boundaries around what actions were legal. Erin Obourn, “Provinces Starting to Rein in E-Cigarette Use,” CBC, December 22, 2014, <https://www.cbc.ca/news/business/e-cigarette-use-slapped-with-growing-provincial-regulation-1.2879168>.

¹²³ CG @ 14; Hedy Fry, “Evidence - HESA (41-2) - No. 38 - House of Commons of Canada,” § Standing Committee on Health (2014), <https://openparliament.ca/committees/health/41-2/38/hedy-fry-7/>.

¹²⁴ Hedy Fry, “Evidence - HESA (41-2) - No. 39 - House of Commons of Canada,” § Standing Committee on Health (2014), <https://openparliament.ca/committees/health/41-2/39/hedy-fry-3/>.

¹²⁵ HESA Committee, “Vaping: Toward a Regulatory Framework for E-Cigarettes.”

¹²⁶ Hélène Buzzetti, “La cigarette électronique dans la mire des députés fédéraux,” *Le Devoir*, December 10, 2014, <https://www.ledevoir.com/politique/canada/426273/la-cigarette-electronique-dans-la-mire-des-deputes-federaux>; “E-Cigarette Regulations,” *CTV National News* (Vancouver, BC: CTV, May 11, 2015), NexisUni, <https://bit.ly/2FjIEdz>.

¹²⁷ Section 7.8(a) gives authority to regulate the appearance of products, but no requirement to make the products look visually distinct from tobacco products was included in the bill.

As was standard procedure,¹²⁹ the eventual regulator, the Tobacco Products Directorate in Health Canada, was instructed in the report to address the report's 14 recommendations when writing a draft bill. Recommendation 2 from the report was the most consequential from the report, as it instructed the government, (whose agent was principally, in this case, Tobacco Products Directorate) to begin drafting a new legislative framework for the regulation of e-cigarettes. Recommendations 4 through 14 laid out guidelines that the legislative framework should try to follow. The report asserted Parliament's control over the legislation drafting process and effectively required bureaucrats who put forward new legislation to justify any departures from the drafting guidelines.

From this point on through the passage of Bill S-5, the path was paved towards passing a policy that expanded federal regulatory authority over the e-cigarette market and allowed the regulator to calibrate the exact regulatory stance towards the e-cigarette market. The consensus view seemed to favor adopting an expansionist stance that was short of what the harm reductionists had advocated for but exceeded the boundaries of the contractionist vision maintained by some in the public health community. A broad agreement to adopt a regulatory stance that would provide e-cigarettes with a large competitive advantage over tobacco cigarettes had emerged from the committee.¹³⁰ The next government would be tasked with seeing that vision through to the passage of implementing legislation.

5.5 The Politics Stream

Classically, Canadian political parties are described to behave in a brokerage model of political competition, wherein the largest parties compete for the same voters over a set of policies that are less ideological and more pragmatic.¹³¹ In general, political parties exist to organize competition between competing interests, primarily on matters of achieving consensus, on

¹²⁸ Section 30.48(1) prohibits marketing a vaping product in a manner that would lead someone to think it is flavored to taste like candy, dessert, cannabis, soft drinks or and energy drink, but no actual flavor is prohibited in the bill's text.

¹²⁹ Bonnie Brown, Nancy Miller Chenier, and Sonya Norris, "Committees as Agents of Public Policy: The Standing Committee on Health," *Canadian Parliamentary Review* 26, no. 3 (September 22, 2003): 4.

¹³⁰ CH @ 45

¹³¹ Jared J. Wesley, "In Search of Brokerage and Responsibility: Party Politics in Manitoba," *Canadian Journal of Political Science / Revue Canadienne de Science Politique* 42, no. 1 (2009): 211–36; William Cross and Lisa Young, "Policy Attitudes of Party Members in Canada: Evidence of Ideological Politics," *Canadian Journal of Political Science / Revue Canadienne de Science Politique* 35, no. 4 (2002): 859–80.

competing principles, or seeking something in between.¹³² E-cigarette regulation is a policy area that most concerns the interests of public health and the tobacco and e-cigarette business. In the case at hand, Canadian politicians sought to seek consensus between interest groups when creating a bill that aimed to garner widespread political support.

As the politics stream became ready to couple, a middle-ground solution in e-cigarette regulation between the preferences of these major interest groups was advanced by Justin Trudeau's Liberal government. The path to that middle ground wound through a change in government, the advancement of the Liberal party's belief in harm reduction policy, and a policy that injured different parts of the fortunes of tobacco and e-cigarette companies. This process yielded a bill that almost every policymaker could vote for.

5.5.1 A Change in Government

Instead of making a political calculation to avoid the issue, the Canadian Conservatives simply ran out of time to introduce an e-cigarette regulation bill.¹³³ The Harper government was originally given four months to respond to the HESA report. But the House broke session by the date the report was to be submitted, July 8, 2015, and a revised deadline of September 21 did not see the tabling of such a report by Minister Ambrose because that very day Parliament was dissolved.¹³⁴

A new election was set to be held on October 19.¹³⁵ During the 2015 Federal Parliamentary election, mentions of e-cigarette regulation by political candidates or parties were essentially nonexistent. At the provincial level, the only party to mention e-cigarettes in its election manifesto were the British Columbia Liberals, who passed e-cigarette regulations while in government in 2016, cheered their accomplishment in the 2017 general election manifesto, and then lost their majority in that election. No provincial party promised further regulatory action on

¹³² Seymour Martin Lipset and Stein Rokkan, *Party Systems and Voter Alignments: Cross-National Perspectives* (Free Press, 1967).

¹³³ CL2 @ 59; CK @ 5; CD @ 34. Some interviewees asserted the Conservatives would have introduced regulations for e-cigarettes that were more restrictive than what the Liberal government offered in bill S-5, while other respondents asserted their pro-business instincts would have led to more lax regulations on e-cigarettes.

¹³⁴ Vogel, "Health Canada E-Cigarette Response Delayed."

¹³⁵ "And They're off! Party Leaders Make Their Pitches as 11-Week Campaign Begins," CBC, August 2, 2015, <https://www.cbc.ca/news/politics/canada-election-2015-stephen-harper-confirms-start-of-11-week-federal-campaign-1.3175136>.

e-cigarettes in their election manifestos, a further indication of the lack of political salience of the issue.¹³⁶

The Canadian public's opinion, or lack thereof, on the matter of e-cigarette regulation may have freed Trudeau and the bureaucracy's hands when writing such a policy. Partisan sorting on the subject of e-cigarette regulation had not yet occurred possibly because of the uncertainty of political actors over which constituencies would benefit or lose out from regulation of the market.¹³⁷ Before the passage of Bill S-5, in response to questions that seemed biased towards finding less support, saw 69% of Canadians agreed that the government should regulate e-cigarettes like tobacco products and 60% of Canadians thought plain packaging would successfully cut down on smoking.¹³⁸ What little partisan polling that was conducted on the issue, occurred after the passage of Bill S-5 and, did not reveal a large partisan divide on the matter of e-cigarette regulation. Canadians supporting all political parties are sympathetic to the goal of preventing youth access to e-cigarettes.¹³⁹ Perceptions of relative risk from using e-cigarettes versus cigarettes are lower among NDP voters than among Liberal or Conservative Party voters.¹⁴⁰ But overall, no party possessed a distinctly different policy preference on the

¹³⁶ I conducted a search of all the English language general election manifestos posted on Poltext from 2012 through 2019 ($n=58$) for the terms: "nicotine", "vaping", "vapour", "tobacco", "smoking" and "e-cigarette". 2012 ($n=7$); 2013 ($n=6$); 2014 ($n=3$); 2015 ($n=8$); 2016 ($n=8$); 2017 ($n=6$); 2018 ($n=9$); 2019 ($n=11$). Christy Clark, "Strong BC Bright Future: Platform 2017" (BC Liberals, 2017), 106, https://www.poltext.org/sites/poltext.org/files/plateformesV2/Colombie-Britannique/BC_PL_2017_LIB_en.pdf; "Electronic Manifestos Canadian Provinces," POLTEXT, 2019, <https://www.poltext.org/en/part-1-electronic-political-texts/electronic-manifestos-canadian-provinces>.

¹³⁷ CD @ 28

¹³⁸ The question; "Do you agree, somewhat agree, somewhat disagree, or disagree with each of the following statements? The government should regulate vaping products like tobacco products even though vaping is considered 95% safer than cigarettes." should have biased the responses towards zero. Consumer Choice Center, "Opinions of Canadians on Consumer Issues: Consumer Choice Survey Summary," Nanos, July 2017, <https://secureservercdn.net/198.71.233.47/823.910.myftpupload.com/wp-content/uploads/2017/07/2017-1041-consumer-choice-populated-report-final-with-tabs-r.pdf?time=1575920703>.

¹³⁹ A poll from April 2019 found that 86% of Canadians supported applying the same advertising restrictions to e-cigarettes that were in place for other tobacco products. There were small differences by geography, age, socioeconomic status, cigarette smoking status and language but nothing that neatly tracked with party. Quebec Coalition for Tobacco Control, "Canadians Support Urgent Government Action to Address Youth Vaping: Leger Poll," Newswire, May 9, 2019, <https://www.newswire.ca/news-releases/canadians-support-urgent-government-action-to-address-youth-vaping-leger-poll-834485134.html>.

¹⁴⁰ The Angus Reid Institute conducted a survey in August 2018 which examined the feelings of Canadians towards e-cigarette regulation segmented by party vote in the 2015 federal elections. Reflecting a similar divide on smoking status, the survey found that 20% of NDP voters had ever vaped compared to 17% of Liberal and 10% Conservative voters. In terms of net percentage point support agreeing with whether switching from smoking to vaping is good for your health Conservatives were +1, Liberals were +8 and NDP voters were +24. While all parties thought vaping did more harm than good, NDP voters (-8 percentage points net support) were less likely than Liberals (-23) or Conservatives (-30) to support that notion. 69% of Canadians supported restricting the promotion and marketing of e-cigarettes, a position that was slightly more supported by Liberals (75%). Dave Korzinski and Shachi Kurl, "Vexed over Vaping: Kids Are Top Concern amid Canadian Uncertainty about Effects of e-Cigarettes," *Angus Reid Institute* (blog), September 18, 2018, <http://angusreid.org/vaping/>.

issue of e-cigarette regulation outright. This situation likely provided political parties with the latitude to broker a policy compromise that satisfied most stakeholders.

The Conservative 2015 federal election manifesto made no mention of tobacco or plain packaging, but it does disparage proposals for harm reduction efforts around illicit drug treatment and cannabis legalization made by its left-wing rivals.¹⁴¹ The NDP and Liberal parties promised to pass plain packaging and legalize recreational cannabis sales in their election manifestos in 2015 but made no mention of e-cigarette regulation.¹⁴² By far the dominant voting issue of concern to Canadians was the economy, distantly followed by health care.¹⁴³ The election ended up yielding a change in government and brought Justin Trudeau's Liberal Party to power as a majority party.¹⁴⁴

5.5.2 Harm Reduction

The Liberal government professed and acted on their belief in harm reduction as a health promotion strategy. They even renamed the government's drug control strategy from the "National Anti-Drug Strategy" to the less punitive-sounding "Canadian Drugs and Substances Strategy".¹⁴⁵ The renewed Federal Tobacco Control Strategy touted employing the principles of harm reduction to tobacco use, especially through the passage of e-cigarette regulations.¹⁴⁶ When Liberal Minister of Health Ginette Petitpas-Taylor invoked the importance of harm reduction in defense of the government's response to the opioid crisis, the illness spread through needle sharing, and vaping.¹⁴⁷ Even cannabis legalization and regulation were framed as a harm

¹⁴¹ Stephen Harper, "Protect Our Economy: Our Conservative Plan to Protect the Economy" (Conservative Party of Canada, 2015), 119, Poltext, https://www.poltext.org/sites/poltext.org/files/plateformesV2/Canada/CAN_PL_2015_PC_en.pdf.

¹⁴² CD @ 41; Justin Trudeau, "Real Change: A New Plan for a Strong Middle Class" (Liberal Party of Canada, 2015), Poltext, https://www.poltext.org/sites/poltext.org/files/plateformesV2/Canada/CAN_PL_2015_LIB_en.pdf; Tom Mulcair, "Building the Country of Our Dreams: Tom Mulcair's Plan to Bring Change to Ottawa" (New Democratic Party, 2015), Poltext, https://www.poltext.org/sites/poltext.org/files/plateformesV2/Canada/CAN_PL_2015_NDP_en.pdf.

¹⁴³ "Economy the No. 1 Issue, but Environment a Growing Concern: Vote Compass," CBC, September 10, 2015, <https://www.cbc.ca/news/politics/vote-compass-canada-election-2015-issues-canadians-1.3222945>.

¹⁴⁴ McKirdy, "Canada Election."

¹⁴⁵ Health Canada, "Pillars of the Canadian Drugs and Substances Strategy," education and awareness, aem, December 12, 2016, <https://www.canada.ca/en/health-canada/services/publications/healthy-living/pillars-canadian-drugs-substances-strategy.html>.

¹⁴⁶ Health Canada, "Seizing the Opportunity: The Future of Tobacco Control in Canada," consultations, aem, February 22, 2017, <https://www.canada.ca/en/health-canada/programs/future-tobacco-control/future-tobacco-control.html>; Diane Finley, "Tobacco Act- Government Orders," § Canada House of Commons (2017), <https://openparliament.ca/debates/2017/11/3/diane-finley-2/>.

¹⁴⁷ Peter Luongo, "Health Committee on Feb. 12th, 2018 | Openparliament.ca," § Health Standing Committee (2018), <https://openparliament.ca/committees/health/42-1/90/peter-luongo-1/>; Ginette Petitpas Taylor, "Debates of Oct. 5th, 2018," § House of Commons (2018), <https://openparliament.ca/debates/2018/10/5/ginette-petitpas-taylor-1/>; Ginette Petitpas Taylor, "Debates of June 14th, 2019," § House of Commons (2019), <https://openparliament.ca/debates/2019/6/14/ginette-petitpas-taylor-4/>.

reduction initiative that would lessen the power of black-market actors and protect young people.¹⁴⁸ Justin Trudeau repeatedly defended cannabis legalization as an initiative informed by a “public health approach” that his government was not planning on extending to other drugs (namely, opioids).¹⁴⁹ This talking point conveniently disregarded e-cigarette regulatory efforts.

NDP and Liberal MPs have a much more extensive record of bringing the topic of harm reduction into the Canadian political debate than their Conservative Party counterparts.¹⁵⁰

However, the NDP has been historically much more open to traditional harm reduction initiatives in the area of gambling and illicit drug usage than their Liberal counterparts.¹⁵¹ This party split in the perception of a lesser threat from a reduced harm product has been found before in public opinion surveys.¹⁵²

Public health groups, particularly those most closely involved in tobacco control (Non-Smoker’s Rights Association and Canadian Cancer Society) also saw the threat and promise of e-cigarettes and calculated that a regulated marketplace was more likely to produce their desired outcome of a country with less smoking and disease than an unregulated one.¹⁵³ They theorized that a regulated market would be responsive to the rulings of a regulator and the worst actions of market participants could be curbed. Other public health groups, like the Canadian Medical Association, Heart and Stroke, and Physicians for a Smoke-Free Canada, were more skeptical

¹⁴⁸ The major difference between the politics of cannabis and e-cigarettes was that while, conservatives were opposed to the expansion of immoral markets like cannabis, there was no similar feeling that expanding the market for nicotine-containing e-cigarettes was immoral. The support of business entities operating outside of a moralistic framework also likely eased the political calculations of Conservatives with regard to e-cigarette regulation. CO @ 34-35; Health Canada, “Harm Reduction: Canadian Drugs and Substances Strategy,” transparency - other, aem, October 20, 2017, <https://www.canada.ca/en/health-canada/services/substance-use/canadian-drugs-substances-strategy/harm-reduction.html>.

¹⁴⁹ Paul Webster, “Debate over Recreational Cannabis Use Legalisation in Canada,” *The Lancet* 391, no. 10122 (February 24, 2018): 725–26, [https://doi.org/10.1016/S0140-6736\(18\)30430-6](https://doi.org/10.1016/S0140-6736(18)30430-6); Travis Lupick, “Trudeau Government Maintains Its War on Hard Drugs as Greens and NDP Consider Alternatives,” *The Georgia Straight*, March 14, 2018, <https://www.straight.com/news/1044336/trudeau-government-maintains-its-war-hard-drugs-greens-and-ndp-consider-alternatives>.

¹⁵⁰ CJ @ 6; “Search: ‘Harm Reduction,’” *OpenParliament.ca*, December 10, 2019, <https://openparliament.ca/search/?q=%22harm%20reduction%22>.

¹⁵¹ Steven Hayle, “The Politics of Harm Reduction: Comparing the Historical Development of Needle Exchange Policy in Canada and the UK between 1985 and 1995,” *The Social History of Alcohol and Drugs* 32 (December 1, 2018): 81–103, <https://doi.org/10.1086/SHAD3201081>; Justin Rex and David J. Jackson, “Window of Opportunity? Internet Gambling in Canada,” *Canadian Public Policy* 35, no. 1 (April 8, 2009): 121–37, <https://doi.org/10.3138/cpp.35.1.121>.

¹⁵² Shachi Kurl and Ian Holliday, “Opioids in Canada: One-in-Eight Have Family or Close Friends Who Faced Addiction,” *Angus Reid Institute* (blog), January 11, 2018, <http://angusreid.org/opioid-crisis/>. The Angus Reid Institute also asked Canadians for their opinion in August 2018 about the use of harm reduction when confronting the country’s opioid crisis. They found that net support for the use of supervised injection sites was above +58 points for Liberal and NDP voters while Conservative net support was at -8 points.

¹⁵³ CD @ 39

that there was an upside to growing the e-cigarette, but they agreed that an unregulated market was likely to produce worse outcomes than a regulated market.¹⁵⁴ Harm reduction logic ended up proliferating through Liberal government decision-making and messaging. This logic was well suited to the e-cigarette regulation discussion and provided momentum to carry the issue beyond the election.

5.5.3 Issue Linkage with Plain Packaging

When political actors in Canada engaged the debate over changing the e-cigarette regulatory framework, the policy was also packaged with characteristics that increased its appeal to the left-wing of Canadian politics. The “issue linkage” employed in bill S-5 primarily refers to the combination of the plain packaging legislation, which at the time, was the strictest such provision in the world as it empowered the regulator to shape the appearance of tobacco products themselves, going deeper than the outside packaging.

Plain packaging was a major milestone that public health groups wanted the Liberal government to adopt.¹⁵⁵ Its inclusion in a bill that altered the regulatory framework for e-cigarettes, seemed to quiet objections to overly expansionist e-cigarette regulatory policies from public health groups.¹⁵⁶ Fulfilling a campaign promise for strong tobacco control policy from both the Liberals and the NDP was too strong a force to raise significant protests from public health groups on the conceptually and practically linked subject of e-cigarette regulation. Oddly, the linkage of harm reduction with plain packaging policy ended up persuading tobacco companies to stand down from making significant protests over the contents of the final form of the e-cigarette regulatory bill (See 5.6.1).

5.6 Coupling the Streams

The problem, policy, and politics streams had all become ready to couple following the 2015 federal election. The election delayed the government’s reply to the HESA report. Health

¹⁵⁴ Action on Smoking & Health et al., “Tobacco and Vaping Products Act: New Developments Lead Some Health Groups to Reconsider Their,” February 12, 2018, <https://www.newswire.ca/news-releases/tobacco-and-vaping-products-act-new-developments-lead-some-health-groups-to-reconsider-their-support-for-bill-s-5-673813903.html>; Véronique Morin, “Federal Report Calls for Regulation of E-Cigarettes,” *CMAJ: Canadian Medical Association Journal* 187, no. 7 (April 21, 2015): 487, <https://doi.org/10.1503/cmaj.109-5020>; Canadian Medical Association, “Submission to the House of Commons Study on E-Cigarettes” (Canadian Medical Association, November 27, 2014), <https://policybase.cma.ca/en/viewer?file=%2fdocuments%2fBriefpdf%2fBR2015-05.pdf#phrase=false>.

¹⁵⁵ Rob Cunningham, “Society Praises Federal Action on Tobacco Plain Packaging,” Canadian Cancer Society, May 31, 2016, <https://www.cancer.ca:443/en/about-us/for-media/media-releases/national/2016/tobacco-plain-packaging/?region=on>.

¹⁵⁶ CIG @ 42-43; CD @ 28-29

Canada's public relations staff stated that its bureaucrats were working on translating the report's recommendations into policy options while the campaign was being conducted.¹⁵⁷ Before the introduction of the new bill, Health Canada remained silent on these matters – indicating only that they were looking into writing a new policy.¹⁵⁸ This period between the HESA report and the introduction of Bill S-5 marked the point where the agency's perspective changed became more open to an expansionist regulatory policy stance towards e-cigarettes.¹⁵⁹

The Tobacco Control Directorate spent the time gathering information on e-cigarette health effects, market size and shape, and international regulatory practices.¹⁶⁰ The Tobacco Control Directorate consulted with e-cigarette users, tobacco companies, law enforcement, as well as public health groups in the process of determining their strategy going forward.¹⁶¹ The scientific publications that marked the interregnum were the 2016 US Surgeon General's Report on e-cigarettes and youth, the 2015 Public Health England Report, and myriad studies on biomarkers, toxicity, cessation, initiation, and gateway effects of e-cigarettes.¹⁶² While these studies made opposing conclusions about the threat or opportunity posed by the e-cigarette market, Tobacco Control Directorate staff proceeded to cite both strains of thought when justifying their positions on e-cigarette regulation.¹⁶³ Those staff eventually concluded that they believed they could write

¹⁵⁷ Kennedy and Whalen, Evidence - HESA (42-1) - No. 5 - House of Commons of Canada; Jane Philpott, "Health Canada 2016-17 Report on Plans and Priorities," report on plans and priorities, Health Canada, March 7, 2016, https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities/2016-2017-report-plans-priorities.html#ii_2.5.1; Branswell, "Health Canada Slow to Regulate E-Cigarettes."

¹⁵⁸ Lucas Richert, "Why Aren't We Regulating e-Cigs?," *Regina Leader Post*, May 16, 2016, Early edition, sec. Opinion.

¹⁵⁹ CE @ 11; CM @ 30; CG @ 5

¹⁶⁰ Public Works and Government Services Canada, "ARCHIVED Study of the Market Size and Growth Trends of the Nicotine-Based Vaping Products Market in Canada (1000174110)," Government of Canada, March 23, 2016, <https://buyandsell.gc.ca/procurement-data/tender-notice/PW-16-00727553>; Camille Bains, "Teens Use E-Cigarettes Because They Are 'Cool, Fun and New': Study," *Times Colonist*, July 19, 2016, sec. News, NexisUni; Tom Blackwell, "Scientific Studies on E-Cigarettes Stuck in Limbo; Ottawa Dragging out Approval Process: Scientist," *National Post*, February 17, 2015, All_but_Toronto edition, sec. News.

¹⁶¹ CO @ 25; Health Canada, "Consultation Summary: Proposals for the Regulation of Vaping Products," guidance, aem, April 9, 2018, <https://www.canada.ca/en/health-canada/services/publications/healthy-living/consultation-summary-proposals-regulation-vaping-products.html>; Regulator Watch, *GROUND WAR / REGULATORY INSIGHTS ON BILL S-5*, 2017, <https://www.youtube.com/watch?v=0xQsmG-TqhQ>.

¹⁶² US Department of Health and Human Services, "E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General" (Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, December 8, 2016), http://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf; McNeill et al., "E-Cigarettes: An Evidence Update"; Goniewicz et al., "Levels of Selected Carcinogens and Toxicants in Vapor from Electronic Cigarettes."

¹⁶³ Health Canada, "Overview of Canada's Tobacco Strategy," education and awareness, aem, May 31, 2018, <https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy/overview-canada-tobacco-strategy.html>.

a regulatory framework that balanced concerns about youth initiation with providing access to reduced-harm products for adults.¹⁶⁴

When Parliament resumed sitting, the government response to the previous session's HESA report on e-cigarettes was the first matter discussed by that committee in the new session.¹⁶⁵ The response promised that the Trudeau government would deliver legislation to regulate the e-cigarette market by the fall of 2016, a promise that was ultimately, kept. The Liberal Party was tasked with creating a regulatory framework for e-cigarettes in response to ongoing pressure from provincial ministers of health, federal bureaucrats, and public health groups to act. This moment of pressure and political opportunity represented the coupling of the streams into a policy window. The eventual federal bill that was introduced to change the regulatory framework engendered little formal opposition from cross-party policymakers during its creation and the policy process leading up to its passage can be described as amicable, even cooperative.

It is difficult to peer inside the thinking of those who were tasked with writing a new regulatory policy for e-cigarettes after the 2015 election. The communications between ministers and bureaucrats are privileged and interviewees uniformly reserved that information from our conversations. We can only compare the HESA report to the Bill that was produced to evaluate which recommendations were agreed to (See Table 6). Only recommendations about nicotine concentration and e-liquid flavors (6 and 14, respectively) were not directly transposed into the implementing legislation. Instead, these potential subjects of future product standards were placed under the statutory authority of Health Canada's Tobacco Control Directorate under the new regulatory framework.¹⁶⁶ The parties swapping drafts eventually settled on a policy that linked harm reduction which appealed to business interests to a public health strategy and produced a piece of legislation that few empowered interests found objectionable.

No single person acted as a policy entrepreneur from start to finish on the issue of e-cigarette regulation. The Trudeau government utilized Minister of Health Jane Philpott and former Paralympic champion Senator Chantal Petitclerc as the nominal public faces leading the push for

¹⁶⁴ After January of 2018 they most often cite Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems et al., *Public Health Consequences of E-Cigarettes*.

¹⁶⁵ Jane Philpott, "Government Response to Vaping: Toward a Regulatory Framework for E-Cigarettes," Government Response (Ottawa, Canada: Standing Committee on Health, September 26, 2016), <http://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-1/response-8512-421-77>.

¹⁶⁶ CO @ 21

e-cigarette regulation in each chamber of Parliament. Philpott and Petitclerc (and later, Philpott's predecessor as Minister of Health Ginette Petitpas-Taylor) worked in tandem to promote the changing the e-cigarette regulatory framework as a public health measure that would advance the interests of both smokers and youth.¹⁶⁷

The civil servants in the Tobacco Control Directorate had been instructed, first by the Harper government, and second by the Trudeau government to write a bill that would clarify federal regulatory authority over e-cigarettes and fulfill a Liberal Party campaign promise concerning plain packaging. These bureaucrats served as the connective tissue that bridged the change in government and ensured continuity in the effort to expand federal regulatory authority over the e-cigarette market. While the Directorate resisted the idea at first, by the time bill S-5 was being drafted, the belief in the harm reduction potential of e-cigarettes had taken hold inside the agency, motivated by what was perceived by the directorate staff as an unfolding scientific consensus on the matter.¹⁶⁸ Directorate staff engaged in a wide-ranging process of consultation with a wide variety of stakeholders in the process of drafting an e-cigarette regulations bill.¹⁶⁹ Drafts were passed back and forth between the Prime Minister's Office, Privy Council Office, Health Canada's Director-General, and the Tobacco Control Directorate during this process.¹⁷⁰

The lack of widespread political controversy around the belief that e-cigarettes could improve the health of cigarette smokers ended up aiding the promulgation of a bill that created a regulatory framework in which regulatory agencies could utilize harm reduction impulses if they saw fit. The resulting legislation, Bill S-5, was written, promoted, and shepherded through to royal assent by the civil servants who would later be tasked with implementing and enforcing the bill's provisions. The development of Bill S-5 proceeded in an orderly fashion as streams were coupled and the opportunity to consider a fully formed e-cigarette regulatory bill arrived in November 2016.

¹⁶⁷ *Minister Philpott and Senator Petitclerc Discuss Bill S-5, the Proposed Tobacco and Vaping Products Act* (Facebook Live, 2016), <https://www.facebook.com/janepaulinephilpott/videos/668128886691529/>.

¹⁶⁸ Health Canada repeatedly testified after the introduction of Bill S-5 that e-cigarettes were less harmful than cigarettes, citing an "emerging global consensus of science". James Van Loon, "Health Committee on Feb. 28th, 2018 | Openparliament.ca," § Health Standing Committee (2018), <https://openparliament.ca/committees/health/42-1/94/james-van-loon-5/>.

¹⁶⁹ CE @ 12; Health Canada, "Health Canada Tobacco Control Directorate and Tobacco and Vaping Industry Meetings," navigation page, aem, June 10, 2019, <https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/meeting-summaries-tobacco-vaping-industry.html>.

¹⁷⁰ These drafts and consultations are protected from public information requests by ministerial advice privileges. No interviewee was comfortable speaking with me about their contents.

5.6.1 Business-Friendly Harm Reduction

In their e-cigarette regulatory efforts, the Liberals employed a business-friendly harm-reductionist strategy that enticed the support of most policymakers, notably those on the right-wing of Canadian politics. Their chosen policy was business-friendly because it had the effect of opening a legal market to large companies where there was not one previously. Their policy was also harm-reductionist because this legal market was purported to be less dangerous than the market it was meant to be displacing. In 2016, business-friendly harm reduction was an idea with widespread appeal in Canadian politics.

The business-friendly nature of this form of harm reduction found a base of support among Conservatives. If no moral lines are crossed by commercializing the sale of a product, then we might expect right-wing parties to warm to the idea of harm reduction as right-wing resistance to such policies usually rests on morality issues. Canadian Conservatives have demonstrated their comfort with expanding access to alcohol and even standing up to protect the interests of tobacco companies.¹⁷¹ During consultations on the contents of Bill S-5, tobacco companies generally approved of the regulatory measures on e-cigarettes, likely because the regulations would permit their entry into the Canadian market receiving a more favorable regulatory stance than the one that existed for their core product, tobacco cigarettes.¹⁷² E-cigarettes as a product category do not violate the Conservative party's moral reservations about sex or mind-warping illicit drugs, and their partiality to business interests further softened their resistance to this form of harm reduction.

Rather than the issue of the establishment of federal regulatory powers over e-cigarettes, Conservative party objections to Bill S-5 primarily stemmed from the imposition of plain packaging on tobacco products.¹⁷³ Tobacco companies expressed public frustration over the way that tobacco cigarettes were being subject to plain packaging in bill S-5 while, combusted cannabis cigarettes were being treated much more gently in companion bill C-45.¹⁷⁴ Tobacco

¹⁷¹ Lisa Xing, "The 10 Biggest Things Doug Ford Has Done in His First 100 Days in Office," CBC, October 6, 2018, <https://www.cbc.ca/news/canada/toronto/doug-ford-first-100-days-1.4851341>.

¹⁷² Health Canada, "Consultation Summary," April 9, 2018.; CG @ 2

¹⁷³ Diane Finley, "Health Committee on March 19th, 2018 | Openparliament.ca," § Health Standing Committee (2018), <https://openparliament.ca/committees/health/42-1/95/diane-finley-1/>. "the Liberals seem to be set on giving ... [a]... gift to contraband in the form of plain packaging". Finley herself is a long-term smoker – CD @ 20.

¹⁷⁴ Imperial Tobacco took out a newspaper ad with the tagline, "Why The Favouritism?" calling out the government on grounds of fairness for imposing stricter labelling regulation on Imperial's combusted tobacco cigarettes than on newly legal combusted

companies made the same arguments against plain packaging in Canada that they made everywhere else; the policy won't improve health, contraband markets will boom, and this is government appropriation of intellectual property.¹⁷⁵ The argument over e-cigarettes never invoked these criticisms, and the creation of a regulatory framework for e-cigarettes aimed to eliminate an unregulated, contraband-like market. In the end, tobacco company protests against the plain packaging policy were ignored by policymakers. The inclusion of plain packaging with e-cigarette regulations provided a sweetener to tobacco companies who stood to lose out from the imposition of plain packaging while gaining from the opening of a legal e-cigarette market.

5.7 Passing Bill S-5

In November 2016, the promised legislation appeared in the Canadian Senate as bill S-5, attached to a plain and standardized packaging provision that would apply to cigarettes, cigars, and smokeless tobacco products. The fact that the study that underpinned the bill was conducted in the House of Commons led to the bill being introduced in the Senate.¹⁷⁶ S-5 sailed through Senate hearings and amendment processes with only minor revisions being made to a legislative review process and the bill passed the Senate in June 2016.¹⁷⁷

Afterward, the bill headed to the House of Commons. It was only at this intermediate stage of the legislative process that the Federal government stepped in to set an endgame goal for tobacco smoking to reach 5 percent prevalence among the adult population by 2035.¹⁷⁸ Setting this goal smacked of being an after-the-fact justification rather than being an initial motivation for moving S-5 forwards.

In early 2018 the House held hearings on the bill and largely kept the Senate's version of S-5 intact with one significant exception. A small controversy erupted over the issue of lifestyle

marijuana products. Amanda Siebert, "Imperial Tobacco Wants the Government to Treat Cigarettes and Cannabis Equally," *Georgia Straight*, October 25, 2017, <https://bit.ly/2Mfstkp>.

¹⁷⁵ Luongo, Health Committee on Feb. 12th, 2018 | openparliament.ca; Jarman, "Attack on Australia"; Eric Crosbie and George Thomson, "Regulatory Chills: Tobacco Industry Legal Threats and the Politics of Tobacco Standardised Packaging in New Zealand," *The New Zealand Medical Journal* 131, no. 1473 (April 13, 2018): 25–41.

¹⁷⁶ CD @ 5

¹⁷⁷ Conservative Senator Judith Seidman successfully pushed for an amendment to Bill S-5 which required the Minister of Health to report back to parliament three years after the passage of the bill instead of the typical five years, to evaluate the progress being made with the bill's implementation. "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/>. Kelvin Kenneth Ogilvie, "Twelfth Report of the Standing Senate Committee on Social Affairs, Science and Technology (Bill S-5)," Senate of Canada, May 2, 2017, <https://sencanada.ca/en/committees/soci/>.

¹⁷⁸ Carly Weeks, "Can Canada Aggressively Lower Tobacco Use by 2035?," *The Globe and Mail*, April 10, 2017, sec. Life and Arts.

advertising.¹⁷⁹ As originally drafted, S-5 did not prohibit all lifestyle advertising, instead, it exempted lifestyle ads distributed by direct mail or placed in areas that were inaccessible to youth, while the companion cannabis regulation bill C-45 prohibited all lifestyle advertising for that new market.¹⁸⁰ The only reasoning given for this choice in the public record comes from Minister of Health Jane Philpott, where she claimed in testimony to the Senate, that banning all lifestyle advertising would not be compliant with the Canadian Charter of Rights and Freedoms.¹⁸¹

The issue of whether the Canadian Charter protects the use of lifestyle advertising has been litigated up to the country's Supreme Court which ruled in *RJR-MacDonald Inc v A-G Canada*.¹⁸² That case ended up setting a common-law definition of lifestyle advertising and ruled that a ban on all tobacco advertising was too burdensome on the expressive freedom of tobacco companies.¹⁸³ In reaction to the decision in *RJR-MacDonald*, the revised *Tobacco Products Act* included a ban on all lifestyle advertising for tobacco products, as such ads did not serve a useful public purpose while allowing more utilitarian brand preference advertising.

Health Canada Tobacco Control Directorate officials claimed they were comfortable taking enforcement actions against e-cigarette companies that crossed the line into promoting their products in a manner appealing to youth after the incident occurred.¹⁸⁴ Public health groups, led by the Quebec Coalition for Tobacco Control, worried that the regulators would not be able to prevent damage from being done, citing past struggles in policing the marketing of flavored cigars and enforcing the prohibition on the sale of nicotine-containing e-cigarettes.¹⁸⁵ The groups called for Health Canada to produce the legal analysis that Minister Philpott was referencing in

¹⁷⁹ Flory Doucas to Bill Casey, Ginette Petitpas Taylor, and James Van Loon, "Bill S-5's Negative Consequences: Children and Non-Smokers Will Be Exposed to Ads for Nicotine-Containing Vaping Products on TV and the Internet," February 11, 2018, http://cqct.qc.ca/Documents_docs/DOCU_2018/MEMO_18_02_11_Letter_HESA_Chair.pdf.

¹⁸⁰ Jody Wilson-Raybould, "An Act Respecting Cannabis and to Amend the Controlled Drugs and Substances Act, the Criminal Code and Other Acts," Pub. L. No. C-45 (2018), <http://www.parl.ca/LegisInfo/BillDetails.aspx?Language=E&billId=8886269>.

¹⁸¹ Judith Seidman and Jane Philpott, "Issue No. 21 - Evidence - April 12, 2017," § Standing Senate Committee on Social Affairs, Science and Technology (2017), <https://sencanada.ca/en/content/sen/Committee/421/soci/21ev-53253-e>.

¹⁸² Manfredi, "Expressive Freedom and Tobacco Advertising."

¹⁸³ Lifestyle advertising associates a product with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring. Manfredi.

¹⁸⁴ Example: "If in the future we were to determine that advertising is happening during Saturday morning children's cartoons, we could take action to further restrict where that advertising could happen." Suzy McDonald and Chantal Petitclerc, "Issue No. 21 - Evidence - April 13, 2017," § Standing Senate Committee on Social Affairs, Science and Technology (2017), <https://sencanada.ca/en/committees/soci/>.

¹⁸⁵ Doucas to Casey, Taylor, and Van Loon, "Bill S-5's Negative Consequences: Children and Non-Smokers Will Be Exposed to Ads for Nicotine-Containing Vaping Products on TV and the Internet," February 11, 2018, 8.

her 2017 Senate committee testimony that concluded a ban on all lifestyle advertising was not Charter-compliant, but this analysis was never publicly produced.¹⁸⁶ The uproar caused by public health groups who lobbied the Minister of Health, Ginette Petitpas-Taylor, triggered the adoption of a Liberal party amendment banning lifestyle advertising for e-cigarettes.¹⁸⁷ Even after the change, marketing for e-cigarettes was less restricted than for other tobacco products, particularly at the point of sale.

One line of Conservative objection to S-5 was an argument that that prohibitions on communicating relative risk in vaping product marketing materials would stymie doctors from informing their patients of the risk reduction a patient would benefit from if they switched from smoking cigarettes to vaping.¹⁸⁸ The tobacco companies and harm reduction advocates pushed this narrative as well.¹⁸⁹ Leaders of the Tobacco Control Directorate did not agree that such advice from a doctor to their patient constituted a marketing promotion and recommended that clarifications defending such activity not need be added to the bill.¹⁹⁰ The Liberal party took their bureaucrat's advice and did not amend the bill further.

No major dissent from the NDP or Liberals was made when Conservatives led the 2014 HESA Committee study of e-cigarette regulations. And no such Conservative (or NDP) dissent ever broke out during the consideration of Bill S-5 proper that ever imperiled the bill from receiving close to unanimous support. Only peripheral issues ever seemed to cause rifts, and these differences were smoothed over by the time the bill was reported out of committee.

Support for S-5's non-plain packaging related provisions from public health groups was lukewarm at best, but there was some openness to the use of e-cigarettes as a harm reduction tool for smokers.¹⁹¹ These public health groups explicitly and consistently stated that using an e-cigarette was less harmful than continuing to smoke tobacco cigarettes.¹⁹² This warmth was

¹⁸⁶ CN @ 35

¹⁸⁷ Elizabeth Thompson, "Canada's Lawmakers Back Away from Allowing 'Lifestyle-Type' Ads for e-Cigs," *ECigIntelligence* (blog), March 7, 2018, <https://ecigintelligence.com/canadas-lawmakers-back-away-from-allowing-lifestyle-type-ads-for-e-cigs/>; Kyle Duggan, "Health Minister Open to Further Restricting E-Cigarette Ads," *IPolitics* (blog), February 15, 2018, <https://ipolitics.ca/2018/02/15/health-minister-open-restricting-e-cigarette-ads/>.

¹⁸⁸ Diane Finley, "Health Committee on Feb. 28th, 2018 | Openparliament.ca," § Health Standing Committee (2018), <https://openparliament.ca/committees/health/42-1/94/diane-finley-6/>.

¹⁸⁹ CG @ 57; CK @ 24

¹⁹⁰ Van Loon, Health Committee on Feb. 28th, 2018 | openparliament.ca. <https://openparliament.ca/committees/health/42-1/94/james-van-loon-5/>

¹⁹¹ CB @ 45

¹⁹² Obourn, "Provinces Starting to Rein in E-Cigarette Use."; CB @ 14

tempered by a concern that tobacco companies would use vaping products to onboard new nicotine consumers who had never smoked.¹⁹³ Overall, public health groups favored making the e-cigarette market legal and endowing the Tobacco Control Directorate with regulatory authority over the products¹⁹⁴.

Ultimately, Bill S-5 passed parliament unanimously at every stage but one of the legislative process.¹⁹⁵ S-5 received royal assent on May 23, 2018, which triggered the opening of Canada’s legal e-cigarette market, a change in patterns in the sale and use of vaping products, and a flurry of regulatory activity.¹⁹⁶ When Bill S-5 received royal assent, public health groups uniformly cheered the occasion with press releases welcoming the new laws.¹⁹⁷ Tobacco companies were more cautious in their public statements.¹⁹⁸ Bill S-5 solidified the bureaucracy’s claim to regulatory authority over the e-cigarette market, so it would survive court challenges to said authority once it was asserted and enforced.¹⁹⁹

5.7.1 Implementation

After passage, the bureaucrats of Health Canada’s Tobacco Control Directorate began working to put into practice the promise of an expansionist e-cigarette regulatory stance that aimed to serve the interests of the public health. Implementing S-5 has taken some time. The pace of writing regulations to implement bill S-5 was much slower than its “companion” cannabis legalization bill, C-45, which received royal assent in June 2018, a month *after* S-5. C-45’s

¹⁹³ CD @ 9

¹⁹⁴ CF @ 7

¹⁹⁵ The lone exception was on a motion in the Senate which would have referred the bill back to the committee stage to reconcile changes between the Commons and Senate versions of the bill. That measure was defeated by a wide margin as Conservative senators could not rally Independent or Liberal senators to their cause. Harder, An Act to amend the Tobacco Act and the Non-smokers’ Health Act and to make consequential amendments to other Acts; Senate of Canada, “An Act to Amend the Tobacco Act and the Non-Smokers’ Health Act and to Make Consequential Amendments to Other Acts – S-5 – Non-Government Motion No. 333 – Refer Government Motion No. 185 and House of Commons Message to SOCI,” Senate of Canada, May 10, 2018, <https://sencanada.ca/en/in-the-chamber/>.

¹⁹⁶ Harder, An Act to amend the Tobacco Act and the Non-smokers’ Health Act and to make consequential amendments to other Acts.

¹⁹⁷ “Heart and Stroke Welcomes Broad Overhaul of Tobacco Act,” Heart and Stroke Foundation of Canada, May 23, 2018, <https://www.heartandstroke.ca/en/what-we-do/media-centre/news-releases/heart-and-stroke-welcomes-broad-overhaul-of-tobacco-act/>.

¹⁹⁸ Mark Rendell and Retail & Marketing, “Big Tobacco’s ‘next Gen’ Evangelists May Be Just Blowing Smoke,” *Financial Post* (blog), May 17, 2018, <http://business.financialpost.com/news/retail-marketing/big-tobaccos-next-gen-evangelists-may-be-just-blowing-smoke>.

¹⁹⁹ CIG @ 22; Pablo Cano Trilla, “Room for Interpretation in Federal Law – Canada Regulatory Report,” ECigIntelligence, October 18, 2018, <https://ecigintelligence.com/still-room-for-interpretation-in-federal-law-canada-regulatory-report/>.

crucial regulations, needed for the cannabis market to begin operations, were finalized in July 2018.²⁰⁰

The regulatory environment before S-5 was characterized as being a “Wild West” environment where quality standards were absent, and rules were scoffed at by retailers and importers.²⁰¹ The first six months after royal assent of S-5 was characterized as a different sort of “Wild West” environment.²⁰² The new Wild West was defined by the presence of multinational corporations who pushed the boundaries of legal marketing activity in the view of more of the Canadian public during a period when the Canadian government was required to notify the World Trade Organization of impending new regulations, so trading partners could adjust.²⁰³ E-cigarette marketing and legally questionable behavior moved out of the vape shop and into convenience stores, televisions, and radios.²⁰⁴ Promotion of e-cigarettes became rampant, fueled by the injection of capital to the sector delivered by tobacco companies newly hawking their own e-cigarette brands.²⁰⁵ British American Tobacco’s local affiliate blanketed Toronto’s subway system with Vype ads and set up pop-up installations that ended up being shut down by the Regulatory Operations and Enforcement Branch under the lifestyle advertising prohibition.²⁰⁶ Television ads for the Vype brand ran over 4000 times over 10 weeks.²⁰⁷ Juul entered the Canadian market in August 2018 and quickly supplanted Vype as the best-selling brand on the market within two months of entry.²⁰⁸ Sales in the Canadian market began shifting towards

²⁰⁰ CJ @ 21; Wilson-Raybould, An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts; Public Works and Government Services Canada Government of Canada, “Cannabis Regulations: SOR/2018-144,” *Canada Gazette Part II* 152, no. 14 (July 11, 2018): 2600–2898.

²⁰¹ CF @ 53; Catherine S. Callbeck, Claude Carignan, and Jane Cordy, “Senate of Canada - Debates,” Pub. L. No. 59, § Senate Floor (2014), https://sencanada.ca/en/content/sen/chamber/412/debates/059db_2014-05-13-e.

²⁰² CH @ 43; “More Can Be Done to Curb Vaping among Canadian Youth, Professor Says,” *The Current* (CBC Radio, November 19, 2018), <https://bit.ly/3663gjZ>.

²⁰³ Canada’s SPS & TBT Notification Authority and Enquiry Point, “G/TBT/N/CAN/513/Add.2,” WTO, September 28, 2018, <https://bit.ly/2RqTEms>.

²⁰⁴ Neil Collishaw, “See Vype Go!,” *Physicians for a Smoke-Free Canada* (blog), June 11, 2018, <http://smoke-free-canada.blogspot.com/2018/06/see-vype-go.html>.

²⁰⁵ CG @ 19; Don Davies, “Health Committee on Dec. 6th, 2018,” § Health Standing Committee (2018), <https://openparliament.ca/committees/health/42-1/128/don-davies-11/>.

²⁰⁶ Tina Yazdani, “E-Cigarette Company Installation Shut down by Health Canada,” *Toronto CityNews*, April 21, 2019, <https://toronto.citynews.ca/2019/04/21/e-cigarette-installation-shut-down/>.

²⁰⁷ CJ2 @ 4; Timothy Dewhirst, “British American Tobacco (BAT) and Retail Merchandising: Vype e-Cigarette Promotion in Ontario, Canada,” *Tobacco Control*, June 24, 2019, <https://doi.org/10.1136/tobaccocontrol-2019-054957>; “Enforcing the Tobacco and Vaping Products Act to Protect Young People from the Current Marketing Practices of the Vaping Industry in Canada” (Physicians for a Smoke-free Canada, May 2019), 39, http://www.smoke-free.ca/eng_home/2019/2019-05%20Vape%20ads.pdf.

²⁰⁸ Howard Willard, “2019 CAGNY Investor Presentation” (Investor, Consumer Analyst Group of New York, New York, NY, 2019), 17, <https://bit.ly/37Xmzxn>.

transnational tobacco company backed brands, fulfilling the ambitions of these companies that notably kept criticisms of the e-cigarette regulatory provisions in bill S-5 quiet before its passage into law.²⁰⁹

Health Canada ended up warning e-cigarette manufacturers, namely the tobacco companies, at the end of the “Wild West” period that much of their advertising efforts qualified as prohibited lifestyle advertising.²¹⁰ Tobacco companies voiced their disagreement, claiming that their marketing efforts do not constitute lifestyle advertising, and have the resources to engage in marketing campaigns that test that definition.²¹¹ Legal action is forthcoming and might be sped up by the introduction of further limitations on the place and character of marketing that is being introduced in regulations.²¹²

Efforts to involve non-business interests in the creation of market regulations included forming a Scientific Advisory Board on Vaping Products in mid-2017 (while S-5 was being debated in Parliament) that was staffed by an international team of academics to guide the Tobacco Control Directorate’s decision-making process through the changing evidentiary landscape concerning the harms and benefits of e-cigarettes.²¹³ One initial task of the board was to draft statements that federal regulators could authorize “regulated health claims” for use in communications (marketing) about e-cigarettes to demonstrate the relatively lower risks to health these products posed compared to tobacco cigarettes.²¹⁴ The claims in active development contained messages like “If you are a smoker, switching completely to vaping is a much less harmful option” and

²⁰⁹ Migle Malinovskyte, “Regulations Fuel Growth: Canada Market Report,” *ECigIntelligence* (blog), March 15, 2019, <https://ecigintelligence.com/regulations-fuel-growth-canada-market-report/>.

²¹⁰ Elizabeth Thompson, “Health Canada Issues Legal Warning over ‘Lifestyle’ Ads for Vype,” *ECigIntelligence* (blog), November 28, 2018, <https://ecigintelligence.com/health-canada-issues-legal-warning-over-lifestyle-ads-for-vype/>; Neil Collishaw, “Is Health Canada Really Going to Let Imperial Tobacco off the Hook for Its Illegal Vaping Ads?,” *Physicians for a Smoke-Free Canada* (blog), February 27, 2019, <http://smoke-free-canada.blogspot.com/2019/02/is-health-canada-really-going-to-let.html>.

²¹¹ Tobacco companies claim that showing pictures of fresh-looking apples and cherries constitutes brand-preference advertising. Public health groups counter that such images promote a subtle message of health and wellness. Sean Boynton, “TransLink Blasted for Allowing Ads for Vaping Products in SkyTrain Stations,” *Global News*, May 29, 2019, <https://globalnews.ca/news/5290229/translink-vaping-ads-skytrain-stations/>; “Enforcing the Tobacco and Vaping Products Act to Protect Young People from the Current Marketing Practices of the Vaping Industry in Canada.”

²¹² Public Works and Government Services Canada Government of Canada, “Vaping Products Promotion Regulations.”

²¹³ Health Canada, “Scientific Advisory Board on Vaping Products,” organizational descriptions, aem, May 3, 2018, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/vaping-products.html>.

²¹⁴ Health Canada, “Meeting on November 20-21, 2017: Scientific Advisory Board on Vaping Products,” organizational descriptions, aem, April 13, 2018, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/vaping-products/meeting-11-17.html>.

“While vaping products emit toxic substances, the amount is significantly lower than in tobacco smoke”.²¹⁵

At the November 2018 meeting of the board, David Hammond, a Professor of Public Health at the University of Waterloo and member of the board, brought worrisome survey findings to share.²¹⁶ Hammond conducted a repeated online panel survey of youth in Canada before and after the passage of S-5 and found rates of youth e-cigarette use had nearly doubled while cigarette smoking rates had risen by almost half.²¹⁷ This combination of findings was viewed as unambiguously bad news for public health as it implies that the feared gateway effect from e-cigarette use to tobacco cigarette use might be playing out in Canada in the wake of the passage of Bill S-5. This prompted calls for further regulatory action to clamp down on the growing vaping market in the country.²¹⁸ Meanwhile, the regulated health claim concept fell by the wayside.²¹⁹

In February 2019, the Tobacco Control Directorate began the process of rulemaking to impose further limits on e-cigarette advertising than are present in Bill S-5’s text, in response to what the agency perceives is a problem of rising youth e-cigarette use.²²⁰ In April 2019, the Tobacco Control Directorate issued another public consultation on matters pertaining to making e-cigarettes less appealing to youth.²²¹ The regulatory measures that may emerge from these consultations have not become public yet, but they are all closer to the contractionist end of the range of regulatory stances compared to the status quo policy. The first measures that would

²¹⁵ Azim Chowdhury, “Canada’s New Regulatory Framework for Vaping Products,” *The National Law Review*, October 9, 2018, <https://www.natlawreview.com/article/canada-s-new-regulatory-framework-vaping-products>.

²¹⁶ Kelly Crowe, “Teen Vaping in Canada Has Taken a ‘worrisome’ Turn,” *CBC*, December 8, 2018, <https://www.cbc.ca/news/health/health-canada-youth-teenage-vaping-smoking-hammond-1.4937593>; Health Canada, “Meeting Summary - November 19-20, 2018: Scientific Advisory Board on Vaping Products,” transparency - other, aem, May 7, 2019, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/vaping-products/meeting-11-18.html>. John Paul Tasker, “‘Troubling Signs’: Health Canada to Review Tobacco Strategy as Smoking Rate Spikes,” *CBC News*, November 20, 2018, <https://www.cbc.ca/news/politics/tasker-health-canada-smoking-troubling-signs-1.4909402>; Health Canada, “Meeting Summary - November 19-20, 2018.”

²¹⁷ David Hammond et al., “Prevalence of Vaping and Smoking among Adolescents in Canada, England, and the United States: Repeat National Cross Sectional Surveys,” *BMJ* 365 (June 20, 2019): l2219, <https://doi.org/10.1136/bmj.l2219>.

²¹⁸ Adam Hunter, “‘We Have a Big Problem’: Spike in Youth Vaping Sparks Calls for Legislation,” *CBC News*, June 20, 2019, <https://www.cbc.ca/news/canada/saskatchewan/vaping-spike-canada-1.5183664>.

²¹⁹ CJ2 @ 18-20

²²⁰ Health Canada, “Consultation Summary: Notice of Intent – Potential Measures to Reduce the Impact of Vaping Products Advertising on Youth and Non-Users of Tobacco Products,” consultations, aem, October 31, 2019, <https://www.canada.ca/en/health-canada/programs/consultation-measures-reduce-impact-vaping-products-advertising-youth-non-users-tobacco-products/notice-document/summary.html>.

²²¹ Health Canada, “Reducing Youth Access and Appeal of Vaping Products.”

affect the packaging and labeling of e-cigarettes were advanced to the first stage of the formal rulemaking process in June 2019.²²² Those new rules, which are likely to be implemented in 2020, would mandate ingredient labeling and child-proofing of e-liquid containers.

A bevy of further regulations is being developed by a regulator that is struggling to keep pace with the market they are being tasked with controlling. The Tobacco Control Directorate has funded numerous public consultations, focus groups, qualitative evaluations, and quantitative studies to make decisions that comport with the concerns of constituents and reflect the best available data.²²³ Finally fleshing out the federal regulatory authority granted by S-5, the first large-scale regulations began being published in *The Canada Gazette*, the country's register of federal regulations in December 2019.²²⁴

5.8 Conclusion

Each stream in the Canadian policy process became ready to couple at a different time. The problem stream reached a state of readiness in the fall of 2014 when the provinces decided that they wanted Health Canada to change the way it was regulating e-cigarettes to address the policy vacuum at the federal level. The status quo had become untenable to all stakeholders, and no one would defend the policy that applied harsher regulatory policies to a less harmful product than tobacco cigarettes. The policy stream became ready soon thereafter as through the winter of 2015 as the standing committee on health in the House of Commons produced a unanimous report that underlined the harm-reductionist logic which would be operationalized as an expansionist framework for nicotine-containing e-cigarettes at the federal level in Canada. The fact that the report was unanimous indicated that no matter the outcome of an impending election, e-cigarette regulatory policy was ready for change. The political stream became ready to couple during 2015 as the Liberal government came to power on a promise to improve health and well-being through the expanded use of harm reductionist and strong tobacco control policies.

The introduction of Bill S-5 in November of 2016 represented the coupling of these streams. Bill S-5 was sculpted in a manner that encapsulated the concept of business-friendly harm reduction. S-5 effectively muted loud dissent from Conservatives and tobacco companies while still being

²²² Government of Canada, "Canada Gazette, Part 1, Volume 153, Number 25."

²²³ James Van Loon, "Canada's Approach to Vaping Products: Responding to Youth Vaping Rates" (The E-Cigarette Summit US 2019, Washington DC, April 29, 2019), <https://www.e-cigarette-summit.us.com/files/2019/05/James-Van-Loon.pdf>.

²²⁴ Public Works and Government Services Canada Government of Canada, "Vaping Products Promotion Regulations."

perceived as a boon to public health, solidifying the support from the NDP and public health groups. The bill adopted an expansionist e-cigarette regulatory stance that was balanced off by concerns that young people and non-tobacco users could be later protected. Bill S-5 ended up empowering federal regulators with new powers that can be tailored to meet policy goals going forward.

In the end, the passage of e-cigarette regulations in Canada represents how policy construction and framing can be leveraged to change regulatory stances towards a new market. Political support can be smoothed over through strategies like issue linkage and the advancement of ideas like business-friendly harm reduction. While the universal rejection of the status quo regulatory stance seems to have primed the country for a change, the arrival at a near consensus policy alternative ensured that policy change would be resilient in the face of varied political landscapes.

Chapter 6 New Zealand

A Cohesive Policy Community Paved the Path to Regulatory Change

Tariana Turia was born to a single mother of Māori, New Zealand's indigenous people, descent in 1944.¹ After an early life spent first engaging in the domestic affairs of raising a family, and then turning to run a tribal health service, Turia was elected to the New Zealand Parliament for the first time in 1996 as a member of the left-wing Labour Party.² In 2003, a policy debate over ownership of New Zealand's foreshore and seabed within the Labour government led by Helen Clark ended up creating such a rift between Turia and the Labour Party that she resigned from the government and formed her own political party. Turia's new Māori Party focused on promoting indigenous rights, wellbeing, and culture.³ After the 2008 Parliamentary election, the Māori party joined the right-wing National Party as a junior partner in coalition government. Turia was appointed the Associate Minister of Health and she took over the tobacco policy portfolio.⁴

The Māori focus on tobacco control stretched back at least a decade before a program called "For Māori by Māori" to promote smoking cessation in the Māori population under the watch of Māori providers.⁵ This was done in response to revelations during the 1997 World Conference on Tobacco or Health in China that Māori had some of the highest lung cancer rates in the world.⁶ Smoking rates among Māori started at levels over twice as high as Paakehaa (New

¹ Richard Lane, "Tariana Turia: Looking Ahead to a Tobacco-Free New Zealand," *The Lancet* 385, no. 9972 (March 14, 2015): 937, [https://doi.org/10.1016/S0140-6736\(15\)60518-9](https://doi.org/10.1016/S0140-6736(15)60518-9).

² Michele Hewitson, "Interview: Tariana Turia," *NZ Herald*, March 4, 2011, sec. New Zealand, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10710307.

³ Louise Humpage, "Does Having an Indigenous Political Party in Government Make a Difference to Social Policy? The Māori Party in New Zealand," *Journal of Social Policy* 46, no. 3 (July 2017): 475–94, <https://doi.org/10.1017/S0047279417000022>.

⁴ Adam Gifford, "Waatea News Update: Sharples Takes Aim at Sports Violence," *Waatea News Update* (blog), August 16, 2010, <http://waatea.blogspot.com/2010/08/sharples-takes-aim-at-sports-violence.html>.

⁵ Michele Grigg, Andrew Waa, and Shane Kawenata Bradbrook, "Response to an Indigenous Smoking Cessation Media Campaign – It's about Whānau," *Australian and New Zealand Journal of Public Health* 32, no. 6 (2008): 559–64, <https://doi.org/10.1111/j.1753-6405.2008.00310.x>.

⁶ NN @ 18-19

Zealanders of European descent).⁷ This stark disparity in smoking prevalence, and its role in contributing two years to a seven-year gap in life expectancy between the groups, has been a salient political issue for decades.⁸ A sense of the scale of the problem is demonstrated by a 1995 government goal to get the proportion of Māori women smoking during *pregnancy under 50%* by 2000.⁹

In 2011, the Māori Party, as a junior partner in the National Party government, pressed in combination with Māori health advocates, to set a goal to make New Zealand Aotearoa (the Māori word for the country) Smokefree by 2025.¹⁰ Explicitly motivated by the inequities afflicting Māori women, Dame Tariana Turia dominated the push to set the Smokefree 2025 goal.¹¹ Smokefree 2025 set an interim goal to halve smoking in all demographic groups by 2015 and for the country as a whole to decrease cigarette smoking prevalence to minute levels (less than 5% of adults) by 2025.¹² This goal was alternately described as ambitious, aspirational, or absurd.¹³ This choice to adopt an ‘endgame’ goal for the tobacco epidemic made New Zealand only the second country in the world after Finland to do so.¹⁴ The immediate policy outcome during the John Key National government era was to set aside some funding to support Māori-targeted cessation services mostly funded by a plan to increase tobacco taxes 10% per year over

⁷ In 2011, 41% of Māori adults were current smokers compared to 17% of Paakehaa. Kylie Mason et al., *The Health of New Zealand Adults 2011 / Key Findings of the New Zealand Health Survey*. (Wellington, N.Z.: New Zealand Ministry of Health, 2012), 23, <https://www.health.govt.nz/system/files/documents/publications/nzhs-health-of-new-zealand-adults-2011-12.pdf>.

⁸ NY @ 5; Ross Barnett, Jamie Pearce, and Graham Moon, “Does Social Inequality Matter? Changing Ethnic Socio-Economic Disparities and Māori Smoking in New Zealand, 1981-1996,” *Social Science & Medicine* (1982) 60, no. 7 (April 2005): 1515–26, <https://doi.org/10.1016/j.socscimed.2004.08.002>.

⁹ Gillian S. Gould et al., “Smoking in Pregnancy Among Indigenous Women in High-Income Countries: A Narrative Review,” *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco* 19, no. 5 (May 1, 2017): 506–17, <https://doi.org/10.1093/ntr/ntw288>; Jenny Salesa, “Progress on Achieving Smokefree 2025 and the Government’s Response to the Report of the Māori Affairs and Health Committees on Achieving Smokefree 2025,” July 4, 2019, https://www.health.govt.nz/system/files/documents/information-release/progress_on_achieving_smokefree_2025_cabinet_paper.pdf.

¹⁰ Tony Blakely et al., “The Maori Affairs Select Committee Inquiry and the Road to a Smokefree Aotearoa,” *The New Zealand Medical Journal (Online)* 123, no. 1326 (2010).

¹¹ NG @ 14-15; Richard Edwards, “Endgames and Smokefree Aotearoa 2025 Update” (PowerPoint, Smokefree Research Symposium, Wellington NZ, October 26, 2016), 14, <https://bit.ly/2Pax6jL>.

¹² Tau Henare, “Inquiry into the Tobacco Industry in Aotearoa and the Consequences of Tobacco Use for Māori” (Māori Affairs Committee, November 2, 2010), 10, https://www.parliament.nz/resource/en-NZ/49DBSCH_SCR4900_1/2fc4d36b0fbdfed73f3b4694e084a5935cf967bb.

¹³ NAD @ 15; NW @ 20; NG @ 4

¹⁴ As a point of contrast, Finland’s first tobacco endgame goal was to achieve 5% smoking prevalence by 2040, making it much less ambitious than New Zealand’s Smokefree 2025 goal. NH @ 46; Jamie Tam, “Cultivating the next Generation of Tobacco Endgame Advocates,” *Tobacco Control* 22, no. suppl 1 (May 1, 2013): i47–48, <https://doi.org/10.1136/tobaccocontrol-2012-050810>.

an extended period.¹⁵ Eventually, the National Party agreed to also pass legislation to put tobacco products in plain packaging in April 2012, after much lobbying from Turia.¹⁶ Perhaps of greater importance to what would follow, the adoption of the Smokefree 2025 goal, was never followed by the adoption of a strategy mapping out how such an ambitious target would be achieved.¹⁷

The creation of the Smokefree 2025 goal was the result of an interplay between political institutions and political opportunities. The creation of this goal later served as an accelerant to changing e-cigarette regulatory policy as a Labour government that was keen to try to meet the goal came to accept that a large change in regulatory policy might be a good idea.

6.1 Regulatory Stances Towards E-cigarettes

Before 2016, New Zealand's regulatory framework for nicotine-containing e-cigarettes essentially mirrored the regulatory framework in Australia and Canada.¹⁸ Nicotine-containing e-cigarettes are classified under the Medicines Act of 1981 as medicines and, as such, could not be sold or supplied in New Zealand without approval from the country's medicines regulator, Medsafe.¹⁹ The relevant governing legislation for tobacco products, the Smoke-Free Environments Act (SFEA) was interpreted by regulators to prohibit advertising selling, supplying, or distributing nicotine-containing e-cigarettes.²⁰ In 2010, Medsafe ruled that e-cigarettes, which either contained nicotine or claimed a therapeutic purpose (i.e. to help smokers quit using cigarettes) would be classified as medicines, not as tobacco products.²¹ The move was prompted by the regulator's decision to warn e-cigarette retailers to refrain from making therapeutic claims about their products.²² Figure 12 illustrates the regulatory framework before

¹⁵ NO @ 4; Louise Thornley et al., "Achieving Smokefree Aotearoa By 2025" (Wellington NZ: University of Otago, ASPIRE 2025, Quit Group Trust and Hapai Te Hauora, August 1, 2017), <https://aspire2025.files.wordpress.com/2017/08/asap-main-report-for-web2.pdf>.

¹⁶ Crosbie and Thomson, "Regulatory Chills."

¹⁷ Richard Edwards, Chris Cunningham, and Janet Hoek, "The Smokefree 2025 Goal Is in Danger of Receding – Will the Ministry of Health's 'Realignment' Get It Back on Track? –," *Public Health Expert, University of Otago* (blog), May 18, 2015, <https://blogs.otago.ac.nz/pubhealthexpert/2015/05/18/the-smokefree-2025-goal-is-in-danger-of-receding-will-the-ministry-of-healths-realignment-get-it-back-on-track/>.

¹⁸ Wilson et al., "Potential New Regulatory Options for E-Cigarettes in New Zealand."

¹⁹ Li, Newcombe, and Walton, "The Prevalence, Correlates and Reasons for Using Electronic Cigarettes among New Zealand Adults."

²⁰ NZ Ministry of Health, "Smoke-Free Environments (Controls And Enforcement) Amendment Bill: Departmental Report" (Wellington NZ: New Zealand Parliament Health Committee, March 16, 2011), 21–23, https://www.parliament.nz/resource/en-NZ/49SCHE_ADV_00DBHOH_BILL10487_1_A176996/6dfc86a1ee521f5f64424117ea42fd097a230a40.

²¹ Medsafe, "Electronic Cigarettes," Medsafe, November 5, 2010, <https://web.archive.org/web/20121010134327/http://www.medsafe.govt.nz/regulatory/guideline/electroniccigarettes.asp>.

²² Martin Johnston, "Medical Rules Lead to Withdrawal of Electronic Quit-Smoking Aid," *New Zealand Herald*, April 16, 2010, sec. National, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10638910.

March 2018. Nicotine-containing e-cigarettes were not permitted to be sold and the only legal routes to access the products were through a personal importation scheme or if a company were to submit the product to Medsafe for premarket approval as a medicine.²³

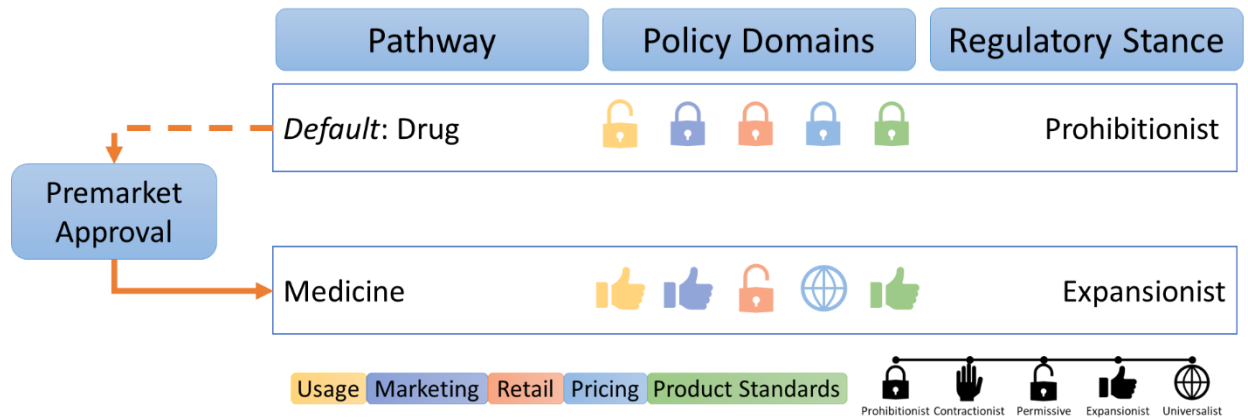


Figure 12: Regulatory Framework for Nicotine Containing E-Cigarettes Before 2018 in New Zealand

If an e-cigarette had been granted permission to be sold as a medicine then such a product would have received an expansionist regulatory stance as it could have been sold at pharmacies, used in public places, marketed with direct-to-consumer advertisements and exempted from the graphic warning labels that were required to be displayed on tobacco products.²⁴ In addition, the cost of such a product could have been publicly subsidized if it qualified for the Prescription Subsidy Scheme.²⁵ If an e-cigarette was imported for personal use then it could be used in the same places as tobacco cigarettes, except for in a few cities where vaping has been carved out from smoking bans, especially in the outdoor areas of restaurants.²⁶ But, no e-cigarette ever received

²³ Jill Lane, “Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products,” Regulatory Impact Statement (Wellington NZ: NZ Ministry of Health, March 29, 2017), 5, 8, 19, <https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/regulation-e-cigarettes-and-emerging-tobacco-and-nicotine-delivery-products>.

²⁴ Peter R. Mansfield et al., “Direct to Consumer Advertising,” *BMJ* 330, no. 7481 (December 30, 2004): 5–6, <https://doi.org/10.1136/bmj.330.7481.5>.

²⁵ Simon Thornley et al., “Few Smokers in South Auckland Access Subsidised Nicotine Replacement Therapy,” *The New Zealand Medical Journal* 123, no. 1308 (January 29, 2010): 16–27.

²⁶ Local councils in New Zealand retain powers to regulate the usage of e-cigarettes in public spaces. Some councils like Porirua and Wellington have considered imposing rules putting e-cigarettes on parity with tobacco cigarettes but have declined to adopt them. Others, like Hamilton, removed e-cigarettes from public smoking ban coverage after the rules had been put in place, effectively backtracking. Lastly, some councils decided to keep the inclusion of e-cigarettes in their usage policies. Virginia Fallon, “Vaping Rules at Odds with Government Aims,” *The Dominion Post*, May 8, 2019, sec. News, National, NexisUni. “Vaping Ban for CBD Goes up in Smoke,” *Hamilton News*, March 22, 2019, sec. Regional, NexisUni. Emma Dangerfield, “Tourist Hotspot Going Smokefree,” *Northern Outlook*, November 7, 2018, sec. National, NexisUni; “Public Areas Now Smokefree,” *Waihi Leader*, August 8, 2019, sec. Regional, NexisUni.

premarket approval from Medsafe, so the entire were considered to be drugs that were subject to a prohibitionist stance that officially barred such products from legal sale.

However, many regulations regarding marketing, retail, and product standards were made fuzzier because it was not clear that these restrictions applied to e-cigarette hardware. The law was clearer in its applicability to nicotine e-liquid. The total effect of this regulatory scheme was that the e-cigarette market grew, but did not professionalize or see the entry of multinational tobacco companies.²⁷ Nevertheless, by 2017, estimates placed the number of people using e-cigarettes in New Zealand each month at around 150,000, a not-insignificant group compared to the 581,000 tobacco cigarette smokers in the country at the time.²⁸

6.1.1 March 2018 Forwards

This framework remained in place until March 2018, when the decision in the case of *Philip Morris v Ministry of Health* determined that all tobacco products sold in the country should be legally allowed to be sold unless expressly prohibited by prior statute (see Section 6.2.3).²⁹ The judge determined that Section 29.2 of the Smoke-Free Environments Act should be read to only prohibit the sale of tobacco products that were not made to be inhaled. As a result, Philip Morris was permitted to sell its heated tobacco product, IQOS, in the country but it was subject to all regulations placed on tobacco products therein.³⁰ This ruling was immediately viewed by the Ministry of Health as applying to nicotine-containing e-cigarettes, thereby legalizing them under a similar regulatory framework as tobacco cigarettes, in effect establishing a permissive regulatory stance towards the e-cigarette market.³¹ The Crown did not appeal the decisions, de facto acceding to the change.

After the decision was handed down, the regulatory framework for e-cigarettes was thrown into chaos. As best as can be deduced, the regulatory framework post-*Philip Morris* is shown in Figure 13. Generally, the medicine pathway was unchanged and nicotine-containing e-cigarettes

²⁷ David Attwood, Daniel Irwin-Brown, and Nick Wenbourne, "In Depth: E-Cig Market and Law in Australia and New Zealand," *ECigIntelligence* (blog), December 18, 2014, <https://ecigintelligence.com/in-depth-e-cig-market-and-law-in-australia-and-new-zealand/>.

²⁸ NZ Ministry of Health, "Indicator: Use Electronic Cigarettes at Least Once a Month," New Zealand Health Survey Annual Data Explorer, March 25, 2019, <https://bit.ly/2PhQ1cg>; NZ Ministry of Health, "Indicator: Current Smokers," New Zealand Health Survey Annual Data Explorer, March 25, 2019, <https://bit.ly/2PhQ1cg>.

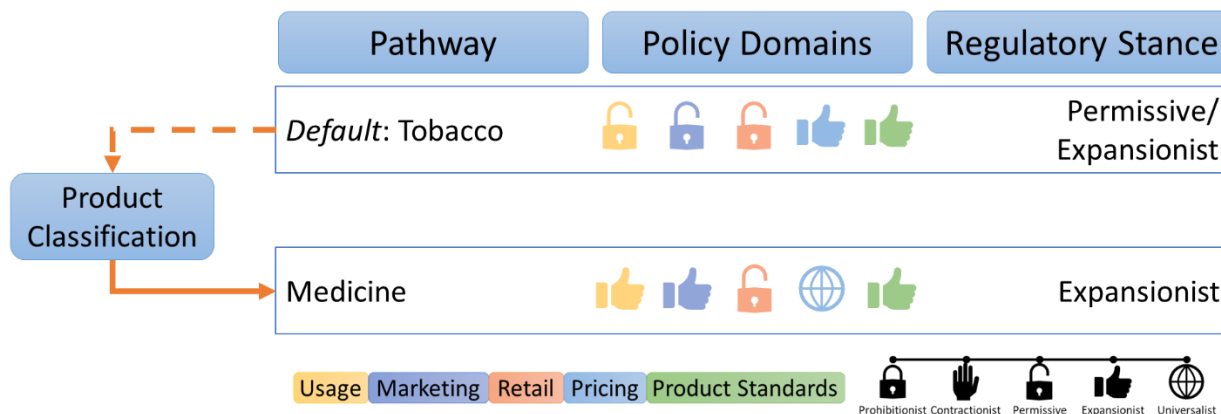
²⁹ Butler, Ministry of Health v Phillip Morris (New Zealand) Ltd, NZDC.

³⁰ Zaharia and Craft, "New Zealand Court Gives Philip Morris Nod to Sell Heated Tobacco..."

³¹ "Vaping, Smokeless, Including Heated Tobacco," Ministry of Health NZ, May 9, 2018, <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco>.

were reclassified by default as tobacco products. Bureaucrats in the Ministry of Health pointed out in policy consultations and cabinet meetings that it was not entirely clear which regulations applied to nicotine-containing e-cigarettes in the tobacco products pathway.³² For example, it seems that the post-*Philip Morris* regulatory framework might have only applied to e-liquid made from tobacco and not to e-cigarette hardware.³³ This made for a confusing set of regulations that applied to some devices and products and not to others. Notably, the Labour government was clear that certain product standards, prohibitions on usage in public places, and excise taxes did *not* apply to e-cigarettes.³⁴ Product standards meant to ensure the quality and safety of e-liquids and e-cigarettes were also nonexistent.³⁵ Officials commented that similar restrictions on e-cigarette marketing and retailing apply, but point-of-sale display bans that apply to tobacco cigarettes are not being enforced for nicotine-containing e-cigarettes.³⁶ Regulatory uncertainty defined the market.³⁷ Amongst this regulatory uncertainty, observers viewed the growth of the market as speeding up.³⁸

Figure 13: Post Philip Morris Regulatory Framework for Nicotine-Containing E-Cigarettes



³² Jenny Salesa and Jill Lane, “Supporting Smokers to Switch to Significantly Less Harmful Alternatives” (Wellington NZ: NZ Cabinet Office, November 21, 2018), sec. 30, <https://bit.ly/2QfoDee>.

³³ While it cannot always be assured that the nicotine in an e-cigarette is derived from tobacco, it is far more economical to produce liquid nicotine from tobacco leaves than from other plants or to synthetically produce this key chemical. After *Philip Morris*, e-cigarette retailers and producers had incentives to claim that their nicotine was produced from tobacco because it qualified the product for a permissive/expansionist regulatory stance instead of the prohibitionist stance that would be applied to synthetically derived nicotine-containing e-cigarettes.

³⁴ Martin Johnston, “Kiwi Smokers Urged to Make New Year’s Switch to Vaping for Health and to Avoid Tax Hike,” *NZ Herald*, December 31, 2018, sec. New Zealand, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12184226.

³⁵ NAC @ 5

³⁶ NQ @ 21

³⁷ NY @ 19

³⁸ NW @ 75

6.1.2 Towards Risk Proportionate Regulation

New Zealand regulatory agencies have gained confidence in a belief over time that, given robust regulatory powers, the risks of expanding the market for e-cigarettes can be mitigated and public health benefits can be gleaned.³⁹ Under the last National government, and the current Labour-coalition government, the changes each government would make to e-cigarette regulatory policy have been described in regulatory impact statements that have been presented to cabinet. These plans coalesced into the Smokefree Environments and Regulated Products (Vaping) Amendment Bill which was introduced in February 2020 to finally change the country's e-cigarette regulatory stance.⁴⁰

Each plan was written by Ministry of Health officials in the Tobacco Control Programme and sought to implement a risk-proportionate regulatory framework to impose restrictions in line with the risk to health that a product posed. Essentially, the officials wanted to provide advantages to help grow the e-cigarette market at the expense of the tobacco products market. The regulatory framework proposed to the National Party government in March of 2017 prohibited the sale of e-cigarettes to persons under the age of 18, restricted the sales of e-cigarettes in vending machines to the same establishments where cigarette sales were allowed in vending machines, prohibited most marketing activity beyond the retail setting, advised businesses to set up voluntary clean air policies, and empowered the Ministry of Health to set product quality, ingredient, and manufacturing standards.⁴¹

In late 2018, a very similar plan was promoted by Ministry of Health officials in a cabinet meeting with the Ardern Labour-coalition government, with several additional provisions that limited marketing to adult-only retailers, disallowed the use of vending machines, and set out pre-market notification responsibilities for manufacturers.⁴² Eventually, the Labour-coalition government's plan would evolve to ensure that usage of e-cigarettes in public places was limited to the same places that tobacco cigarettes are allowed to be used.⁴³ By September 2019, Ministry

³⁹ Salesa and Lane, "Supporting Smokers to Switch to Significantly Less Harmful Alternatives," 7.

⁴⁰ Salesa and Lane, "Supporting Smokers to Switch to Significantly Less Harmful Alternatives"; Lane, "Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products."

⁴¹ Lane, "Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products."

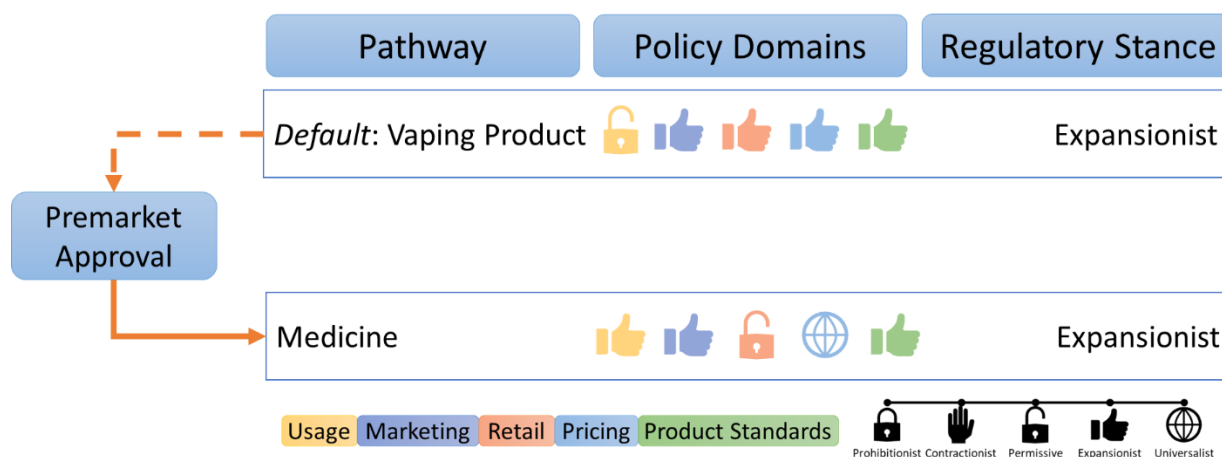
⁴² Salesa and Lane, "Supporting Smokers to Switch to Significantly Less Harmful Alternatives," sec. 6.1.

⁴³ Hannah Martin, "Plan to Ban Vaping in Bars, Restaurants, Schools and Workplaces in New Zealand," Stuff, November 23, 2018, <https://www.stuff.co.nz/national/health/108816764/plan-to-ban-vaping-in-bars-restaurants-schools-and-workplaces-in-new-zealand>.

of Health officials announced that e-cigarette flavors would be limited in any legislation to tobacco, mint, and menthol and that further powers to establish product standards limiting the appeal of e-cigarettes to non-smokers would be added going further.⁴⁴

In February 2020, on the eve of COVID-19-spurred lockdowns, the Labour government introduced a bill to legalize and regulate the e-cigarette market.⁴⁵ The government aimed to fast-track the Smokefree Environments and Regulated Products (Vaping) Amendment Bill to passage before the country’s September 2020 elections.⁴⁶ Figure 14 lays out the expansionist regulatory stance towards the e-cigarette market that the bill would put in place.

Figure 14: Proposed Regulatory Framework for E-Cigarettes under the Smokefree Environments and Regulated Products (Vaping) Amendment Bill



E-cigarettes would be granted competitive advantages over substitute tobacco cigarettes in marketing, retail, pricing, and product standards. In Marketing, public health campaigns, subject to the approval of the Director-General of Health, would be allowed to encourage cigarette smokers to switch to vaping. In retail, vape shops will be allowed to register with the Ministry of Health and be granted special permission to sell flavors beyond mint, menthol, and tobacco. For

⁴⁴ This announcement reflected survey data indicating that these flavors were preferred by older e-cigarette users in New Zealand. Cira Olivier, “Plans for Vaping Regulation but Fear of Job Losses, More Smoking,” *The Daily Post*, November 16, 2019, sec. Regional; Lucy Warhurst, “Ministry of Health Proposes More Regulations after Survey Shows School Children Vaping,” *Newshub*, September 19, 2019, sec. NZ, <https://www.newshub.co.nz/home/new-zealand/2019/09/ministry-of-health-proposes-more-regulations-after-survey-shows-school-children-vaping.html>. Hayley Guiney, Alana Oakly, and Greg Martin, “E-Cigarette Use and Perceptions among Current and Ex-Smokers in New Zealand,” HPA Report (Wellington NZ: Health Promotion Agency, January 2019), 16, <https://bit.ly/2HjywRT>.

⁴⁵ Lidia Kelly, “New Zealand Moves to Ban Vaping Ads, Sales to Minors,” *Reuters*, February 23, 2020, <https://www.reuters.com/article/us-newzealand-vaping-idUSKCN20H00M>.

⁴⁶ “Full Interview: Associate Health Minister Jenny Salesa on Q+A with Jack Tame,” *1NEWS* (Auckland: TVNZ, February 23, 2020), <https://www.tvnz.co.nz/one-news/new-zealand/full-interview-associate-health-minister-jenny-salesa-q-jack-tame>.

pricing, policymakers have not yet expressed interest in levying an excise tax on e-cigarettes. For product standards, e-cigarettes will not have to carry graphic health warning labels, be subject to plain packaging provisions, and will not be subject (yet) to nicotine concentration limits. These expansionist policy proposals are balanced off by several provisions aimed to limit the appeal and availability of the devices to young people and avoid some of the pitfalls suffered by Canada and the United States, like limiting the sales of products sold in retailers that allow youth inside (grocery stores, and pharmacies) to tobacco, mint, and menthol flavors. All these changes would create an expansionist regulatory stance towards the e-cigarette market.

Summary

New Zealand proceeded from a Prohibitionist to a Permissive/Expansionist regulatory stance almost by accident. The coming decision to formally adopt an Expansionist regulatory stance can be explained by a confluence to an influential research community that favored tobacco harm reduction policies, a problem in the form of lackluster progress towards meeting a self-imposed tobacco control goal, and a political community that largely favored the regulatory stance on offer from the policy community.

6.2 Problem Stream

The issue of e-cigarette regulation bubbled up in the consciousness of the New Zealand public through the country's media, but these institutions proved less than consequential in the ripening of the problem stream in the current case. Just two companies, NZME, and Stuff control 90% of New Zealand's online and print journalism market.⁴⁷ Public media is sustained and important in television and radio.⁴⁸ The editorial choices of these actors made little difference in how a lack of e-cigarette availability or regulation became framed as a problem.

E-cigarettes came to be perceived by policymakers as a problem worthy of intervention due to a collision of two decisions. The first decision of consequence was the establishment of the Smokefree 2025 goal and the subsequent unwillingness of policymakers to present a strategy to

⁴⁷ Mel Bunce, *The Broken Estate: Journalism and Democracy in a Post-Truth World* (Bridget Williams Books, 2019), 2.

⁴⁸ Merja Myllylahti and Sarah Baker, "JMAD New Zealand Media Ownership Report 2019" (Auckland, New Zealand: AUT research center for Journalism, Media and Democracy, May 12, 2019), https://www.aut.ac.nz/__data/assets/pdf_file/0010/329770/JMAD-2019-Report.pdf.

meet the ambitious goal. As the country repeatedly fell short of meeting the interim Smokefree 2025 goals, an appetite for trying something new in tobacco control grew.

The second decision of consequence was the unexpected turn of events in the case of *Philip Morris v Ministry of Health* which triggered the unscheduled legalization of the sale of nicotine-containing e-cigarettes in the country in March 2018. The decision left the country with a regulatory framework that satisfied no one and created the impetus to revise the regulatory framework for e-cigarettes in a more expansionist direction.

6.2.1 Tobacco Control Policy Progress

Tobacco cigarette smoking in New Zealand has remained on a long downward trajectory for over 40 years, largely as a result of a sustained tobacco control campaign, that has been a comprehensive and evidence-based approach.⁴⁹ New Zealand's tobacco epidemic has been slightly different from other countries in this study because it has consistently impacted nearly as many women as men.⁵⁰

Over time New Zealand has adopted a tobacco control policy regime that, like the other case countries, ranks among the world's strongest contractionist regulatory stances.⁵¹ Regulation of tobacco products began through voluntary agreements with the tobacco industry to place warning labels on packages and to remove advertising from television and radio through the 1960s and 70s.⁵² This era was defined by a strong tobacco industry-supported on multiple fronts by local tobacco farmers, advertising agencies, and political parties who benefitted from the tobacco industry's financial largesse.⁵³

The foundation of the current policy regime was created in the form of the Smoke-Free Environments Act of 1990 (SFEA) which was shepherded to passage by then Labour Party Health Minister and future Prime Minister, Helen Clark.⁵⁴ That bill banned or restricted most

⁴⁹ Chris Money and Susie Keegan, "Evaluation of the Tobacco Excise Increases – Final Report" (Wellington NZ: NZ Ministry of Health, November 27, 2018), 28, <https://bit.ly/2QEbo7O>.

⁵⁰ D. R. Hay and F. H. Foster, "Intercensal Trends in Cigarette Smoking in New Zealand 1: Age, Sex and Ethnic Status.," *The New Zealand Medical Journal* 97, no. 755 (May 1984): 283–85.

⁵¹ World Health Organization, *WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2019: Offer Help to Quit Tobacco Use*.

⁵² Studlar, "Ideas, Institutions and Diffusion."

⁵³ George Thomson and Nicholas Wilson, *Resource Document, a Brief History of Tobacco Control in New Zealand* (Wellington, N.Z.: AFPHM (N.Z.), 1997), sec. 8.3, <https://bit.ly/2LaWPTN>.

⁵⁴ Michael Carr-Gregg, "Interaction of Public Policy Advocacy and Research in the Passage of New Zealand's Smoke-Free Environments Act 1990," *Addiction* 88 (1993): 35S–41S, <https://doi.org/10.1111/j.1360-0443.1993.tb02160.x>.

tobacco marketing activities, restricted public smoking, and set a government-wide strategy for tobacco control for the first time.⁵⁵ The SFEA also created the Health Sponsorship Council to fund the replacement of tobacco sponsorships; wherein the Benson & Hedges Fashion Design Awards became the Smokefree Fashion Design Awards and motorsports' Rothmans Rally became the Smokefree Rally.⁵⁶

An SFEA Amendment passed in 1997 by a right-wing coalition government further restricted tobacco marketing, increased the minimum age of sale for tobacco products from 16 to 18, and empowered the Ministry of Health to set product standards.⁵⁷ In 2003, then PM of a Labour-led coalition government, Helen Clark and then-Associate Minister of Health Steve Chadwick led the drive to amend the SFEA to ban smoking in almost all workplaces.⁵⁸

After the adoption of the Smokefree 2025 goal (see page 149), in 2011, amendments to the SFEA passed by the right-wing coalition government tightened rules on tobacco retailing to keep tobacco products and advertisements for those products out of sight at shops.⁵⁹ In 2012, the Health Sponsorship Council was dissolved and replaced by the Health Promotion Authority which had a broader mission than its predecessor. In between these milestone legislative achievements, right-wing governments occasionally acted to weaken some of the more progressive policies, such as the insertion of exemptions on tobacco sponsorships for international sporting competitions.⁶⁰ Since the 2011 SFEA Amendments, the country has largely relied upon using tobacco tax increases as its primary driver on tobacco control policy progress. The same period was also marked by passing a point-of-sale display ban as well as adopting plain packaging once Australia had cleared up the legality of the measure both national and international court.⁶¹

Nonetheless, at an increasing pace since the 1990s, governments across the political spectrum have managed to find tobacco control legislation that adopted an ever-increasing contractionist

⁵⁵ Studlar, "The Political Dynamics of Tobacco Control in Australia and New Zealand."

⁵⁶ These programs were modeled on similar tobacco sponsorship buyout efforts that began first in Australia (see note 100 at page 99). ND @ 14; Claire Regnault, "Smokin'! When Cigarettes and Fashion Went Hand in Hand," Te Papa's Blog, March 30, 2017, <https://bit.ly/2NzduTJ>.

⁵⁷ Murray Laugesen and Boyd Swinburn, "New Zealand's Tobacco Control Programme 1985-1998," *Tobacco Control* 9, no. 2 (June 1, 2000): 155-62, <https://doi.org/10.1136/tc.9.2.155>.

⁵⁸ Cairney, Studlar, and Mamudu, *Global Tobacco Control*, chap. 7.

⁵⁹ Claire Trevett, "New Law: Smokes, Tobacco in Shops to Be Hidden," *NZ Herald*, July 14, 2011, <https://bit.ly/341uRCE>.

⁶⁰ Thomson and Wilson, *Resource Document, a Brief History of Tobacco Control in New Zealand*, sec. 7.5.

⁶¹ Crosbie and Thomson, "Regulatory Chills."

regulatory framework that was agreeable and worthwhile of passage. The effects of this contractionist policy regime have largely been favorable to the health of the New Zealand population at large. The prevalence of tobacco cigarette smoking fell steadily over time, especially among Paakehaa.⁶² All of this has resulted in current cigarette smoking rates falling to 14.9% of New Zealand adults in 2017/18 while 3.8% of adults were counted as current e-cigarette users in the same period.⁶³ But, none of this progress is moving at a pace to be on track to meet the final Smokefree 2025 goal, and interim goals have already been missed.⁶⁴

6.2.2 Falling Off Track to Meet the Smokefree 2025 Target

Over time, the commitment of politicians to reach the Smokefree 2025 goal has been unsteady at best.⁶⁵ But, surveys of the New Zealand public have found that awareness of the goal's existence is high, while understanding of the target is only middling.⁶⁶ Smokers are more likely to believe than non-smokers that the goal entails getting smoking prevalence to zero or ending tobacco sales altogether.⁶⁷ This misunderstanding among the target population for policy change did not speed the country towards achieving its goal. Instead, it only made the goal seem harsher and less achievable.

The policy community vacillated between a belief that tobacco control in New Zealand was working, but progress was too slow, and that because tobacco control had inadvertently exacerbated Māori health disparities, it wasn't working at all.⁶⁸ Oddly, this belief in the declining efficacy of traditional tobacco control measures was held both by the public health policy

⁶² Money and Keegan, "Evaluation of the Tobacco Excise Increases – Final Report," 67.

⁶³ Since 2015/16, the rate of current vaping rose 2.4 percentage points while the rate of current smoking fell by 1.4 percentage points. NZ Ministry of Health, "Indicator: Use Electronic Cigarettes at Least Once a Month"; NZ Ministry of Health, "Indicator: Current Smokers."

⁶⁴ Some were keen to point out the goal was aspirational in nature, and that there have been no formal mid-term targets that have been failed to be reached. Nick Wilson et al., "Modelling the Number of Quitters Needed to Achieve New Zealand's Smokefree 2025 Goal for Māori and Non-Māori," *The New Zealand Medical Journal* 131, no. 1487 (December 14, 2018): 30–37. ND @ 17

⁶⁵ NP @ 29; Richard Edwards, Janet Hoek, and George Thomson, "Smokefree 2025: Patterns and Trends in References to the Smokefree Goal in Political Speeches and Press Releases," *The New Zealand Medical Journal* 127, no. 1398 (July 18, 2014): 122–25.

⁶⁶ Philip Gendall, Janet Hoek, and Richard Edwards, "What Does the 2025 Smokefree Goal Mean to the New Zealand Public?," *The New Zealand Medical Journal* 127, no. 1406 (November 28, 2014): 101–3; Richard Edwards et al., "Support for a Tobacco Endgame and Increased Regulation of the Tobacco Industry among New Zealand Smokers: Results from a National Survey," *Tobacco Control* 22, no. e1 (May 1, 2013): e86–93, <https://doi.org/10.1136/tobaccocontrol-2011-050324>.

⁶⁷ Gendall, Hoek, and Edwards, "What Does the 2025 Smokefree Goal Mean to the New Zealand Public?," fig. 2.

⁶⁸ The exacerbation stems from the faster decline in smoking rates among Paakehaa than Māori. NAC @ 7; NS @ 36-37; Louise Thornley et al., "Smokefree Aotearoa 2025 Progress Report 2017" (ASPIRE 2025, August 2017), <https://aspire2025.files.wordpress.com/2017/08/asap-progress-report-for-web.pdf>.

community and the more free-market/libertarian policy community.⁶⁹ There was a widely held concern that the country had become overly reliant on traditional tobacco control measures and that they worried about impoverishing smokers.⁷⁰ While this excise tax-driven economic pressure has been consistently found to increase smoking cessation, in the face of US \$25 cigarette packs, even public health advocates became gun-shy about arguing for further tobacco excise tax increases.⁷¹ The socioeconomic and racial composition of the remaining smokers in New Zealand has caused left-wing minded public health advocates to become nervous about the distributional effects of excise tax rises.⁷² Dissatisfaction with the rate of progress in smoking reduction has become palpable, and there is an awareness that without doing something different, the Smokefree 2025 goal will remain out of reach.⁷³

6.2.3 Philip Morris v Ministry of Health

In December 2016, British American Tobacco alerted the Ministry of Health that Philip Morris was planning on begging to sell its heated tobacco product in the country in violation of the SFEA's ban on the sale of tobacco "for chewing or any other oral use (other than smoking)".⁷⁴ That month, officials from the Ministry of Health's Tobacco Control Programme held a meeting with Philip Morris employees and informed them that the ministry believed selling heated tobacco would violate the SFEA.⁷⁵ They asked Philip Morris not to sell the products, but Philip Morris demurred. Instead, they debuted IQOS at a New Year's Eve 2017 party on Waiheke Island and sales began in shops, thereafter.⁷⁶

⁶⁹ Jenesa Jeram, "Smoke and Vapour: The Changing World of Tobacco Harm Reduction" (Wellington NZ: The New Zealand Initiative, May 11, 2018), https://www.scimex.org/_data/assets/file/0007/322927/Smoke-and-Vapour-Embargoed-Fri-11-May.pdf.

⁷⁰ Maintaining a 10 cigarette a day habit on the minimum wage cost nearly one-quarter of that worker's income. Health Promotion Agency, "Cost of Smoking," Smokefree NZ, June 9, 2019, <https://www.smokefree.org.nz/smoking-its-effects/cost-of-smoking>; Marewa Glover and David Sweanor, "How to Stop Smoking (Hint: It's Not Making Cigarettes More Expensive)," *The Spinoff* (blog), August 4, 2017, <https://thespinoff.co.nz/society/04-08-2017/how-to-stop-smoking-hint-its-not-making-cigarettes-more-expensive/>.

⁷¹ Frank J. Chaloupka, Ayda Yurekli, and Geoffrey T. Fong, "Tobacco Taxes as a Tobacco Control Strategy," *Tobacco Control* 21, no. 2 (March 1, 2012): 172–80, <https://doi.org/10.1136/tobaccocontrol-2011-050417>.

⁷² "Shock Increases' on Cigarette Tax Ineffective, Says ASH - 'There Was No Plan,'" *INews Breakfast* (TVNZ, June 24, 2018), <https://www.tvnz.co.nz/one-news/new-zealand/shock-increases-cigarette-tax-ineffective-says-ash-there-no-plan>.

⁷³ NAC @ 9

⁷⁴ ND @ 40

⁷⁵ Luke Cunningham Clere, "Brief of Evidence of Brendon Neville Baker," PMI Science, December 2017, [https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_brief-of-evidence-of-brendon-neville-baker-\(nz-moh\)_december-2017.pdf](https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_brief-of-evidence-of-brendon-neville-baker-(nz-moh)_december-2017.pdf).

⁷⁶ Luke Cunningham Clere, "Closing Submissions on Behalf of the Ministry of Health" (PMI Science, March 2018), para. 36(e), https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_closing-submissions-on-behalf-of-moh_march-2018.pdf.

On March 3, 2017, a Ministry of Health employee purchased a pack of Philip Morris’s heated tobacco from a shop.⁷⁷ Then in May 2017, the Ministry of Health laid charges against Philip Morris for violating the SFEA.⁷⁸ In court, the Ministry of Health argued that heated tobacco was not being smoked, and therefore was not allowed to be sold.⁷⁹ Philip Morris’ counsel countered that the prohibition on sales of tobacco products that were not smoked only meant to apply to tobacco products that were not inhaled, like chewing tobacco, oral snuff, and Swedish snus.⁸⁰ In the end, the district court judge sided with Philip Morris’ interpretation of the statute and ruled that heated tobacco could be sold in New Zealand, but that it was also subject to tobacco product regulations.⁸¹ This meant that heated tobacco would be subject to the strictly contractionist policy stance currently in place for tobacco cigarettes, including advertising prohibitions, plain packaging, and excise taxation.⁸²

Most importantly, in May of 2018, after consultation with legal experts, the Ministry of Health announced it would not appeal the case to a higher court.⁸³ The ruling that inhaled tobacco products, which the Ministry of Health had concluded included e-cigarettes, which were now legally allowed to be sold, and required policy to change to conform to the new legal reality.⁸⁴ The Ministry had already concluded that it wanted a legal and regulated e-cigarette market to be created in New Zealand. The opportunity to take the first step towards legality fell into their lap.⁸⁵ In effect, the court decision promulgated the opening of a market and begged Parliament to pass a new regulatory framework into law.⁸⁶ While e-cigarette retailers and manufacturers

⁷⁷ Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC paragraph 3.

⁷⁸ Deidre Mussen, “Charges Laid against Philip Morris,” Ministry of Health NZ, May 18, 2017, <https://www.health.govt.nz/news-media/media-releases/charges-laid-against-philip-morris>.

⁷⁹ Ben Rumsey, “Investigation into IQOS Device, HEETS Tobacco Sticks and Evidence of Combustion” (Wellington: CRL Energy Ltd, November 17, 2017), https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_crl-energy-ltd---investigation-into-iqos-device-heets-tobacco-sticks-and-evidence-of-combustion_november-2017.pdf.

⁸⁰ David Boldt and Matt Sumpter, “Defendant’s Submissions” (Champan Tripp, March 7, 2018), https://www.pmiscience.com/resources/docs/default-source/NCDC-vs-Morris/nz_pm-submission_march-2018.pdf.

⁸¹ Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC paragraphs 33–35.

⁸² ND @ 46; It should be noted that the excise tax for tobacco is based on the weight of the tobacco leaf in a product. Philip Morris’ heated tobacco product contains about 36% as much tobacco per stick as a combustible cigarette. This tax structure creates a price advantage for heated tobacco in New Zealand relative to cigarettes that is one of the largest in the world. Philip Morris International, “Investor Information,” May 1, 2018, 51, 53, <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzODEwfENoaWxkSUQ9NDA1MDYxfFR5cGU9MQ==&t=1>; Liber, “Heated Tobacco Products and Combusted Cigarettes.”

⁸³ “Vaping, Smokeless, Including Heated Tobacco”; Salesa and Lane, “Supporting Smokers to Switch to Significantly Less Harmful Alternatives,” 7.

⁸⁴ “Vaping, Smokeless, Including Heated Tobacco.”

⁸⁵ NH @ 4

⁸⁶ “Vaping, Smokeless, Including Heated Tobacco.”

preferred to establish voluntary standards on all these matters, public officials stated that they wanted to codify policy.⁸⁷ The consequence of the unexpected court outcome was that the sale of e-cigarettes in New Zealand became legal overnight.⁸⁸ Political actors, like the Associate Minister of Health under the new Labour government, Jenny Salesa, were faced with the choice of allowing e-cigarette manufacturers and retailers to self-regulate or to pass a new regulatory framework were then spurred into action.⁸⁹

Summary of the Problem Stream

New Zealand's reaction to e-cigarettes changed over time, but certain decisions by disparate actors all tipped the balance of the tobacco control conversation towards a state defined by a building concern about the failure of Māori to sufficiently improve their smoking prevalence rates. This growing concern can be traced to several causes; the political rights of Māori in the New Zealand government, the decision to set a Smokefree 2025 endgame goal, and the decision to defund all but one tobacco control advocacy group in 2016. By the time the 2018 decision in Philip Morris arrived, everything had been laid out to match the major problem of impending failure to meet the ambitious Smokefree 2025 goal and the minor problem of a confusing regulatory system to the solution of imposing an expansionist regulatory framework on the nicotine-containing e-cigarette market. A series of mobilized and credible policy entrepreneurs helped push such a policy through an open policy window.

6.3 Policy Stream

The development of an expansionist e-cigarette regulatory policy in New Zealand took place in an academic community that closely interfaced with the Ministry of Health. The deep links between academics, who developed a largely positive disposition towards tobacco harm reduction, and government officials shaped the direction of e-cigarette regulatory policy even as tobacco industry interference constantly threatened to undermine public support for tobacco harm reduction. This section traces the development of a policy consensus that favored adopting an expansionist regulatory stance towards e-cigarettes.

⁸⁷ Hamish McNeilly, "VAPING PACKAGING, FLAVOURS CONCERN," *Dominion Post*, June 9, 2018.

⁸⁸ Zaharia and Craft, "New Zealand Court Gives Philip Morris Nod to Sell Heated Tobacco..."

⁸⁹ NAD @ 11

6.3.1 The Bureaucracy

The two units of the national bureaucracy who were primarily tasked with establishing and enforcing a regulatory framework for e-cigarettes were the Ministry of Health and the Ministry's pharmaceutical regulating arm, Medsafe. Ministry of Health officials attempted to contain the growth of the e-cigarette market but eventually concluded that effort to be a failure before they aided in the process of creating a change in the regulatory stance towards e-cigarettes.

The New Zealand Ministry of Health initially gave e-cigarettes a cordial greeting when they arrived in the country. At the first mention of e-cigarettes in the New Zealand media in December 2007, the Ministry welcomed the devices being used in areas where smoking was banned but noted that if the devices contained nicotine they would need to be registered as medicines with Medsafe.⁹⁰

New Zealand's medicines regulator, Medsafe, was created by the passage of the Medicines Act of 1981.⁹¹ The agency possesses similar powers to other industrialized countries' medicines regulators including premarket review.⁹² By dint that nicotine-containing e-cigarettes contain a chemical that Medsafe has deemed to be a medicine, the regulator considers all nicotine-containing e-cigarettes to be under its regulatory purview.⁹³ However, only one nicotine-containing e-cigarette appears to have ever been submitted for consideration as a therapeutic product to Medsafe, and that product never made it to market.⁹⁴

An early e-cigarette retailer, AFP International, claimed that in 2008, Medsafe had clarified its lack of interest in regulating cigarette sales, which supposedly carried over to a lack of intent to regulate e-cigarettes.⁹⁵ By 2010, Medsafe changed its mind and began warning retailers, like Dunedin-based OnlinePharmacy to stop selling nicotine-containing e-cigarettes as they were

⁹⁰ Martin Johnston, "No Smoke, No Fire, Just Nicotine," *NZ Herald*, December 7, 2007, sec. National, <https://bit.ly/2kwsZ2M>.

⁹¹ The full name of the agency is the New Zealand Medicines and Medical Devices Safety Authority. Abdul F. Mutlib, "The Regulatory Approach to Medicines in New Zealand," *Drug Information Journal* 30, no. 4 (October 1996): 905–12, <https://doi.org/10.1177/009286159603000406>.

⁹² Moshe Maor, "Organizational Reputations and the Observability of Public Warnings in 10 Pharmaceutical Markets," *Governance* 24, no. 3 (July 1, 2011): 557–82, <https://doi.org/10.1111/j.1468-0491.2011.01536.x>.

⁹³ Medsafe, "Guideline on the Regulation of Therapeutic Products in New Zealand: Part 1: Overview of Therapeutic Product Regulation" (NZ Ministry of Health, October 2014), sec. 4.4, <https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/overview-of-therapeutic-product-regulation.pdf>.

⁹⁴ Lane, "Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products," para. 84.

⁹⁵ "E-Cigarette Seller Hit with Warning," *New Zealand Herald*, December 31, 2010, sec. National, <https://bit.ly/2Nck6km>.

doing so in violation of the Medicines Act.⁹⁶ Medsafe never appeared to do more than warn retailers that they violated the Medicines Act, and no records of formal prosecution for violations of the ban on nicotine import and sale can be found. Medsafe concluded it would be very difficult, expensive, and of limited value to prove in a court that a particular nicotine-containing liquid meant for use in an e-cigarette derived its nicotine from a natural tobacco leaf and not from synthetic sources.⁹⁷ As a result, by 2017, the Ministry of Health bluntly assessed that it was “unable to effectively enforce the law”.⁹⁸

By April 2010, the Ministry of Health was still saying in media statements that more research was needed to prove that e-cigarettes assisted in smoking cessation before it could regulate the devices as medicines.⁹⁹ At the same time, the Ministry was advising Parliament that e-cigarettes were an option for smokers to use in cessation, although they warned the devices were not yet approved for that therapeutic use by Medsafe.¹⁰⁰ This line of reasoning echoes through advice given by the Ministry to Parliament in 2011, when it reiterated that cessation trials would be required before they would throw their weight behind opening commercial sales of the devices.¹⁰¹

By 2013, Ministry officials were quoted as being worried about gateway effects into smoking that could follow the expansion of the e-cigarette market and recommending people use Medsafe approved smoking cessation aids instead of e-cigarettes.¹⁰² By 2014, Ministry of Health officials stated they were actively considering regulatory options for the products, recognizing the deficiency of clarity and control in the existing regulatory framework.¹⁰³ Internal consultations

⁹⁶ Martin Johnston, “Smoker Wants E-Ciggie Nicotine at a Shop near Him,” *NZ Herald*, April 14, 2010, sec. New Zealand, <https://bit.ly/2m4FUJN>; Johnston, “Medical Rules Lead to Withdrawal of Electronic Quit-Smoking Aid”; “E-Cigarette Seller Hit with Warning.”

⁹⁷ Lane, “Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products,” para. 68.

⁹⁸ Lane, 19.

⁹⁹ Martin Johnston, “E-Ciggie May Help Smokers to Quit,” *NZ Herald*, April 12, 2010, sec. New Zealand, <https://bit.ly/2k1fBU0>.

¹⁰⁰ Debbie Edwards and Karen Evison to Tariana Turia and Tony Ryall, “Interim Advice to the Māori Affairs Select Committee: Tobacco Control Programme in New Zealand,” May 13, 2010, 16–17, <https://www.parliament.nz/resource/0000131433>.

¹⁰¹ NZ Ministry of Health, “Smoke-Free Environments (Controls And Enforcement) Amendment Bill: Supplement To Departmental Report” (Wellington NZ: New Zealand Parliament Health Committee, March 23, 2011), 18,

https://www.parliament.nz/resource/en-NZ/49SCHE_ADV_00DBHOH_BILL10487_1_A178747/9f4414b7a4ae04c5e7d5494ad4f171e8cec7ed74.

¹⁰² Martin Johnston, “\$40 a Pack to Hit ‘smokefree’ Goal,” *NZ Herald*, March 3, 2013, sec. New Zealand, <https://bit.ly/2k8quUg>; Susan Edmunds, “Sexy and Safe? How New Fake Cigarettes Help Smokers Quit,” *New Zealand Herald*, September 8, 2013, sec. National.

¹⁰³ Matthew Theunissen, “Fear Fake Cigarettes Encourage Killer Habit,” *New Zealand Herald*, May 31, 2014, sec. National, <https://bit.ly/2IHQKF7>.

on the matter concluded in early 2015, with few noticeable external changes to Ministry policy.¹⁰⁴ While consultations continued, Ministry of Health officials claimed they were trying to regulate the flourishing black market in e-liquid on their hands, but they were not empowered to do more than send warning letters to retailers to crack down on such commerce.¹⁰⁵ However, through 2015, Ministry officials were still unwilling to recommend the products as potential cessation aids and was reportedly continuing to enforce provisions barring the retail sale in shops, mostly in the form of cease and desist letters that were sent to retailers.¹⁰⁶ No evidence of tougher enforcement measures being taken could be found.

Tonally, everything changed around December 2016 when Nicky Wagner, took over as Associate Health Minister for Peseta Sam Lotu-Iiga upon his retirement from public service.¹⁰⁷ By late 2017, the Ministry was saying in public communications that vaping was “significantly less harmful than smoking tobacco” and that tobacco cigarette smokers would benefit from switching to the new devices.¹⁰⁸ That message from the Ministry of Health has endured ever since. The reason for the shift is not clear, but like everyone else in the field, Ministry of Health Officials, particularly those in the Tobacco Control Programme, were on an intellectual journey through the evidence on the effects of e-cigarettes on public health.¹⁰⁹

By June 2019, the Health Promotion Authority within the Ministry of Health, rolled out a web-based marketing campaign extolling the virtue of switching from cigarettes to e-cigarettes as a great way to quit smoking.¹¹⁰ They explicitly claimed that vaping products had the potential to

¹⁰⁴ NZ Ministry of Health, “Four Monthly Report: 1 July 2014 to 28 February 2015,” June 24, 2015, 15, https://www.parliament.nz/resource/en-NZ/51SCHE_EVI_00DBSCH_ANR_66333_1_A458446/e26fb36d2eeaf3186954bc30d509045dc9b66d27.

¹⁰⁵ NC @ 28-30

¹⁰⁶ Kathryn Ryan, “The Crackdown on Nicotine Products for E-Cigarettes.,” *Nine to Noon* (Radio New Zealand, February 17, 2015), <https://www.radionz.co.nz/national/programmes/ninetoon/audio/20167508/the-crackdown-on-nicotine-products-for-e-cigarettes>.

¹⁰⁷ Chris Bramwell, “English Names New Cabinet Line-Up,” RNZ, December 18, 2016, <https://www.rnz.co.nz/news/political/320712/english-names-new-cabinet-line-up>.

¹⁰⁸ Diane Caruana, “NZ Health Ministry Releases Statement about E-Cig Use for Smoking Cessation,” *Vaping Post* (blog), October 17, 2017, <https://www.vapingpost.com/2017/10/17/nz-health-ministry-releases-statement-about-e-cig-use-for-smoking-cessation/>; Jessie Chiang, “Ministry Changes Tune on Smoking Alternatives,” Radio New Zealand, October 22, 2017, <https://www.radionz.co.nz/news/national/342114/ministry-changes-tune-on-smoking-alternatives>.

¹⁰⁹ NAC @ 13

¹¹⁰ Salesa, “Progress on Achieving Smokefree 2025 and the Government’s Response to the Report of the Māori Affairs and Health Committees on Achieving Smokefree 2025.”

contribute to achieving Smokefree 2025 by disrupting significant health inequities in New Zealand society.¹¹¹

6.3.2 Empowering a Cohesive Coalition

Three primary groups were able to cooperatively speak with a single voice when agitating for e-cigarette regulatory policy change. Each group brought separate fonts of expertise and credibility to the policy debate around e-cigarettes in New Zealand. The first group was the tobacco harm reduction (THR) advocates academics based primarily at the University of Auckland who were colleagues of Murray Laugesen, the first non-industry scientist in the world to study e-cigarettes. The second group was a group of academics who were based at the University of Otago and were less enthusiastic about the potential for e-cigarettes to improve public health. Finally, the group was strengthened by the presence of non-governmental organizations that supported the use of e-cigarettes, particularly Hāpai te Hauora. This coalition also viewed the nascent domestic vaping industry, comprised of small business owners trying to sell their wares to smokers, as separate from the tobacco industry. The forthright nature of some of the domestic vaping industry's leaders served to build trust and even scored them invitations to serve on the Ministry of Health E-cigarette Technical Expert Advisory Group, which created detailed recommendations to the Ministry outlining a comprehensive set of product standards that could be included in a future regulatory framework.¹¹²

The role played by grassroots e-cigarette advocacy groups in New Zealand may have been important to building momentum towards the creation of this amicable coalition of THR advocates. However, it is difficult to determine if their presence was instrumental in creating a policy window as their actions were not wholly different from vapers in other countries. Their contributions no doubt provided endless anecdotes that fueled policy change efforts, but it is difficult to translate how this community readied the ground for policy change.

¹¹¹ Tobacco Control Team, Public Health and Prevention, "Public Education Campaign –Vaping," Business Case - Application For Financial Approval (Wellington NZ: NZ Ministry of Health, June 11, 2019), 4, <https://www.health.govt.nz/system/files/documents/pages/business-case-public-education-campaign-vaping-redacted-11jun2019.pdf>.

¹¹² Gillian Bonnett, "Third of Vaping Advisory Group Come from E-Cigarette Industry," *Radio New Zealand News*, October 3, 2019, sec. National, <http://global.factiva.com/redir/default.aspx?P=sa&an=RNZNEW0020191002efa30005m&cat=a&ep=ASE>; Deborah Woodley, "Information Relating to the Electronic Cigarette Technical Expert Advisory Group," Official Information Act Request, May 28, 2019, <https://www.health.govt.nz/system/files/documents/information-release/h201902789.pdf>.

6.3.2.1 *The unbroken line of credible policy entrepreneurs from Murray Laugesen on*

The presence of credible public health actors in the New Zealand policy stream that favored THR policy from an early date enabled future changes in the regulatory stance to become likely and even acceptable to a vast array of policymakers. New Zealand has a solid research community focusing on the subject. Laugesen's presence and work set up THR advocates to successfully change the e-cigarette regulatory framework towards an expansionist stance. The academic discussion around e-cigarettes contained more THR advocates than in Australia. But even those persons who were e-cigarette skeptics were much less skeptical than counterparts across the Tasman Sea in Australia.

The progenitor THR advocate in New Zealand was a former Ministry of Health official, Murray Laugesen, who was instrumental in passing the SFEA and other tobacco control policies in the 1980s and 1990s who transitioned to working in a para-academic position in his retirement.¹¹³ Laugesen's presence as a THR advocate was also made clear and raised to a level of importance as the paper of record referred to his advocacy for e-cigarettes in the same breath that it also called him the "nation's most high-profile tobacco expert".¹¹⁴ Laugesen worked to cultivate the development of his younger Auckland-based colleagues including Christopher Bullen, Hayden McRobbie, Marewa Glover, and Natalie Walker who would later come to dominate the framing of e-cigarettes in New Zealand policy circles.¹¹⁵ Laugesen's colleagues would end up shaping the scientific and policy debate around e-cigarettes in New Zealand, even as he withdrew from active participation.

Dr. Laugesen published some of the first scientific literature about modern nicotine-containing e-cigarettes in partnership with the Chinese firm, RuYan, that is credited with inventing the device category.¹¹⁶ In June 2007, RuYan staff based in Australia asked Laugesen if he would perform toxicological studies on their new electronic nicotine delivery system.¹¹⁷ These early tests focused on the chemical constituents of the vapor produced by the RuYan e-cigarette and the

¹¹³ Laugesen, *My Life in Public Health*, chap. 8.

¹¹⁴ Isaac Davison, "Call for E-Cigs to Help Quit Smoking," *The New Zealand Herald*, July 21, 2012, <http://global.factiva.com/redirect/default.aspx?P=sa&an=NZHLD00020120720e8710000s&cat=a&ep=ASE>.

¹¹⁵ Laugesen, *My Life in Public Health*, chap. 10.

¹¹⁶ Murray Laugesen, "Second Safety Report on the Ruyan® E-Cigarette" (Health New Zealand, April 9, 2008), <https://bit.ly/2IE17tV>; Murray Laugesen, "Safety Report on the Ruyan® E-Cigarette Cartridge and Inhaled Aerosol" (Health New Zealand, October 30, 2008), <https://bit.ly/1BVuvWY>.

¹¹⁷ Laugesen, *My Life in Public Health*, 254.

findings indicated the product contained many fewer hazardous compounds than tobacco cigarette smoke. Laugesen's work continued to build as he incorporated more New Zealand-based academics in world-first trials examining nicotine delivery and craving reductions from e-cigarettes and the world's second randomized controlled trial examining the use of nicotine-containing e-cigarettes for smoking cessation.¹¹⁸ Laugesen and his colleagues even organized several additional e-cigarette trials that were funded by the New Zealand government's Health Research Council that focused on underserved demographics like Māori and those suffering from mental illness.¹¹⁹

This line of policy entrepreneurs became the subject matter experts that the Ministry of Health called on to advise them over the intervening years. Chris Bullen stepped into the role of primary adviser after Murray Laugesen reached the age of retirement.¹²⁰ Hayden McRobbie eventually superseded Bullen in the role.¹²¹ McRobbie, a clinical academic with professional roots in both New Zealand and the United Kingdom, emerged as the figurehead scholar-advocate and Ministry of Health's clinical advisor on matters concerning e-cigarettes.¹²² McRobbie obtained his doctorate at London's Queen Mary University, where he studied with Robert West and Peter Hajek, UK academics who would later become prominent THR advocates.¹²³ McRobbie had worked as a consultant to the Ministry since 2008 and would end up chairing the Ministry's E-Cigarette Technical Expert Advisory Group.¹²⁴

¹¹⁸ C. Bullen et al., "Effect of an Electronic Nicotine Delivery Device (e Cigarette) on Desire to Smoke and Withdrawal, User Preferences and Nicotine Delivery: Randomised Cross-over Trial," *Tobacco Control* 19, no. 2 (April 2010): 98–103, <https://doi.org/10.1136/tc.2009.031567>; Bullen et al., "Electronic Cigarettes for Smoking Cessation."

¹¹⁹ Chris Bullen et al., "The Effectiveness and Safety of Combining Varenicline with Nicotine E-Cigarettes for Smoking Cessation in People with Mental Illnesses and Addictions: Study Protocol for a Randomised-Controlled Trial," *BMC Public Health* 18, no. 1 (04 2018): 596, <https://doi.org/10.1186/s12889-018-5351-7>; Walker et al., "Nicotine Patches Used in Combination with E-Cigarettes (with and without Nicotine) for Smoking Cessation"; Natalie Walker et al., "Effectiveness and Safety of Nicotine Patches Combined with E-Cigarettes (with and without Nicotine) for Smoking Cessation: Study Protocol for a Randomised Controlled Trial," *BMJ Open* 9, no. 2 (February 1, 2019): e023659, <https://doi.org/10.1136/bmjopen-2018-023659>.

¹²⁰ ND @ 4

¹²¹ NN @ 22

¹²² Jill Lane to Louisa Wall, "Regulation of Vaping Products in New Zealand," Parliamentary Informational Briefing, December 11, 2017, https://www.parliament.nz/resource/en-NZ/52SCHE_EVI_75507_297/0a6fdf0216c4ee38adbe50251f1b70f65ee4f70c.

¹²³ Hayden McRobbie et al., "Electronic Cigarettes for Smoking Cessation and Reduction," *The Cochrane Database of Systematic Reviews* 12 (2014): CD010216, <https://doi.org/10.1002/14651858.CD010216.pub2>; "Hayden McRobbie," The Conversation, January 30, 2019, <https://theconversation.com/profiles/hayden-mcrobbe-680077>.

¹²⁴ His original work for them focused on his specialty of running stop-smoking services in healthcare settings. NAC @ 21-22; NZ MoH, "Response to Inquiry on Technical Expert Advisory Group," *Twitter* (blog), April 12, 2018, <https://twitter.com/minhealthnz/status/984630486495444993>; "Electronic Cigarette Technical Expert Advisory Group," Ministry of Health NZ, September 12, 2018, <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco/electronic-cigarette-technical-expert-advisory-group>; Bonnett, "Third of Vaping Advisory Group Come from E-Cigarette Industry."

New Zealand's public health-focused non-governmental organizations have played important roles in the development of the countries strongly contractionist regulatory stance towards tobacco cigarettes. In 2016, the extant policy community around tobacco policy in New Zealand was severely disrupted when the Ministry of Health was instructed to shift tobacco control funding away from tobacco control advocacy organizations (ASH, Smokefree Coalition, and Te Ara Hā Ora) and into stop smoking treatment services.¹²⁵ Progress towards Smokefree 2025 was disrupted overnight as policy community collaboration turned into a competition for a pot of funds that had shrunk by three-fourths in size.¹²⁶ Eventually, the advocacy groups that were defunded either wound down operations, like the Smokefree Coalition, or transitioned into functioning with unpaid staff, like ASH.¹²⁷ Hāpai te Hauora remained the sole government-funded tobacco control advocacy group. Hāpai is an organization focused primarily on Māori health and their continued funding allowed the problem of Māori smoking to remain a focal point in the tobacco control discussion. Even though Hāpai is funded with public dollars, that has not stopped the group pressing for policies that are likely beyond the scope of what political realities will allow, like the banning of the sale of tobacco cigarettes by 2025.¹²⁸ Hāpai's status as the lone publicly-funded tobacco control advocacy organization cemented its role as a valued partner of the government when it sought external strategic and policy advice.¹²⁹

One wing of the policy community which has remained more skeptical of e-cigarettes than Laugesen's colleagues formed the group ASPIRE 2025 and released a policy strategy to achieve Smokefree 2025 in 2017.¹³⁰ This second group of academics with expertise in tobacco control policy was based at the University of Otago. While they did not always see the world through the perspective of Murray Laugesen, important compromises were struck between the groups of researchers and a unified message was able to be presented regarding what an ideal e-cigarette

¹²⁵ Simon Collins, "Smokefree Lobbyists Face Chop," *New Zealand Herald*, June 26, 2016, sec. New Zealand, <https://bit.ly/343M8LB>.

¹²⁶ NW @ 18-19

¹²⁷ Jo Lawrence-King, "Smokefree Coalition; Victim of Its Own Success," *Hauora: Everyone's Right* (blog), October 15, 2016, <https://hauora.co.nz/smokefree-coalition-victim-of-its-own-success/>; Rachel Thomas, "\$1.7b in and \$43m out: The Government's 'double Standard' on Tobacco," *Stuff*, May 18, 2018, <https://www.stuff.co.nz/national/health/103904329/17b-in-and-43m-out-the-governments-double-standard-on-tobacco>.

¹²⁸ Isaac Davison, "Ban Cigarette Sales by 2025 and Encourage Vaping to Hit Smokefree Goal, MPs Told," *NZ Herald*, May 22, 2018, sec. New Zealand, <https://bit.ly/2IMquQA>.

¹²⁹ Jill Lane to Jenny Salesa and David Clark, "Tobacco Stakeholder Strategy," Memo In Confidence, March 6, 2018, https://www.health.govt.nz/system/files/documents/information-release/h201900886_response.pdf.

¹³⁰ Thornley et al., "Achieving Smokefree Aotearoa By 2025."

regulatory framework would look like in New Zealand. This is not to say that others outside of Otago and Auckland have worked on coming up with a unified position going forward.¹³¹ Otago and Auckland researchers met repeatedly to come up with a consensus viewpoint on what constitutes an appropriate regulatory framework.¹³² As new evidence arose of the utility of e-cigarettes for smoking cessation and the relative safety of the products, skeptics like Edwards, Hoek, and Thompson evolved their stances in response.¹³³ They all came to agree that e-cigarettes could be more tightly regulated as their potential substitute product was subjected to ever harsher rules.¹³⁴ They referred to this strategy as risk-proportionate regulation and it became the watchword echoed by stakeholders inside and outside of the public sector alike.¹³⁵

6.3.2.2 *Excommunicating Marewa Glover*

Marewa Glover was instrumental in pushing e-cigarette regulation and tobacco control issues from the Māori perspective.¹³⁶ Māori by birth, her early work in the area was conducted in cooperation with Murray Laugesen and every other relevant tobacco control academic in the country.¹³⁷ Before 2014, Glover expressed a healthy skepticism towards the value of e-cigarettes as a public health tool as she was particularly concerned that tobacco companies might co-opt the market to their own less publicly-minded ends.¹³⁸ In 2015, after changing her mind about the efficacy of e-cigarettes, Glover began to work in tandem with McRobbie and was tagged as instrumental in the initial push to change the Ministry's stance.¹³⁹

¹³¹ NY @ 7

¹³² Louise Thornley et al., "Achieving Smokefree Aotearoa By 2025: Engagement with Stakeholders – Summary Report" (Wellington NZ: University of Otago, ASPIRE 2025, Quit Group Trust and Hapai Te Hauora, August 2017), <https://aspire2025.files.wordpress.com/2017/08/asap-engagement-with-stakeholders-summary-report-for-web.pdf>.

¹³³ NH @ 18; Joanna MacKenzie, "'No Evidence' Legalising e-Cigs Lowers Smoking Rates," RNZ, March 30, 2017, <https://www.rnz.co.nz/news/national/327771/no-evidence-legalising-e-cigs-lowers-smoking-rates>.

¹³⁴ NP @ 21-22

¹³⁵ NY @ 10-11

¹³⁶ AC @ 33

¹³⁷ Natalie Walker et al., "The Combined Effect of Very Low Nicotine Content Cigarettes, Used as an Adjunct to Usual Quitline Care (Nicotine Replacement Therapy and Behavioural Support), on Smoking Cessation: A Randomized Controlled Trial," *Addiction* 107, no. 10 (2012): 1857–67, <https://doi.org/10.1111/j.1360-0443.2012.03906.x>; Marewa Glover et al., "Transition to a Smoke-Free Culture within Mental Health and Drug and Alcohol Services: A Survey of Key Stakeholders," *International Journal of Mental Health Nursing* 23, no. 2 (2014): 183–91, <https://doi.org/10.1111/inm.12035>; Murray Laugesen et al., "Four Policies to End Commercial Cigarette and Smoking Tobacco Sales by 2020 or Sooner" (End Smoking NZ, May 14, 2010), https://www.parliament.nz/resource/en-NZ/49SCMA_EVI_00DBSCH_INQ_9591_1_A46506/147ab5873d9c4958c097fbc643429184af110a38.

¹³⁸ Edmunds, "Sexy and Safe?"

¹³⁹ NR @ 63-64

The New Zealand public health community has virtually excommunicated one of its own who has tarnished her reputation by taking a \$1.5 million grant from Philip Morris International's Foundation for a Smoke-Free World.¹⁴⁰ An article was published in the subfield's flagship journal, *Tobacco Control*, that excoriated the Foundation for a Smoke-Free World and without naming her, Glover, for facilitating a modern form of colonization of indigenous peoples.¹⁴¹ Glover was not seen as indispensable to the coalition of THR advocates in the country.

Her stances on tobacco control policy issues drifted further from the public health community after receiving funding from the Foundation for a Smoke-Free World. For example, in the deliberation over a 2019 bill that would create a civil offense for smoking in a car with a child, Glover testified that 'bodies heal' from secondhand smoke and that children will recover their full health once exposed to tobacco smoke.¹⁴² This claim even offended members of the right-wing National Party who called her claim 'outrageous'. In August 2019, the Ministry of Health even sent out letters to District Health Boards warning them not to collaborate with Glover's center to fulfill obligations the country had made under Article 5.3 of the FCTC to avoid undue tobacco industry influence.¹⁴³

The place of Hāpai te Hauora as the sole nationally-funded tobacco control advocacy organization provided far more credibility as a leading indigenous voice in policy debates around e-cigarettes.¹⁴⁴ The fact that there were so many other capable policy entrepreneurs in the space made Glover's departure from credibility an easy obstacle to overcome.¹⁴⁵

6.3.2.3 *Disempowered Dissenters*

There were some holdouts from this eventual coalition, most of whom were public health-oriented non-governmental organizations, most prominent among them being the Asthma and Respiratory Foundation.¹⁴⁶ These groups, like other e-cigarette skeptics in other countries, relied

¹⁴⁰ Guyon Espiner, "Gloves off: Smoking Researcher Shunned over Philip Morris Funding," RNZ, August 22, 2019, <https://bit.ly/2ZoV5ex>.

¹⁴¹ Andrew Waa et al., "Foundation for a Smoke-Free World and Healthy Indigenous Futures: An Oxymoron?," *Tobacco Control*, May 10, 2019, tobaccocontrol-2018-054792, <https://doi.org/10.1136/tobaccocontrol-2018-054792>.

¹⁴² Zane Small, "MPs Aghast over Tobacco Researcher Marewa Glover's Claim 'bodies Heal' from Secondhand Smoke," *Newshub*, August 21, 2019, sec. Politics, <https://bit.ly/2TRePX3>.

¹⁴³ Ashley Bloomfield to District Health Board Chief Executives, "Reminder about New Zealand's International Obligations Regarding Tobacco Control and the Need to Avoid Potential Influence from Tobacco Companies," Memo, August 22, 2019, <https://bit.ly/2lJAvHX>.

¹⁴⁴ Collins, "Smokefree Lobbyists Face Chop."

¹⁴⁵ NY @ 25

¹⁴⁶ Nicki Harper, "E-Cigarette as Quit Tool Fires up Debate," *Hawke's Bay Today*, December 16, 2017, sec. Regional.; NP @ 34

on a message that e-cigarettes were being targeted for sales to youth, that they were not effective smoking cessation devices, and that they were generally unsafe to use.¹⁴⁷

Certain Māori groups also resisted the introduction of e-cigarettes into the country.¹⁴⁸ Most prominently, Tariana Turia has come out firmly against the expansion of e-cigarettes and sees addiction to corporately supplied nicotine as akin to colonialism, no matter the form the nicotine is delivered.¹⁴⁹ Turia viewed Smokefree 2025 as getting to an endgame on smoking, getting rid of the symbolic and actual colonization threat of nicotine addiction, and the requisite harm it wrecked on her community.¹⁵⁰ Other Māori groups express a belief that e-cigarettes represent yet another mass-marketed evil.¹⁵¹

The dissenters lacked support from two key components of the THR-supporting coalition; government bureaucrats and academics. The Ministry of Health and Medsafe had long abandoned seeing the e-cigarette market as worthy of the prohibitionist policy it used to be subject to. Academics supporting e-cigarettes had to be imported from the United States to make the case against the products in media appearances, while THR-supporters could rely on local experts.¹⁵² Thus far, it does not appear as though e-cigarette skeptics have disrupted the ripening of the policy stream.

Summary

Even as rifts break out in policy preferences among the policy community eager to see e-cigarette regulation be adopted in New Zealand, the community has not fractured in any meaningful sense. Letter writing campaigns agitating for action are signed by almost the entire spectrum of persons interested in policy reform and there is general agreement on the contours of

¹⁴⁷ Asthma and Respiratory Foundation NZ, “Study Highlights the Urgent Need for Vaping Education,” Scoop Health, January 23, 2020, <https://www.scoop.co.nz/stories/GE2001/S00022/study-highlights-the-urgent-need-for-vaping-education.htm>.

¹⁴⁸ NS @ 25

¹⁴⁹ NH @ 12

¹⁵⁰ NH @ 43

¹⁵¹ NV @ 3; Maori Council, “Maori Council Calls Time on the Vaping Industry,” Scoop Politics, October 9, 2019, <https://www.scoop.co.nz/stories/PO1910/S00096/maori-council-calls-time-on-the-vaping-industry.htm>; Maori Council, “Time to Smack the Smoke and Vaping Companies out of the Park,” Scoop Politics, September 4, 2019, <http://www.scoop.co.nz/stories/PO1909/S00049/time-to-smack-the-smoke-and-vaping-companies-out-of-the-park.htm>.

¹⁵² Stanton Glantz claimed on New Zealand television that vaping is between two-thirds and three-quarters as bad as smoking. “Vaping ‘about as Bad as Smoking’ Warns Prominent US Anti-Smoking Activist,” *Seven Sharp* (Auckland: TVNZ, May 29, 2019), <https://www.tvnz.co.nz/one-news/new-zealand/vaping-bad-smoking-warns-prominent-us-anti-activist>.

policy that needs to be adopted.¹⁵³ Non-governmental organizations have worked with academics to put aside the fears of those who oppose any expansion of an e-cigarette market and to cleave off participation from actors deemed to hold positions too far from group consensus.

Government bureaucrats eventually joined this consensus. In this way, a broadly acceptable policy that aimed to further the goals of Smokefree 2025 by expanding access to e-cigarettes became the consensus policy alternative to the status quo in New Zealand.

6.4 Politics Stream

The political stream ripened at a relatively early stage in this process, but a lack of urgency seems to have slowed the issues rise towards actual policy change. If we apply the multiple streams approach to agenda-setting rather than to policy change, then we might find that the streams have truly ripened in New Zealand. Policy entrepreneurs have been able to sell the concept of tobacco harm reduction being a good idea to two successive governments led by opposing parties.

6.4.1 Parliament

New Zealand became a British colony in 1840 when the Treaty of Waitangi was signed by indigenous Māori chiefs and British settlers.¹⁵⁴ Before 1993, New Zealand had what Arend Lijphart called ‘the only true example’ of a Westminster system left in the world.¹⁵⁵ The Parliament became unicameral after the upper house was abolished in 1950, eliminating any check on the power of the lower house.¹⁵⁶ Since 1867, several seats in the legislature have been reserved for representatives of Māori descent to assimilate Māori into European political institutions.¹⁵⁷ The other significant feature of the Parliament is that it has been selected by a

¹⁵³ Derek Cheng, “Jacinda Ardern Says Vaping Laws Must Protect Young People,” *NZ Herald*, November 26, 2019, sec. New Zealand, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12288833.

¹⁵⁴ Claudia Orange, *An Illustrated History of the Treaty of Waitangi* (Bridget Williams Books, 2015), chap. 2.

¹⁵⁵ Arend Lijphart, “The Demise of the Last Westminster System? Comments on the Report of New Zealand’s Royal Commission on the Electoral System,” *Electoral Studies* 6, no. 2 (August 1, 1987): 97–103, [https://doi.org/10.1016/0261-3794\(87\)90016-3](https://doi.org/10.1016/0261-3794(87)90016-3).

¹⁵⁶ Arend Lijphart, *Patterns of Democracy: Government Forms and Performance in Thirty-Six Countries*, 2nd ed (New Haven: Yale University Press, 2012), 23.

¹⁵⁷ These motives may not have been pure of heart because the separate electorates also ensured that Paakehaa electorates would be guaranteed to be majority Paakehaa. The fact that Māori were only granted four seats in the legislature compared to the twenty they had requested and would have deserved based on a principle of equal representation speaks to these alternate motives. Māori were effectively gerrymandered into political irrelevance by this system which kept their representation at just four electorates. After the Electoral Act of 1993 allowed the number of Māori electorates to rise and fall with the size of Māori voter rolls, the number of Māori electorates rose to seven by 2008. Susan A. Banducci, Todd Donovan, and Jeffrey A. Karp, “Minority Representation, Empowerment, and Participation,” *The Journal of Politics* 66, no. 2 (May 2004): 534–56, <https://doi.org/10.1111/j.1468-2508.2004.00163.x>; Raymond Miller, *Democracy in New Zealand*, 2015, chap. 9, <http://site.ebrary.com/id/11061508>.

mixed-member proportional system similar to the one used to elect the German Bundestag since 1996.¹⁵⁸ These institutional features combine to produce a sovereign Parliament which is not subject to external checks on its power beyond elections which occur on an unusually rapid three-year cycle. Additionally, this parliament elevates minority Māori voices and places them in positions to make or break governments that have been repeatedly formed as coalitions between several parties with different ideological outlooks and constituencies.¹⁵⁹

New Zealand voted minority coalition governments into power in the elections of 2008, 2011, and 2014 which were all led by the right-wing National Party and the center-left/indigenous rights Māori party along with the ACT and United Future, small right-wing parties.¹⁶⁰ The Māori party initially lent the John Key-led National government a decisive majority in 2008 but in subsequent elections, the Māori Party contribution to the governing majority dwindled along with the party's policy influence.¹⁶¹ During its brief interlude with power, the party was able to set the course which has led to changing the regulatory framework for e-cigarettes years after the Māori Party left government.

6.4.2 National Party Government Considers E-Cigarette Regulatory Policy Change

Vaping came as an opportunity to do something different and something positive on public health for a government lacking such bona fides. The first mention of e-cigarettes on the floor of the New Zealand Parliament was made by Tariana Turia in 2009 in response to a question about tobacco harm reduction strategies from a fellow MP.¹⁶² The next year, National MP Tau Henare, wondered aloud in Parliament why e-cigarettes with nicotine were not allowed to be imported into the country if they could help some smokers (like himself) quit their habit.¹⁶³

¹⁵⁸ Lijphart, *Patterns of Democracy*, 21.

¹⁵⁹ Rachel Simon-Kumar, "Inclusionary Policy and Marginalised Groups in Aotearoa/New Zealand Process, Impacts and Politics," *Kōtuitui: New Zealand Journal of Social Sciences Online* 13, no. 2 (July 3, 2018): 246–60, <https://doi.org/10.1080/1177083X.2018.1488750>.

¹⁶⁰ Paarth Mittal, "Electoral Reform in New Zealand," *On Politics* 12, no. 1 (April 30, 2019): 95–112.

¹⁶¹ Thomas O'Brien, "Political Entrepreneurship in the Field of Māori Sovereignty in Aotearoa New Zealand," *The British Journal of Sociology* 70, no. 4 (2019): 1179–97, <https://doi.org/10.1111/1468-4446.12611>.

¹⁶² Iain Lees-Galloway and Tariana Turia, "4319 (2009). Iain Lees-Galloway to the Associate Minister of Health" (2009), https://www.parliament.nz/en/pb/order-paper-questions/written-questions/document/QWA_04319_2009/4319-2009-iain-lees-galloway-to-the-associate-minister.

¹⁶³ Tau Henare et al., "Excise and Excise-Equivalent Duties Table (Tobacco Products) Amendment Bill" (2010), https://www.parliament.nz/en/pb/hansard-debates/rhr/document/49HansS_20100428_00001161/henare-tau-excise-and-excise-equivalent-duties-table.

National Party Associate Minister of Health Peeta Sam Lotu-Iiga was incredibly cautious and suspicious of e-cigarette legalization.¹⁶⁴ While attending a 2015 tobacco control symposium at the University of Auckland, Lotu-Iiga commented that there was not yet enough evidence available to allow the *unregulated* use of e-cigarettes.¹⁶⁵

However, National exploration of the potential of e-cigarettes eventually yielded a response from PM Key stating that more data was needed to understand the role e-cigarettes should play in the country, a point on which the opposition Labour leader Andrew Little agreed.¹⁶⁶ By the summer of 2016, Lotu-Iiga recommended the rules prohibiting the sale or supplying of e-cigarettes with nicotine be changed to allow the sale of such products in New Zealand.¹⁶⁷ Discussions in Cabinet Committee meetings began to reflect a viewpoint that e-cigarettes were certainly less harmful than tobacco cigarettes and continuing to apply a stricter regulatory framework to a less dangerous product was becoming harder to justify.¹⁶⁸ 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.¹⁶⁹

Media commentators at the time noticed that tobacco companies had adopted a quietly supportive position in favor of regulatory reform, likely because such a policy change would allow them to enter a newly legal market.¹⁷⁰ 98% of respondents to the inquiry favored changing the regulatory framework for e-cigarettes to make their sale legal, although there was much less agreement about the details of that framework.¹⁷¹ Ministry of Health officials counseled the cabinet to take a “precautionary approach” when formulating an e-cigarette regulatory policy.¹⁷²

¹⁶⁴ NO @ 16; NY @ 22

¹⁶⁵ S Phillips, “Minister Says More Evidence Needed on E-Cigarettes - Updated,” *Fuseworks Media*, March 12, 2015, <http://global.factiva.com/redir/default.aspx?P=sa&an=FUSMED0020150312eb3c003bh&cat=a&ep=ASE>.

¹⁶⁶ Nicholas Jones, “Plain Packaging for Tobacco Likely to Be in Place Early next Year,” *NZ Herald*, May 31, 2016, sec. New Zealand, <https://bit.ly/2kIZeM7>.

¹⁶⁷ Jones, “E-Cigarette Sales to Be Allowed under a New Government Proposal.”

¹⁶⁸ NF @ 11-12

¹⁶⁹ 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, <https://bit.ly/2JkQKIM>.

¹⁷⁰ Rosanna Price, “Vaping Hole in Tobacco Giants’ New ‘Good Guy’ Act: Experts,” *The Press*, August 8, 2016.

¹⁷¹ For example, 53% believed that marketing should be regulated in the same way as tobacco products and 44% thought it was important to prohibit use in the same areas as tobacco smoking was prohibited. New Zealand Ministry of Health, *Consultation on Electronic Cigarettes: Analysis of Submissions*. (Wellington NZ: NZ Ministry of Health, 2017), http://natlib-primo.hosted.exlibrisgroup.com/NLNZ:NLNZ:NLNZ_ALMA21286331210002836.

¹⁷² Martin Johnston, “E-Cigarettes Can Save Lives: Vendor,” *The New Zealand Herald*, September 12, 2016.

As a result, the consultation ended with the Cabinet deciding not to move forward with changing the regulatory framework, heeding the advice of the Ministry of Health.¹⁷³

When National Party Prime Minister John Key resigned from Parliament in December 2016 and Bill English stepped into the role, a requisite cabinet reshuffle followed.¹⁷⁴ Once English reshuffled his cabinet in 2016, he brought in Nicky Wagner as the Associate Minister of Health in charge of the tobacco policy portfolio, the tone of the Ministry on the subject of e-cigarette regulation changed.¹⁷⁵

After she was installed, Ministry of Health officials approached Wagner to tell her that something needed to be done about e-cigarettes.¹⁷⁶ Wagner ended up liking the concept and purpose of e-cigarettes much more than Lotu-Iiga, was much more comfortable with evidence finding a lack of harm; she ended up viewing e-cigarettes as a pragmatic solution to the smoking problem.¹⁷⁷ In February 2017, Nicky Wagner even demonstrated, to a great coughing fit, a variety of e-cigarettes in front of her caucus room, causing a great laugh to arise from her colleagues.¹⁷⁸ Her comfort with the issue led to the announcement in March 2017, that the government intended to pass legislation that would legalize the sale of nicotine-containing e-cigarettes in the coming year.¹⁷⁹ In the regulatory impact statement that the Ministry of Health produced to evaluate such a policy change, a wealth of information conveying the bureaucratic perspective is divulged. For example, the Ministry considered comparator country regulatory frameworks they could emulate, choosing between Australia, Canada, the United Kingdom, and the United States.¹⁸⁰ The Ministry eventually wrote a draft bill, which for unknown reasons was

¹⁷³ Anusha Bradley, “E-Cigarettes Fail to Get Health Ministry Support,” Radio New Zealand, September 17, 2016, <http://www.radionz.co.nz/news/national/313550/e-cigarettes-fail-to-get-health-ministry-support>; New Zealand Ministry of Health, *Consultation on Electronic Cigarettes*.

¹⁷⁴ Isaac Davison, “Bill English Reveals His Reshuffled Cabinet in Wellington,” *NZ Herald*, December 18, 2016, sec. New Zealand, Bay of Plenty Times, Rotorua Daily Post, Hawke’s Bay Today, Northern Advocate, Whanganui Chronicle, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11769283.

¹⁷⁵ *Lotu-Iiga left Parliament altogether once Key stepped down as PM*. NAC @ 14; Bill English, “Ministerial List for Announcement (for Appointment on 20 December 2016),” New Zealand Cabinet Office, December 20, 2016, <https://web.archive.org/web/20161220145819/https://www.beehive.govt.nz/sites/all/files/Ministerial%20List.pdf>. “Sam Lotu-Iiga to Leave Parliament,” RNZ, December 13, 2016, <https://www.rnz.co.nz/news/political/320289/sam-lotu-iiga-to-leave-parliament>.

¹⁷⁶ NG @ 9

¹⁷⁷ NW @ 45; NH @ 47

¹⁷⁸ NG @ 7

¹⁷⁹ Jones, “E-Cigarettes Will Be Legalised.”

¹⁸⁰ Lane, “Regulation of E-Cigarettes and Emerging Tobacco and Nicotine-Delivery Products,” sec. Appendix One.

not immediately submitted to Parliament.¹⁸¹ This draft bill might be characterized as a victory for business-friendly harm reduction in the New Zealand context. Business, in the form of the tobacco industry, approved of abandoning a prohibitionist policy and unleashing a new market. The right-wing government, without moral hackles to raise in this instance of harm reduction, was inclined to agree.

The progress being made towards changing e-cigarette regulatory policy was abruptly halted as the 51st New Zealand Parliament was dissolved on August 22, 2017, and an election was set to be held four and a half weeks later.¹⁸² Just as the regulatory legislation was beginning to solidify, political winds suddenly shifted and pulled the country to the left. E-cigarettes had no formal legal regulatory framework that would be in place for the foreseeable future. A vacuum was created, which was in turn exacerbated by the *Philip Morris* decision the following March.

6.4.3 Change of Government puts Coalition led by Labour in Charge

The regularly scheduled 2017 general election saw the sudden rise of Jacinda Ardern and her Labour party to power.¹⁸³ E-cigarettes did not feature as an issue of any importance in the ensuing election campaign.¹⁸⁴ Instead, the campaign was dominated by Labour's promises to address a housing affordability crisis and child poverty while the Nationals promised to fight crime and maintain economic stability.¹⁸⁵ The National Party won the most seats in Parliament

¹⁸¹ The bill was eventually submitted in the next session of Parliament by Wagner, but then out of power it only had the status of a private-members bill and did not represent official government policy. NG @ 12; Nicky Wagner, "Smoke-Free Environments (Regulation of E-Cigarettes) Amendment Bill" (2018), <https://bit.ly/2Zte08j>.

¹⁸² "Election Timeline 2017," NZ Parliament, 2017, <https://www.parliament.nz/electiontimeline/index.html>.

¹⁸³ James Barrett, "Candidate Brand Personality and the 2017 New Zealand General Election," in *Political Marketing and Management in the 2017 New Zealand Election*, ed. Jennifer Lees-Marshment, Palgrave Studies in Political Marketing and Management (Cham: Springer International Publishing, 2018), 67–84, https://doi.org/10.1007/978-3-319-94298-8_5.

¹⁸⁴ The Māori Party which played the important role of creating the Smokefree 2025 was eliminated entirely from Parliament after losing the single constituency that voted for their candidates in 2014. During the 2017 election the Māori party suggested that e-cigarette purchases be subsidized like nicotine replacement therapies. This only would have been possible if Medsafe approved an e-cigarette to be sold as a therapeutic device. As the only party to explicitly mention the issues of e-cigarettes in its platform, the election results indicate this position was likely overlooked in the larger context of the election other issues like poverty, education, and housing. More likely, the problem that spurred the formation of the Māori Party in 2004, the issue of Māori land rights in coastal areas, had largely been resolved by the 2017 enabling Māori voters to return to supporting the Labour party as had been the case in 1999 and 2002. NO @ 20; Nicholas Jones, "Subsidise E-Cigarettes to Help Smokers Quit: Māori Party Co-Leader Marama Fox," *NZ Herald*, March 1, 2017, sec. New Zealand, <https://bit.ly/2kJpGp5>; "HEALTH Party: Policy, at a Glance Issue: National Labour Greens NZ First Māori," *The Dominion Post*, September 16, 2017, sec. National, NexisUni; Keri Mills, Carlo Berti, and Verica Rupar, "What Kind of Country We Want for Our Children: An Analysis of Media Coverage of the 2017 New Zealand General Election," *Kōtuitui: New Zealand Journal of Social Sciences Online* 13, no. 2 (July 3, 2018): 161–76, <https://doi.org/10.1080/1177083X.2018.1476390>; Jack Vowles, "Surprise, Surprise: The New Zealand General Election of 2017," *Kōtuitui: New Zealand Journal of Social Sciences Online* 13, no. 2 (July 3, 2018): 147–60, <https://doi.org/10.1080/1177083X.2018.1443472>.

¹⁸⁵ Eleanor Ainge Roy, "New Zealand's General Election: All You Need to Know," *The Guardian*, September 19, 2017, sec. World news, <https://www.theguardian.com/world/2017/sep/19/new-zealands-general-election-all-you-need-to-know>.

but was short of a majority. National instinctively partnered with the libertarian ACT Party. Labour partnered with the pro-environment Greens. This put the right-wing populist New Zealand First's party leader and the country's longest-serving MP, Winston Peters in the position of 'kingmaker' concerning who would form a government.¹⁸⁶ Eventually, Peters chose to go into government with Labour and serve as Deputy Prime Minister, gaining concessions from Labour to place New Zealand First in the cabinet along with promises to balance the goals of environmental sustainability with economic prosperity.¹⁸⁷

The initiative to change e-cigarette regulatory policy slowed its pace after the National Party lost its governing majority in the 2017 election. However, the coalition led by PM Jacinda Ardern formed by Ardern's Labour, Greens, and New Zealand First slowly began moving forward on the issue again.¹⁸⁸ The progress towards introducing a new regulatory framework moved forward without urgency until the *Philip Morris v Ministry of Health* decision landed just six months into the new government's term.

6.5 Coupling the Streams

While it has yet to become a fully realized piece of legislation, the policy streams in New Zealand seem to have ripened and are ready to couple. The process of moving from a defined problem to a solution took several governments and much discussion, but it was marked by goodwill and cooperation along the way. The Ministry of Health describes its goal to be the creation of a risk-proportionate regulatory framework. Advocates agreed, stating that such a framework can manage the potential problems e-cigarettes pose by putting more contractionist policies in place on tobacco cigarettes.¹⁸⁹

In the wake of the *Philip Morris* decision, e-cigarette retailers tried to implement self-imposed regulations that were, effectively, promises to provide clean products that were responsibly marketed and to not sell e-cigarettes to children.¹⁹⁰ While companies were still waiting for

¹⁸⁶ This framing is incorrectly gendered, as Peters eventually chose to form New Zealand's third government led by a female prime minister, but this is the language that was used contemporaneously by press sources. Phil Taylor, "Winston Peters the Kingmaker," *NZ Herald*, October 19, 2017, sec. The Big Read, <https://bit.ly/2m54DgV>.

¹⁸⁷ Roy, "New Zealand Labour Signs Coalition Deal and Makes Winston Peters Deputy PM."

¹⁸⁸ "Vaping Gets the Backing of the Ministry of Health," *Sunday Morning* (Radio New Zealand, October 22, 2017), <https://bit.ly/2IvPzz4>.

¹⁸⁹ NH @ 8

¹⁹⁰ Eric Crampton, "The Deregulated Interregnum," *Offsetting Behaviour* (blog), March 15, 2018, <https://offsettingbehaviour.blogspot.com/2018/03/the-deregulated-interregnum.html>.

regulatory legislation to be introduced, in August 2019, British American Tobacco, Imperial Tobacco, and local e-cigarette company VAPO all began airing advertisements in the New Zealand media.¹⁹¹ Much of this advertising was later deemed by the Advertising Standards Authority to contravene community standards and it was put to an end.¹⁹² Even Philip Morris continued to upset norms and insult local standards. In March 2019, Philip Morris made a public pitch to the Labour government that it was willing to stop selling tobacco cigarettes if the government provided significantly lower excise rates on heated tobacco and e-cigarettes, in effect, an expansionist regulatory stance.¹⁹³ Jacinda Ardern addressed the offer head-on and turned the idea down.¹⁹⁴

Then, beginning in July 2019, Guyon Espiner, an investigative reporter for Radio New Zealand, began to raise eyebrows around the country as he exposed the motives of Philip Morris in advancing e-cigarette regulatory reform in New Zealand. Espiner documented that Philip Morris' aggressive behavior pushing its novel tobacco products had continued after the Ministry of Health court case and the tax break proposal. The company began distributing its tobacco heating devices at half-price through Māori social, cultural, and sporting institutions.¹⁹⁵ Minister Salesa, rejected Philip Morris' claim that it was looking out for the health of Māori by promoting reduced-risk products.¹⁹⁶ Following on that revelation, Espiner was able to confirm that Philip Morris' American sister company, Altria, was planning on bringing JUUL e-cigarettes to the country by the end of the year.¹⁹⁷ Finally, Espiner uncovered a Philip Morris initiative that sought to partner with poverty advocates to distribute its IQOS device to poor smokers.¹⁹⁸ These

¹⁹¹ Matthew Theunissen, "VAPING ADS FIRE UP BEFORE LAW CHANGE," *Waikato Times*, August 29, 2019.

¹⁹² C Baggott and Imperial Brands, "Imperial Brands - Myblu Vape Device, Television [2019] NZASA 305 (15 October 2019)" (New Zealand Advertising Standards Authority, November 5, 2019), <http://www.nzlii.org/cgi-bin/sinodisp/nz/cases/NZASA/2019/305.html?query=nicotine>; C Wright and Imperial Brands, "Imperial Brands - My Blu, Radio [2019] NZASA 425 (10 December 2019)" (New Zealand Advertising Standards Authority, January 22, 2020), <http://www.nzlii.org/cgi-bin/sinodisp/nz/cases/NZASA/2019/425.html?query=nicotine>.

¹⁹³ Madison Reidy, "Philip Morris Calls for Tax Break in Switch from Cigarettes to Tobacco Sticks," RNZ, March 7, 2019, <https://www.rnz.co.nz/news/business/384121/philip-morris-calls-for-tax-break-in-switch-from-cigarettes-to-tobacco-sticks>.

¹⁹⁴ Craig McCulloch, "Philip Morris Call for Tax Breaks Dismissed by Government," RNZ, March 7, 2019, <https://www.rnz.co.nz/news/political/384187/philip-morris-call-for-tax-breaks-dismissed-by-government>.

¹⁹⁵ Guyon Espiner, "Big Tobacco Targeting Māori with E-Cigarettes," RNZ, July 10, 2019, <https://bit.ly/2LNjjw0>.

¹⁹⁶ "Jenny Salesa 'Skeptical' about Big Tobacco's Claims," *Checkpoint* (RNZ, July 12, 2019),

<https://www.rnz.co.nz/national/programmes/checkpoint/audio/2018703915/jenny-salesa-skeptical-about-big-tobacco-s-claims>.

¹⁹⁷ Guyon Espiner, "Exclusive: Youth Addiction Worry as High-Nicotine Vape JUUL to Hit NZ," RNZ, July 11, 2019, <https://bit.ly/2ZtzfuO>.

¹⁹⁸ Guyon Espiner, "Philip Morris Tried to Target Poor through Poverty Group and Counties Manukau DHB," RNZ, August 27, 2019, <https://www.rnz.co.nz/news/in-depth/397544/philip-morris-tried-to-target-poor-through-poverty-group-and-counties-manukau-dhb>.

revelations had the effect of increasing the level of incredulity that THR advocates had to face as they continued to push for e-cigarette regulatory framework changes.¹⁹⁹

This ongoing morass of voluntary standards and questionable behavior on the part of e-cigarette manufacturers combined to emphasize the vacuum in regulation that existed. The reticence of the Labour government to introduce e-cigarette regulation is curious, but the fact that they did not scrap the initiative points to the fact that the policy window to introduce legislation did not close. Instead, it became subject to the whims of politicians waiting for an opportune moment to act.

6.5.1 Labour Takes its Time Delivering Legislation

The Labour party spent nearly a decade in opposition before the election of the Ardern government.²⁰⁰ Once they returned to power, they required time to gain focus, expertise, and direction for their policies. Tobacco control and the regulation of e-cigarettes were not unique in this respect. Instead of passing e-cigarette regulation, the government focused on advancing its KiwiBuild policy to alleviate a shortage of affordable housing, its Wellbeing Budget that sought to prioritize something other than economic growth and passing gun control in the wake of the Christchurch Massacre.²⁰¹

Deputy Prime Minister Winston Peters is famously a longtime smoker.²⁰² He has denigrated the Smokefree 2025 as “National Party bulldust” and was said to have recently become a dual user of both cigarettes and e-cigarettes.²⁰³ Peters’ New Zealand First party is best characterized as a Nationalist, Populist, and Right-Wing.²⁰⁴ But their viewpoint on e-cigarette regulation is that the products should be available and well regulated, and able to be used for smoking cessation.²⁰⁵ As

¹⁹⁹ Katie Fitzgerald, “Tobacco Giant Philip Morris’ Attempt to Target Poor Kiwis ‘absolutely Not’ Okay - Jenny Salesa,” *Newshub*, August 28, 2019, sec. Politics, <https://www.newshub.co.nz/home/politics/2019/08/tobacco-giant-philip-morris-attempt-to-target-poor-kiwis-absolutely-not-okay-jenny-salesa.html>.

²⁰⁰ Just 6 of 46 Labour MPs in Adren’s government had served in Parliament when Helen Clark was Prime Minister.

²⁰¹ Jason Walls, “KiwiBuild Reset: Government Axes Its 100,000 Homes over 10 Years Target,” *NZ Herald*, September 4, 2019, sec. New Zealand, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12264757; Christoph Schumacher, “New Zealand’s ‘Well-Being Budget’: How It Hopes to Improve People’s Lives,” *The Conversation*, May 30, 2019, <http://theconversation.com/new-zealands-well-being-budget-how-it-hopes-to-improve-peoples-lives-118052>; German Lopez, “New Zealand Parliament Votes 119-1 to Ban Assault Weapons, Less than a Month after a Mass Shooting,” *Vox*, April 10, 2019, <https://www.vox.com/2019/4/10/18304415/new-zealand-gun-control-mosque-shootings-assault-weapons-ban>.

²⁰² Davison, “Call for E-Cigs to Help Quit Smoking.”

²⁰³ NAA @ 55; Laura Walters, “Government Divided over National Smokefree Target,” *Stuff*, July 24, 2018, <https://www.stuff.co.nz/national/politics/105708464/government-divided-over-national-smokefree-target>.

²⁰⁴ Jack Vowles, “Parties and Society in New Zealand,” in *Political Parties in Advanced Industrial Democracies*, ed. Paul Webb, Comparative Politics (Oxford: Oxford Univ. Press, 2002).

²⁰⁵ NAD @ 8-9

junior partners in government, the Greens have not invested any resources in developing their e-cigarette regulatory policy.²⁰⁶ Instead, they will support any policy Labour brings forward.

Initially, Associate Minister of Health Jenny Salesa tried to float a ban on smoking in cars with children in early 2018 and got no support from her party until the following year.²⁰⁷ Salesa was viewed as not being concerned with e-cigarettes or Smokefree 2025 as an urgent policy problem.²⁰⁸ She was thought to be the policy actor who needed to be the entrepreneur in government as tobacco policy was contained in her portfolio.²⁰⁹ Over time, she stepped into that role while never hurrying up the pace of policy change. Civil servants in the Ministry of Health, likely boosted by the appointment of ASH board member Ashley Bloomfield to Director General (head bureaucrat of the Ministry of Health), eventually impressed upon the politicians that they should focus on the matter.²¹⁰ Minister Salesa's office remained in close contact with officials in the Tobacco Control Programme throughout as inquiries about various details of forthcoming legislation were bounced back and forth between political actors and bureaucrats.²¹¹

In June 2018, the Labour government commissioned a study from Ernst & Young to examine the necessity of continued increases in the tobacco excise tax rate and whether the Smokefree 2025 goal should be re-evaluated.²¹² By this point, even public health groups began to feel that tobacco taxes were losing their punch even as cigarette prices rose to ever more eye-watering heights (around US \$25 per pack).²¹³ When Ernst & Young reported back to the Ministry of Health later that year, they emphasized that the tax increases were steadily chipping away at smoking prevalence, but that they were not resolving Māori inequality and that more would need

²⁰⁶ NT @ 34

²⁰⁷ "Smoking to Be Banned in Cars When Children under 18 Are Present, Govt Announces," *NZ Herald*, February 9, 2019, sec. New Zealand, https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12202406; Katie Fitzgerald, "Government Looking into Banning Smoking in Cars with Kids - Jenny Salesa," *Newshub*, November 8, 2018, sec. Politics, <https://www.newshub.co.nz/home/politics/2018/11/government-looking-into-banning-smoking-in-cars-with-kids-jenny-salesa.html>.

²⁰⁸ NW @ 62

²⁰⁹ NY @ 34-35

²¹⁰ AC @ 38; NW @ 65-67; Stacey Kirk, "Government Appoints New Director General of Health," *Stuff*, May 22, 2018, <https://www.stuff.co.nz/national/politics/104113582/government-appoints-new-director-general-of-health>.

²¹¹ Deborah Woodley, "Information on Companies Entering Vaping Market," Official Information Act Request, September 3, 2019, https://www.health.govt.nz/system/files/documents/information-release/h201904148_0.pdf.

²¹² George Thomson and Louise Delany, "How Should Governments Deal with Multinational Consulting Firms That Work for the Tobacco Industry?," *Blog - Tobacco Control*, August 23, 2018, <https://blogs.bmj.com/tc/2018/08/23/how-should-governments-deal-with-multinational-consulting-firms-that-work-for-the-tobacco-industry/>.

²¹³ NQ @ 6-7; Johnston, "\$40 a Pack to Hit 'smokefree' Goal"; Hirono and Smith, "Australia's \$40 per Pack Cigarette Tax Plans."

to be done to reach Smokefree 2025 goals.²¹⁴ The report highlighted the potential for a properly regulated e-cigarette market to meet the Smokefree 2025 goal.²¹⁵ Advocates made the pitch to Salesa that, like Clark and Turia before her, she could cement her legacy by achieving Smokefree 2025.²¹⁶ Like her predecessors, Salesa repeatedly promised to deliver a formal Smokefree 2025 Action Plan but none has materialized in public, even though Official Information Act Requests indicate that such a plan is under development in the Ministry of Health.²¹⁷

Momentum towards altering New Zealand's e-cigarette regulatory framework to become more expansionist in its stance continued to grow through the end of 2018 and into 2019 as the introduction of a long-promised amendment to the SFEA grew nearer.²¹⁸ In an October 2018 meeting, Ardern's cabinet assigned an SFEA Amendment bill (described in Figure 14) that would implement a risk-proportionate framework on e-cigarettes a low level of priority.²¹⁹ In early 2019, the Health Promotion Authority within the Ministry of Health began releasing data indicating that New Zealanders were perceiving e-cigarettes as being equally harmful to cigarettes.²²⁰ In response, the Health Promotion Authority was authorized to conduct a rather unusual public education campaign, which was titled "Switch to Quit".²²¹ "Switch to Quit" encouraged cigarette smokers to switch to e-cigarette products to quit smoking by discouraging

²¹⁴ Money and Keegan, "Evaluation of the Tobacco Excise Increases – Final Report," 24.

²¹⁵ Money and Keegan, 25.

²¹⁶ NW @ 68

²¹⁷ NY @ 19-20, NQ @ 26; Salesa, "Progress on Achieving Smokefree 2025 and the Government's Response to the Report of the Māori Affairs and Health Committees on Achieving Smokefree 2025"; Richard Edwards et al., "Achieving Smokefree Aotearoa by 2025": A New Action Plan to Achieve Our Smokefree Goal – Public Health Expert, University of Otago, New Zealand," *Public Health Expert, University of Otago* (blog), September 7, 2017, <https://blogs.otago.ac.nz/pubhealthexpert/2017/09/07/achieving-smokefree-aotearoa-by-2025-a-new-action-plan-to-achieve-our-smokefree-goal/>; Deborah Woodley, "Information on Smokefree Aotearoa 2025," Official Information Act Request, September 19, 2019, <https://www.health.govt.nz/system/files/documents/information-release/h201906649.pdf>.

²¹⁸ Cancer Society CWC, *Sally Stewart MOH, SEMINAR ON ACHIEVING A SMOKEFREE AOTEAROA BY 2025* (Christchurch, 2017), <https://vimeo.com/245992555>; Sally Stewart, "Ministry of Health" (Seminar, Vaping to Stop Smoking, Christchurch, N.Z., May 29, 2019), <https://www.health.govt.nz/system/files/documents/information-release/h201903897.pdf>.

²¹⁹ The bill received a priority of 5, on a scale of 7, where 1 is the most urgent. A category 5 bill is supposed to be reported to the Parliamentary Council Office within a year. "About the Legislation Programme," Department of the Prime Minister and Cabinet, 2019, <https://dpmc.govt.nz/publications/about-legislation-programme>; Salesa and Lane, "Supporting Smokers to Switch to Significantly Less Harmful Alternatives," sec. 6.1.

²²⁰ Just 47% of respondents to the 2017/18 New Zealand Smoking Monitor said e-cigarettes were less harmful to health than tobacco cigarettes. Guiney, Oakly, and Martin, "E-Cigarette Use and Perceptions among Current and Ex-Smokers in New Zealand," 5.

²²¹ Tobacco Control Team, Public Health and Prevention, "Public Education Campaign –Vaping."

the dual use of the two products and clarifying the relative risk levels between them.²²² In June, Salesa stated that e-cigarettes were ‘vital’ to efforts to lower Māori women’s smoking.²²³

But as time ran on, and the EVALI scare developed in the United States, the role that e-cigarettes would play in New Zealand’s Smokefree 2025 effort evolved as well.²²⁴ The work done to arrive at a policy consensus between Otago and Auckland showed in the messaging to New Zealand media during the outbreak in the US. Otago-based researchers asked for cool heads to prevail and to wait for more evidence to emerge when e-cigarette skeptical colleagues in other countries were trying to push for contractionist e-cigarette policies.²²⁵

Ministry of Health and Labour government messaging has maintained a promise to deliver the SFEA Amendments in the decennial New Zealand Cancer Action Plan to promote vaping to support smokers to switch.²²⁶ Their tone on the policy varied between being optimistic about the potential of e-cigarettes to help smokers quit over to the required admonitions against youth usage of the products.²²⁷ By November 2019, Minister Salesa confirmed that the Ministry of Health was trying to “get this legislation right” before introducing the bill to Parliament.²²⁸

The Smokefree Environments and Regulated Products (Vaping) Amendment Bill was finally delivered to Parliament in late February 2020 and was fast-tracked towards passage.²²⁹ The regulatory framework, described in Figure 14, would set an expansionist regulatory stance

²²² Virginia Fallon, “Government Recommends Smokers Dump the Cigarettes and Pick up the Vape,” Stuff, May 6, 2019, <https://www.stuff.co.nz/national/health/112485473/government-recommends-smokers-dump-the-cigarettes-and-pick-up-the-vape>; Alt New Zealand, “Govt’s ‘Vaping to Quit Smoking’ Website Applauded,” New Zealand Doctor, June 11, 2019, <https://www.nzdoctor.co.nz/article/undoctored/govts-vaping-quit-smoking-website-applauded>.

²²³ “Vaping Vital to Lower Smoking Rates among Māori Women - Salesa,” RNZ, June 10, 2019, <https://www.rnz.co.nz/news/national/391650/vaping-vital-to-lower-smoking-rates-among-māori-women-salesa>.

²²⁴ Vikram P. Krishnasamy, “Update: Characteristics of a Nationwide Outbreak of E-Cigarette, or Vaping, Product Use—Associated Lung Injury — United States, August 2019–January 2020,” *MMWR. Morbidity and Mortality Weekly Report* 69 (2020), <https://doi.org/10.15585/mmwr.mm6903e2>.

²²⁵ Charlotte Cook, “Vape Users: No Need for Alarm over Death in US, Expert Says,” RNZ, August 25, 2019, <https://www.rnz.co.nz/news/national/397423/vape-users-no-need-for-alarm-over-death-in-us-expert-says>.

²²⁶ NZ Ministry of Health, “New Zealand Cancer Action Plan 2019–2029” (Wellington: NZ Ministry of Health, September 1, 2019), 36, <https://www.health.govt.nz/system/files/documents/publications/new-zealand-cancer-action-plan-2019-2029.pdf>; Andrew Macfarlane, “Government Moving to Close Legal Loophole Allowing Sale of Vaping Products to under 18s,” *TVNZ*, August 1, 2019, <https://www.tvnz.co.nz/one-news/new-zealand/government-moving-close-legal-loophole-allowing-sale-vaping-products-under-18s>.

²²⁷ “Vaping Flavours, Colours and Marketing in Government’s Firing Line,” *Q+A* (TVNZ1, September 3, 2019), <https://www.tvnz.co.nz/one-news/new-zealand/vaping-flavours-colours-and-marketing-in-governments-firing-line>.

²²⁸ Gillian Bonnett, “E-Cigarette, Vaping Legislation Delays Worry Experts,” RNZ, November 28, 2019, <https://www.rnz.co.nz/news/national/404355/e-cigarette-vaping-legislation-delays-worry-experts>.

²²⁹ Jenny Salesa, “Smokefree Environments and Regulated Products (Vaping) Amendment Bill,” Pub. L. No. 222–1 (2020), https://www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_94933/smokefree-environments-and-regulated-products-vaping.

towards e-cigarettes that is measured and careful in certain respects in an attempt to limit the appeal of the products to young people.²³⁰ On the occasion of the media tour she introduced the bill, Jacinda Ardern provided some enlightening commentary demonstrating that her instinct was to introduce a bill that was less expansionist than the one she delivered. Ardern claimed that while she would have originally banned the sale of all flavors of e-cigarettes, the evidence that had been presented to her over the past few months had convinced her that flavored product availability was important to those persons who successfully quit smoking by starting to vape.²³¹ The proposed regulatory framework has mostly been criticized by right-wing figures for being advanced on an accelerated timeframe (and during COVID-19-induced lockdown) and for not being lenient enough on the e-cigarette market.²³² None of these criticisms seem to be impairing the progress of the bill, as the country's government and health bureaucracy are steadily building trust and political capital via their extremely competent response to the COVID-19 pandemic.²³³

6.6 Conclusion

Like Australia and Canada, New Zealand first approached e-cigarette regulation with a prohibitionist policy inherited from an earlier era. The process of abandoning the older policy for a new one stemmed from the creation of a two-pronged problem that could be solved with one common policy solution. New Zealand's ambitious Smokefree 2025 goal is widely recognized to be unreachable, especially for Māori, without taking drastic action. The case of *Philip Morris v Ministry of Health* unexpectedly legalized the sale of e-cigarettes, albeit without much formal regulation. The combination of indicators pointing to a faltering tobacco control policy with a focusing event in the form of the court case caused the problem stream to decisively ripen. Māori political empowerment, embedded in the structure of Parliament and the choices made by past

²³⁰ Katrina Melville, "Smokefree Environments and Regulated Products (Vaping) Amendment Bill," Bill Digests (Wellington NZ: New Zealand Parliament, March 5, 2020), <https://www.parliament.nz/en/pb/bills-and-laws/bills-digests/document/52PLLaw26131/smokefree-environments-and-regulated-products-vaping>.

²³¹ "Jenny Salesa Defends Delay to Release Vaping Legislation," *Breakfast* (Auckland: Newstalk ZB, February 24, 2020), <https://www.newstalkzb.co.nz/on-air/mike-hosking-breakfast/audio/jenny-salesa-defends-delay-to-release-vaping-legislation/>.

²³² Eric Crampton, "What's so Urgent about Vaping Regulation at This Moment?," *NZ Herald*, April 1, 2020, sec. Business, Premium, https://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=12321512; Dan Satherley, "Vaping Ad and Flavour Bans Slammed as 'Short-Sighted', 'Knee-Jerk,'" *Newshub*, February 24, 2020, sec. Politics, <https://www.newshub.co.nz/home/politics/2020/02/vaping-ad-and-flavour-bans-slammed-as-short-sighted-knee-jerk.html>.

²³³ Anna Fifield, "New Zealand Isn't Just Flattening the Curve. It's Squashing It.," *Washington Post*, April 7, 2020, sec. Asia & Pacific, https://www.washingtonpost.com/world/asia_pacific/new-zealand-isnt-just-flattening-the-curve-its-squashing-it/2020/04/07/6cab3a4a-7822-11ea-a311-adb1344719a9_story.html; Tess Nichol, "The Extremely Competent, Somewhat Boring Civil Servant Who Has New Zealanders' Hearts Aflutter," *Slate Magazine*, April 6, 2020, <https://slate.com/news-and-politics/2020/04/new-zealand-covid-19-coronavirus-ashley-bloomfield.html>.

governments, allowed Māori issues to be considered important enough to address on the national policy agenda. This path-dependently led to the creation of the Smokefree 2025 goal. Political forces eventually warmed to the idea of e-cigarettes being an acceptable tool to help reach the Smokefree 2025, but there was little rush to finalize the regulations.

At the center of this story though, is a coalition of bureaucrats, academics, and non-governmental organizations that all agreed that the e-cigarette market should be subject to regulatory policies that were less strict than tobacco products. This coalition advanced a brand of tobacco harm reduction in the guise of risk-proportionate regulation that was acceptable to most every political party and was seen as a Pareto improvement over the status quo of first, prohibition, and then post-*Philip Morris*, an informal permissive regulatory stance. This THR coalition advanced a vision that New Zealand could solve its Smokefree 2025 problem as well as the trouble created by the *Philip Morris* case in a matter that could be broadly acceptable to the governing coalition. Their vision of risk-proportionate regulation would aim to shift smokers from tobacco cigarettes to e-cigarettes while hopefully stemming a rising tide of youth use that has swamped other jurisdictions. Whether they can accomplish this goal remains to be seen, but the stage has been set for this legislation to proceed through Parliament once it is delivered.

Chapter 7 Cross Case Lessons

Similarities, Differences, and Lessons from EVALI

The case studies in the prior chapters illustrated in detail how the lack of international consensus in approaches to e-cigarette regulation may have been created. Even countries that started in similar situations diverged in response to unique events and circumstances. Their stories illustrate that regulatory policymaking, like so much in politics, is not an exercise in rational deliberation of experts who simply dictate their conclusions to supplicant legislatures.

Bureaucracies prefer to expand their power. Politicians do not want to take unnecessary risks. Public health and business interests sometimes find themselves in agreement.

This study boils down to a simple question; why did some countries change regulatory stances while others stayed put? Australia kept a regulatory stance that was developed before e-cigarettes were even a viable commercial market. New Zealand and Canada decided to adopt new regulatory stances toward this market. Certain conditions were necessary to open a policy window to change a regulatory framework. The need for multiple conditions to be present to open a policy window to change the regulatory stance for e-cigarettes illustrates the necessity of paying close attention to the details in any case study. This study carefully documented how each case study changed its regulatory framework over time. To leverage the multiple cases at work in this comparative study, we must now engage with the isolated explanations of policy change and stasis to determine if the findings in one country are generalizable first to other cases in the study, and second to other proximate cases. Here the similarities and differences between each of the primary case studies are broken out by Kingdon's streams to illustrate the key lessons to be gleaned comparing across cases. Then, a comparison of the rhetorical framing of each regulatory framework is considered for what it can tell about the relative goals and values of each case. Then the experience of the case countries when confronting the simultaneous focusing event of the EVALI outbreak, an incident that defined the global media environment after my fieldwork

had concluded, will be explored. Each country reacted to EVALI in a manner that reiterated its commitment to achieving pre-established regulatory goals.

7.1 Lessons Learned

At an abstract level in the Multiple Streams Approach, the problem and policy streams had to become primed before they could successfully merge with a primed politics stream. First, the problem stream became primed once the current regulatory policy was deemed a failure. The regulatory policy failed by being rejected by the courts as illegal, rejected by bureaucracies as not worth enforcing, or it failed to achieve its goals. Next, the policy stream became primed once a policy community came to a consensus on an alternative to the failed regulatory policy. Finally, the politics stream was primed when left-wing politicians were permitted to support a regulatory policy change favored by business groups because the policy community agreed the alternative policy was preferable to the failed policy. This freed right-wing politicians to support the alternative policy without facing a political penalty. As regulatory policy change is not typically an important issue for voters, a permission structure had to be created that allowed all politicians to agree to the policy community's consensus alternative regulatory policy, insulating politicians from electoral consequences. This section explains in great empirical detail how these conclusions were arrived at in each of Kingdon's streams and how they fit together.

7.1.1 Problem Stream

The problem stream defined the largest difference between the cases of regulatory policy change and stasis. New Zealand and Canada have identifiable focusing events that led to the rejection of the pre-existing regulatory stance and precipitated the drive towards change. Bureaucracies in those countries aided this drive to change by abandoning the enforcement of prohibitionist policies. And in New Zealand, general frustration with a failure to make adequate progress in tobacco control for the Maori population deepened suspicion towards the effectiveness of the status quo. None of these forces were present in Australia. The unifying lesson across the three cases is that unless a status quo regulatory stance was rejected, in either a *de jure* or *de facto* manner, the problem stream did not become ready to couple with the problem or politics stream. This section summarizes the findings regarding the importance of the failure of tobacco control and the rejection of the regulatory stance by the bureaucracy in the subsequent development of the problem stream across the three cases.

7.1.1.1 Failure of Tobacco Control

In the case of New Zealand, failure to make adequate progress towards the goal of reaching the country's Smokefree 2025 target, particularly for the indigenous Māori, increased the appetite to abandon New Zealand's regulatory stance towards e-cigarettes.¹ By contrast, Australia lacked an ambitious public tobacco control target that was on track to be missed. Without an impetus to change policy course, without the condition of 15% of Australians continuing to smoke turning into a real problem that needs to be solved, there is no reason to change course for these entities.²

In New Zealand, health inequity played an important role in defining the problems that changing the e-cigarette regulatory framework could address.³ Health inequity and an implicit dissatisfaction with the progress of tobacco control for Māori rose on the political agenda because the country's structure of representation reserved seats in Parliament for indigenous Māori and the adoption of a mixed-member proportional electoral system encouraged the formation of coalition governments.⁴ This structure fomented the creation of the Smokefree 2025 goal which successive governments have targeted as an ambitious, but worthwhile, target that would substantially redress health inequities if it were to be achieved.⁵ The presence of the looming Smokefree 2025 target along with pressure being applied to form the policy and political realms enabled the Ministry of Health bureaucrats to abandon the continued enforcement of the prohibitionist e-cigarette regulatory stance in the wake of *Philip Morris v Ministry of Health*.⁶

Canada's experience with tobacco control policy failure had more to do with a failure to enforce federal policy on the nascent e-cigarette retail market than it did with failing to reach federal targets. The federal tobacco endgame target in Canada was only proposed after all political parties had agreed to change the e-cigarette regulatory stance in the HESA Committee report.⁷ Instead, Canada's geographic proximity to the United States border aided the growth of e-cigarette retailers and e-cigarette use in Canada.⁸ Ready access to supplies across a friendly

¹ See 6.2.2 Falling Off Track to Meet the Smokefree 2025 Target on page 171.

² See 4.2.1 Tobacco Control Progress and Skeptics' Framing on page 92.

³ Edwards, "Endgames and Smokefree Aotearoa 2025 Update."

⁴ Mittal, "Electoral Reform in New Zealand."

⁵ Blakely et al., "The Maori Affairs Select Committee Inquiry and the Road to a Smokefree Aotearoa."

⁶ See 6.2.3 Philip Morris v Ministry of Health on page 172.

⁷ See 5.7 Passing Bill S-5 on page 151.

⁸ Hammond et al., "Retail Availability and Marketing of Electronic Cigarettes in Canada."

tariff-free border meant that retailers could supply themselves from the United States easily. This growth in e-cigarette retailers seeded the growth in the e-cigarette user base and the number of confrontations Canadians had with e-cigarette users.⁹ These confrontations led to calls for regulation of e-cigarette use in public spaces which bubbled up to become local and provincial legislation.¹⁰ These moves to regulate e-cigarette use at the local level illustrated vividly the need for a change in the federal regulatory stance for e-cigarettes to provincial and territorial officials charged with protecting the public health. Their agreement on the need for federal change precipitated in a call to action that resulted in a change to the country's regulatory stance towards e-cigarettes.¹¹

The result of policy stasis in Australia could be viewed as an active choice to maintain the current prohibitionist policy stance through events ranging from the TGA's poisons scheduling to the House's Committee reporting process.¹² That perspective misses what differentiated Australia from the other cases; no reason to change the e-cigarette regulatory stance became prominent enough for the Commonwealth to change course. No actor was pushed to change because there was no failure of tobacco control problem to solve.

7.1.1.2 Rejecting the Regulatory Stance

The process of readying the problem stream for coupling in New Zealand and Canada relied upon bureaucrats deciding that the prohibitionist regulatory stance was not worth enforcing. The 2012 decision to stop confiscating e-cigarette materiel in Canada and the 2018 decision to not appeal the ruling in *Philip Morris v Ministry of Health* in New Zealand marked turning points where the central government bureaucracy decided to abandon its regulatory stance. New Zealand's hand was forced halfway to changing its regulatory stance after *Philip Morris v Ministry of Health* was decided against the government by the country's perceived tobacco control failures.¹³ The 2012 decision to abandon enforcement led directly to a concerted call in 2014 from provincial and territorial ministers of health for a change in the country's e-cigarette

⁹ Tilson, "Regulating E-Cigarettes as Drugs Is Not the Best Solution."

¹⁰ Strang et al., "Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems."

¹¹ Vogel, "Provinces Press for E-Cigarette Crackdown."

¹² Australian Government Department of Health Therapeutic Goods Administration, "Scheduling Delegate's Final Decisions, March 2017: 2.1 Nicotine," Text, Therapeutic Goods Administration (TGA), March 23, 2017, <https://www.tga.gov.au/book-page/21-nicotine-0>; Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*.

¹³ Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC.

regulatory stance that Canada's federal bureaucracy was forced to respond to.¹⁴ The New Zealand case illustrates the importance of the bureaucrat's decision to surrender the status quo regulatory stance rather than the judiciary's decision to invalidate the old policy. Canada's experience even demonstrates that a policy that was held up to be legal in court was not, by itself, reason enough to continue its enforcement, as bureaucrats there also abandoned the old prohibitionist e-cigarette regulatory stance because they rejected the idea there was utility to be gained from enforcing the policy.¹⁵

The assent of bureaucrats to abandoning the prior regulatory stance provided a great deal of validation to the arguments other had made to abandon the old policy (see the prior section), and thus, served to prime the focusing event needed to begin drafting a new regulatory stance. The decision to abandon the prohibitionist regulatory stance emanated from a belief that the old regulatory framework was failing to deliver utility the bureaucrats wanted. From the Australian perspective, everything was under control and there was no pressure to change strategy.

Australian bureaucrats never stopped enforcing the prohibitionist regulatory framework, thereby setting up one more bulwark to policy change. The utility of enforcing the rules of the ACCC and the TGA was never questioned as giving consumers good information and protecting people from ingesting poison continued to be viewed as worthy causes of the time and attention of bureaucracies. As there was no point where this utility was brought into question, no follow-on focusing event ever brought the regulatory stance into question. Without such a force, policy inertia held sway.

7.1.2 Policy Stream

Two primary policy communities were concerned about the regulation of e-cigarettes; a public health policy community, and a community composed of tobacco and e-cigarette manufacturers. The public health policy community, who was consistently influential with left-wing politicians, favored changing the e-cigarette regulatory framework in Canada and New Zealand while opposing such change in Australia. The tobacco and e-cigarette manufacturers commanded influence with right-wing politicians in every case country. In every case, the tobacco and e-

¹⁴ CICS, "News Release - Provinces and Territories Talk Health Care."

¹⁵ Geller et al., Evidence on E-Cigarettes.; André F.J. Scott, *Zen Cigarette Inc v. Canada (Health)*, 2012 FC 1465 (Federal Court 2012); Robert Strang et al., "Provincial/Territorial Chief Medical Officers of Health Position Statement on Electronic Nicotine Delivery Systems" (Council of Chief Medical Officers of Health, July 25, 2014).

cigarette manufacturers made the same request of politicians; to abandon the prohibitionist e-cigarette regulatory framework. When explaining variance in outcomes, it makes sense to focus on the difference in the public health community.

The public health policy communities differed in two primary ways between the cases. First, the New Zealand public health policy community actively worked with persons who self-identified as tobacco harm reduction advocates while Australia's policy community shunned those persons who identified as such. Second, the Canadian and New Zealand public health policy communities were effectively able to reach consensus on a chosen alternative regulatory stance as being preferable to the status quo. No such alternative stance was ever agreed to in Australia. These factors combined to mobilize a push for change in policy from the public health community that was recognized as legitimate by politicians and policymakers in the cases where change was observed.

7.1.2.1 Reaching a Consensus Alternative Policy

When a public health community decided by consensus to back an alternative to the status quo, we observed that policy change was more universally accepted across the political spectrum. 'Consensus' is an important qualifier here. As we saw in Australia, there were isolated members of the public health community who supported changing the country's regulatory stance towards e-cigarettes. Those individuals were unable to sway the bulk of the public health community to join their perspective, and the evidence for this possible intransigence stems from the fact that most of the Australian public health community did not believe the status quo was not working well. Australia's policy community in favor of tobacco harm reduction policy was not the dominant force within the policy stream on this issue. Instead, their contributions were outweighed by a better positioned and more influential advocacy community that was skeptical of the expansion of e-cigarette sales. Without a driving force to push the community to coalesce around an alternative policy, inertia won out.

The preferred regulatory stance of the public health policy community towards e-cigarettes aligned with outcomes in all case countries. When problems were created by the sudden uncontrolled legalization of e-cigarette sales, by a perceived failure in the tobacco control policy regime, or by a rejection of the old regulatory framework as adequate for a jurisdiction's needs, then the incentive to coalesce around an acceptable alternative was heightened. New Zealand and

Canada-based policy community members were quick to abandon defenses of their respective country's regulatory frameworks for e-cigarettes. In Australia, the bulk of the public health policy community decided that maintaining the status quo was their preferred option. When the public health policy community shifted their preference from the status quo, left-wing politicians were permitted to follow.

The chosen consensus alternative policy in New Zealand and Canada were functionally similar. Both public health policy communities preferred applying more contractionist regulations to tobacco cigarettes than to e-cigarettes. Both communities wanted to keep young people from using e-cigarettes. When presented with choosing between the status quo prohibitionist stance, adopting a contractionist stance, or adopting an expansionist stance — both public health communities encouraged choosing an expansionist stance. Nearly every public health advocate who was interviewed in this study believed that a tobacco cigarette smoker would suffer less disease and premature death if they switch completely to using an e-cigarette. Encouraging this switch between products then became a delicate exercise in choosing to apply certain contractionist regulations to the new market and its close substitute.

The public health policy communities in New Zealand and Canada shifted its internal debate away from whether the e-cigarette market should be legal and towards discussions over which policies should be applied to which market. The consensus alternative policy extended only as far as the basic concept that regulatory agencies should be empowered to regulate the e-cigarette market and that regulation should be harsher for tobacco cigarettes than e-cigarettes. It then became the job of bureaucrats and politicians to decide on the exact outlines of first, legislation, and then regulations. The results of the chosen policies in achieving these goals have been mixed, but efforts to improve upon the mistakes made by one jurisdiction by the next are evident.

7.1.2.2 Policy Learning

Overall, the role of policy learning in this study was limited to determining the details of regulatory frameworks rather than the broader regulatory stance. Policy communities that agreed on the adoption of an expansionist regulatory framework appeared to learn lessons from the failures of others who dispositively agreed with them. Lessons have not yet transferred between policy communities who disagree on the proper regulatory stance for e-cigarettes. For the time

being, policy convergence driven by policy learning in this area will remain relegated to the smaller details of regulatory policy rather than the overarching goal and intent.

In the illustrative example of this smaller dynamic, both Canada's and New Zealand's efforts relied heavily on government bureaucrats to create an expansionist e-cigarette regulatory stance. In each case, the process was slow and drawn out over the course of nearly two years. The policies that each bureaucracy put forward at the end of that process adopted policies that substantially expanded the regulatory authority of the bureaucracy to set rules over the e-cigarette market. The bureaucracy functioned professionally, as officials considered evidence and input from stakeholders as they attempted to write policies that actively learned from the mistakes of others to avoid repeating their errors.

In the example of e-cigarette flavors, we can see this iterative learning process in action. When Canadian officials wrote their product standards for flavors, they only prohibited marketing flavors that claimed to taste like candy, dessert, cannabis, soft drinks, and energy drinks.¹⁶ Arguably, this was done to curb the worst practices that Canada was observing in the United States as small e-cigarette retailers sold flavors like 'unicorn puke' and 'gummi bear' that were assumed to be inherently appealing to youth.¹⁷ After the opening of the legal Canadian e-cigarette market was marred by rising rates of youth e-cigarette usage – in 2019, Canadian bureaucrats had to scramble to implement relatively contractionist rules on e-cigarette marketing and product standards.¹⁸

While Canada struggled to reverse the tide against youth e-cigarette use, throughout 2019, New Zealand officials wrote e-cigarette regulations that reacted to even more current data from the US and Canada about the role that flavorings played in youth and adult vaping.¹⁹ The eventual policy proposed in New Zealand's legislation limited the sale of e-cigarette flavors sold in non-specialty retailers (any store that is not an adult-only vape shop) to menthol and tobacco flavors, while no limits on flavors were placed on businesses who registered with the Ministry of Health as e-

¹⁶ Harder, An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts.

¹⁷ Robert K. Jackler and Divya Ramamurthi, "Unicorns Cartoons: Marketing Sweet and Creamy e-Juice to Youth," *Tobacco Control* 26, no. 4 (July 1, 2017): 471–75, <https://doi.org/10.1136/tobaccocontrol-2016-053206>.

¹⁸ Health Canada, "Backgrounder: Regulation of Vaping Products in Canada," backgrounders, gcnews, December 19, 2019, <https://www.canada.ca/en/health-canada/news/2019/12/backgrounder-regulation-of-vaping-products-in-canada.html>.

¹⁹ "Jenny Salesa Defends Delay to Release Vaping Legislation."

cigarette retailers and who agreed to limit entry to persons who could prove they were over the age of 18.²⁰ This policy seems to react to evidence that the appeal of sweet- and fruit-flavored e-cigarette products to adult smokers is a major factor behind switching to e-cigarettes from tobacco cigarettes.²¹ However, initiation of e-cigarette use by youth also seems to be linked to flavor availability.²² The rationale behind New Zealand’s policy is that keeping all flavors except those that are least attractive to youth out of non-specialty retailers, while preserving the availability of flavors in retailers that are only accessible to adults, will minimize health risks to young people while preserving some upside for adults. Whether this policy keeps a lid on youth e-cigarette use in New Zealand remains to be seen, but we can be certain that each case country will be closely observing the other’s results. Policy communities around the globe with interests in expansionist e-cigarette regulation will be watching and learning, too. Those policy communities interested in promoting alternative stances may be watching and drawing different lessons.²³

7.1.2.3 Harm Reduction

New Zealand and Australia handled the entry of individuals associated with tobacco companies, in the same manner, ostracization from public health credibility. However, New Zealand’s policy community worked closely with actors who had ties to the e-cigarette industry.²⁴ Crucially, these actors had established their bona fides as credible public health advocates in the years before e-cigarettes arrived in their country. The New Zealand policy community was also willing to cleave off members who strayed too far from a consensus policy position or who worked too closely with the increasingly disruptive tobacco industry.²⁵ Australia effectively marginalized the few public health policy community members who pushed for a change in the regulatory stance that was sympathetic to the ideals of tobacco harm reduction.²⁶ The Canadian public health

²⁰ Salesa, Smokefree Environments and Regulated Products (Vaping) Amendment Bill.

²¹ Christopher Russell et al., “Changing Patterns of First E-Cigarette Flavor Used and Current Flavors Used by 20,836 Adult Frequent e-Cigarette Users in the USA,” *Harm Reduction Journal* 15, no. 1 (June 28, 2018): 33, <https://doi.org/10.1186/s12954-018-0238-6>.

²² John Buckell and Jody L. Sindelar, “The Impact of Flavors, Health Risks, Secondhand Smoke and Prices on Young Adults’ Cigarette and e-Cigarette Choices: A Discrete Choice Experiment,” *Addiction (Abingdon, England)* 114, no. 8 (August 2019): 1427–35, <https://doi.org/10.1111/add.14610>; Adam M. Leventhal et al., “Flavored E-Cigarette Use and Progression of Vaping in Adolescents,” *Pediatrics* 144, no. 5 (November 2019), <https://doi.org/10.1542/peds.2019-0789>.

²³ See 7.3 EVALI on page 218 for an example of this divergent pattern of policy learning.

²⁴ See 6.3.2.1 The unbroken line of credible policy entrepreneurs from Murray Laugesen on, at page 179.

²⁵ Espiner, “Gloves Off.”

²⁶ See 4.3.2 THR Advocates Dissent from the Consensus at page 102.

policy community was never presented with clear opportunities to perform similar ostracizations, as the public health community was never as centralized in its position or as influential in the debate as the provincial and territorial Ministers of Health.

Harm reduction as a generic concept was in vogue during Justin Trudeau's early years in government, as progress in opioids, criminal justice, and cannabis regulation were closely tied to harm reduction concepts.²⁷ Regulated marketplaces were seen as preferable to unregulated marketplaces, as the worst actions of market participants could be curbed with proper regulatory oversight. The appetite to apply similar harm reduction principles to tobacco policy was strong among Canadian politicians and the public health policy community.²⁸ While Australia and New Zealand both have histories of experimenting with harm reductionist programs in the areas of substance use and sex work, in neither country was harm reduction a prominent policymaking philosophy. The presence or absence of a harm-reductionist policymaking streak must be further investigated in other jurisdictions to determine its relative importance to shaping the preferences of actors in the public health policy community for e-cigarette regulation.

The concept of business-friendly harm reduction showed appeal in the Canadian and New Zealand contexts, wherein right-wing parties that did not traditionally approve of harm reduction efforts in other areas of public health concern approved of such efforts in the realm of e-cigarette regulation. Nicotine has not traditionally presented the moral quandaries that more traditionalist, less-egalitarian right-wing political parties that have invoked in their opposition to harm reduction initiatives in the realm of sexually-transmitted infections and injection drug safety. Businesses who sell nicotine are viewed as legitimate members of society and allowing new opportunities to advance their interests has been deemed compatible with general classical liberal positions taken by right-wing political parties. The appeal of business-friendly harm reduction may be a phenomenon that will continue propagating through other venues and the concept merits further study.

7.1.3 Politics Stream

The issue of e-cigarette regulatory policy never achieved political salience during an election in any case examined. Prime Ministerial attention to the issue was almost entirely lacking as well.

²⁷ Health Canada, "Harm Reduction."

²⁸ CD @ 39

Federal structures do not seem to have operated in a manner that offers clean predictions about the likelihood of changing a regulatory stance towards a market. The role of the tobacco industry was played up by politicians when it suited the cause of regulatory policy stasis, but it was played down when regulatory policy change was imminent. But the role of tobacco companies in the policy process did not differ much between the cases. The difference, then, in the operation of the political stream between cases boils down to a single variable, whether the left-of-center political parties came to support changing the country's regulatory stance towards e-cigarettes. The political calculations either played out as a latent issue (Australia) or as a depolarized issue (New Zealand and Canada), largely because the left-wing party supported changing the e-cigarette regulatory stance. In this section, I discuss how the first two factors are not powerful predictors of change while the last fact was consequential in the cases at hand.

7.1.3.1 Federalism

The influences of governmental structure and centralization on the outcomes observed in the case studies was limited. New Zealand's centralized governing structure limited the amount of pressure that regional governments could apply to the central government to change the impetus for regulatory framework reform. However, the lessons from Australia and Canada are an exercise illustrating the importance of timing more than the importance of government structure on the likelihood of changing a regulatory stance. Further, it does not seem that differences in the forms of federal structure between the countries had much of an effect on the outcomes of interest in this study.

The Australians faced a cadre of e-cigarette regulatory policy entrepreneurs who favored the creation of a truly liberalized marketplace for the products devoid of any contractionist or even permissive (relative to tobacco cigarettes) component policies.²⁹ These policy entrepreneurs focused on attempting to pass their chosen policies at the Commonwealth level while public health-minded policy entrepreneurs were successfully passed contractionist regulatory policies at the State and Territory level.³⁰ The traction that the latter group gained at the regional government level set the stage for maintaining the status quo at the Commonwealth level. E-

²⁹ See 4.4.2 THR Advocates Latch onto David Leyonhjelm on page 108.

³⁰ See 4.4.1 Skeptics Push Regional Regulation into Effect on page 105.

cigarettes were successfully defined as a threat to the hard-won gains against smoking that the country had made.

In Canada, provincial and territorial legislation regulating the use and marketing of e-cigarettes was passed after a Federal Parliamentary report was finalized.³¹ Because federal political actors reached unanimous agreement on the outlines of a proper regulatory framework for e-cigarettes before regional governments could finalize legislation, the possibility of maintaining the prohibitionist status quo had diminished. The lesson seems to be that there is a first-mover advantage towards carving the path that the political actors would later follow. But, a lack in the consistency of observations that contribute to this small finding, undermines my confidence in its broader applicability.

7.1.3.2 The Role of the Tobacco Industry

In every case country, the tobacco industry and e-cigarette manufacturers consistently favored moving away from prohibitionist regulatory stances towards e-cigarettes. Their motives were consistently business-related, and their rhetoric always supported the advancement of public health through expanded consumer choice. However, support for change in regulatory policy from these companies was in the final analysis, inconsequential.

One could argue that there was a difference of degree in the mistrust and dislike of the tobacco industry among the public health community, bureaucracy, and government officials in Australia relative to New Zealand and Canada. Those groups watched the tobacco industry in Australia fight a scorched-earth legal battle against tobacco product plain packaging in the last decade.³² The Australian Commonwealth government's center and left-wing opposition had no appetite to reward the tobacco industry in any way with new revenue streams.³³ It was easier for them to insist that tobacco companies should sell e-cigarettes as medicines than to do any grappling with what an acceptable regulatory framework that liberalized e-cigarette sales would look like. Efforts to abandon the old prohibitionist regulatory framework would reward their mortal enemies. The relationships between THR policy entrepreneurs and tobacco companies in

³¹ See 5.4.1 HESA Committee on page 139.

³² Jarman, "Normalizing Tobacco?"; Jarman, "Attack on Australia."

³³ See 4.4 Politics Stream at page 104.

Australia only served to close the door to regulatory reform tighter, and attributing that to some remaining animosity would be reasonable.

By contrast, the tobacco industry's interests in changing the e-cigarette regulatory framework were put into the background in Canada and New Zealand. With left-wing governments leading the charge towards regulatory reform, the benefits to public health were foregrounded in the public-facing policy debate. In Canada, tobacco companies made the strategic choice to focus their policy concerns on the matter of plain packaging.³⁴ While these companies stood to benefit from the change in e-cigarette regulations, they did not focus their lobbying efforts on that matter. The interests of tobacco companies in the e-cigarette market were effectively hidden behind the interests of small businesses. In that circumstance, abandoning the prohibitionist regulatory stance served the interests of all parties through the strategy of business-friendly harm reduction. Whether tobacco companies would benefit from the new regulatory framework was subdued beneath more pressing concerns.

New Zealand's regulatory policy battle has been marked by a tobacco industry eager to be seen acting like a good corporate citizen. However, the left-wing coalition government has taken little interest in hearing out the concerns of large tobacco companies. Select small e-cigarette manufacturers have been allowed to participate in the policy advisory process, but their concerns do not diverge far from the main public health community in the country. Even when e-cigarette manufacturers are in the room with policymakers, their influence seems to be minor at best.

7.1.3.3 Left-Wing Party Support

In the case studies considered here, one country resisted changing its regulatory stance towards e-cigarettes and two countries changed. The country that resisted change (Australia) began the study period with a left-wing government and transitioned to a right-wing government in 2015. The countries that changed policy began the study period with right-wing governments and moved to left-wing governments later on. This pattern of political party governance seems to have been consequential as the ascendance of left parties in New Zealand and Canada paved the way to a change in the regulatory stance towards e-cigarettes, that may not have happened

³⁴ Siebert, "Imperial Tobacco Wants the Government to Treat Cigarettes and Cannabis Equally."

without a change in the party in power. To draw a through-line between the cases, we must note what differed in their political configurations at a national level.

In both New Zealand and Canada, right-wing parties expressed that they favored changing e-cigarette policy before they lost power. In Australia, only the extreme right flank of the right-wing government ever expressed their support for e-cigarette regulatory policy change. Additionally, in both Canada and New Zealand, most left-wing parties expressed their favor for changing e-cigarette regulatory policy as well. By contrast, the Australian left-wing has vociferously denied their support to liberalizing their country's e-cigarette regulatory policy. Consequently, in Australia, the center-right of the government has also held back their support from such a regulatory policy change.

What then, can consistently explain this fact pattern? Cross-party consensus leads to change, while party division and polarization maintain the status quo. Across all the cases, the left-wing political party's support for changing the e-cigarette regulatory framework proved to be a sufficient condition for policy change going forwards. In Canada, the Liberals and NDP reached a unanimous agreement with Conservatives on the path forwards to an e-cigarette regulatory framework, thereby enabling policy change to proceed. In New Zealand, Labour and Green provided their support for abolishing the prohibitionist e-cigarette regulatory framework joining the Nationals who had initially led the push for change. Notably, remaining Māori Party leaders favored changing the country's e-cigarette regulatory framework, while retired party founder Taranaki Turia continued to oppose such a change.³⁵ In cases where left-wing parties lent their support, they created permission structures that allowed changing the e-cigarette regulatory framework to proceed without carrying downside political risk for the parties involved. Australia's Commonwealth Labor Party stands apart from the other major left-wing parties in the study as being wholly resistant to creating a legal market for e-cigarettes.³⁶ Australian Labor uniformly resisted changing e-cigarette policy, denying the Coalition government consensus on the issue. This is the only case where a political party prepared to turn e-cigarette regulation into

³⁵ Ripeka Timutimu, "Government to Regulate Vaping," Māori Television, August 20, 2018, <https://www.maoritelevision.com/news/politics/government-regulate-vaping>.

³⁶ AQ@ 10; AW @ 35

a voting issue among the cases. This action stood apart from those of other left-wing parties in the case studies for two reasons.

First, the Commonwealth Labor Party has remained out of power in Australia during the entire period where e-cigarette regulatory policy has become salient. Where Australian Labor has been in power at the regional level, they have favored imposing restrictions on e-cigarette sale and usage in a manner indistinguishable from their right-wing counterparts.³⁷ Without putting the Commonwealth Labor Party into government, we cannot know whether common ground with right-wing parties could be found to change the e-cigarette regulatory framework. The findings from New Zealand and Canada indicate that finding such common ground is possible, but left-wing politicians would need to be prodded forwards to solve a problem if they are to begin seeking such a policy change.

Second, the Australian Labor Party managed to alter the political calculation of their right-wing counterparts on the issue of e-cigarette regulations. This is notably different from Canada, where all parties reached unanimous agreement on an alternative regulatory framework for e-cigarettes before the 2015 Federal election which brought the center-left into government.³⁸ The Canadian left-wing did not calculate that withholding their support from e-cigarette regulatory policy change would have been a winning political decision. Instead, when the left-wing came to power in Canada following the 2015 Federal elections, the Liberal party employed an issue linkage strategy that attached tobacco plain packaging to e-cigarette regulatory policy reform as a sweetener to public health groups.³⁹ Everyone in Canada could point to the piece of Bill S-5 that they liked best and that characteristic enabled the smooth passage of a policy that had the support of almost everyone. In New Zealand, the multi-member proportional representation scheme increases the likelihood of the formation of coalitional governments and forces policymakers to find common ground with ideologically distinct coalition partners. Reforming the prohibitionist e-cigarette regulatory stance turned out to be an initiative that all three members of the Ardern government from the right-wing populist New Zealand First Party to the left-wing Greens could

³⁷ See 4.4.1 Skeptics Push Regional Regulation into Effect on page 105

³⁸ HESA Committee, "Vaping: Toward a Regulatory Framework for E-Cigarettes."

³⁹ CIG @ 42-43; CD @ 28-29

agree upon. The depolarized nature of the progressing of the regulatory policy debate in Canada and New Zealand is a notable contrast to Australia.

A further contrast between Canada and Australia can be seen in the actions of the political parties who reacted differently to the writing up of committee reports that assessed the need to change e-cigarette regulatory policy in each country. In both cases, the committee was chaired by incumbent right-wing parties. In the case of Canada, the left-wing parties signed on to a unanimous recommendation to adopt an expansionist e-cigarette regulatory policy. In Australia, the right-wing committee members splintered—the committee chair wrote a dissenting report, and the left-wing joined with a center-right member to write the majority.⁴⁰ Close analysis revealed that in Australia, the right-wing committee member never sought to write a consensus report or even successfully obtained the support of their party leadership.⁴¹

In sum, the cooperation of left-wing parties seems to be crucial to changing e-cigarette regulatory stances in the cases at hand. Left-wing parties have behaved as though e-cigarette regulatory policy is not a vote-winner, but right-wing parties have behaved as if the subject is a vote-loser. Voters do not mention the subject as being pivotal to determining their vote. The issue remains one of low salience in the political arena. Only left-wing support for change has been able to de-polarize this issue and lead to the opening of a policy window.

7.1.4 Coupling and Policy Windows

In the case studies where policy change happened, the time elapsed between a focusing event and the introduction of legislation to change regulatory policy numbered in years. The task of re-writing regulatory frameworks was assigned to the Canadian and New Zealand bureaucracies that would implement the new regulatory stance. The bureaucrats took their time to craft what they believed to be an evidence-based regulatory policy that expanded their powers over markets and provided them with tools to make necessary adjustments to policies as new evidence of the effects of policy choices was published. The urgency to pass e-cigarette regulatory legislation was relatively low in each primary case study. When legislation eventually appeared, it represented the slow and grinding work of policy crafting in partnership with expertise.

⁴⁰ AQ @ 3-4; Standing Committee on Health, Aged Care and Sport, *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, 141.

⁴¹ AQ@ 10

The work of coupling the streams in Australia was bungled by THR policy entrepreneurs who remained insensitive to the political calculation and problem definitions available to be exploited.⁴² The entrepreneurs' chosen policy alternative of a broadly expansionist and lightly governed e-cigarette market was unresponsive to electoral concerns of the government who feared losing votes to the left-wing if they were too friendly to business interests.⁴³ The politicians recruited to their cause were not natural allies to public health or harm reduction causes.⁴⁴ When presented with the opportunity to recruit converts to their coalition, the THR policy entrepreneurs were unable to sell their wares and were roundly defeated.

By contrast, the policy entrepreneurship on the issue in Canada was quiet, consensual, and conducted hand-in-glove by policymakers, public health groups, and bureaucrats.⁴⁵ A solution (an expansionist stance) that was responsive to an issue (dissatisfaction with the prohibitionist stance) was constructed in a manner that made it attractive to all political parties (linking plain packaging with business-friendly harm-reduction). The New Zealand Ministry of Health also bridged the gap in its policy advice to two successive governments to create a policy that few have found objectionable in a similar manner (excluding the use of policy linkage) to the Canadian case.⁴⁶ The New Zealand case is defined by a court case that invalidated a pre-existing regulatory stance and created an acute focusing event to which the Ministry of Health and government officials chose to deliberately respond.⁴⁷ The cases of policy change are therefore defined by entrepreneurship that is opportunistic, cooperative, and constrictive while the case of policy stasis is defined more by impatience and antagonism.

Summary

Certain conditions were necessary to create a policy window to change the regulatory framework for e-cigarettes. Within the Multiple Streams Approach, the problem and policy streams had to become primed before they could successfully merge with the politics stream. First, the problem stream became primed once the current regulatory policy banning the sale of e-cigarettes was

⁴² See 4.5 Failure to Couple the Streams at page 110.

⁴³ McGowan, "The Australian Election 2019 Has (Finally) Been Called."

⁴⁴ See 4.4.2 THR Advocates Latch onto David Leyonhjelm at page 108.

⁴⁵ See 5.5 The Politics Stream at page 141.

⁴⁶ "Ministry to Consider Risk-Proportionate Regulation for Vaping and Heated Tobacco Products," Ministry of Health NZ, May 9, 2018, <https://www.health.govt.nz/news-media/news-items/ministry-consider-risk-proportionate-regulation-vaping-and-heated-tobacco-products>.

⁴⁷ Butler, *Ministry of Health v Phillip Morris (New Zealand) Ltd*, NZDC.

deemed a failure. The regulatory policy failed by being rejected by the courts as illegal, rejected by bureaucracies as not worth enforcing, or it failed to achieve its goal to advance the fight against smoking. Next, the policy stream became primed once the public health policy community came to a consensus preference on a policy to expand access to e-cigarettes to replace the failed e-cigarette sales ban. Finally, the politics stream was primed when left-wing politicians were given permission to support a regulatory policy change favored by business groups because public health groups and health bureaucracies agreed that the alternative policy was preferable to the old. This freed right-wing politicians to support regulatory policy change without facing a political penalty. As regulatory policy change is not typically an important issue for voters, a permission structure had to be created that allowed all politicians to agree to the policy community's consensus alternative regulatory policy, insulating politicians from electoral consequences. Once left-wing politicians, right-wing politicians, public health non-governmental organizations, tobacco companies, e-cigarette companies, and government bureaucrats concluded that they would benefit more from the adoption of the alternative regulatory policy than if they defended the failed policy, a policy window to change the failed e-cigarette regulatory framework opened.

7.2 Framing the Regulatory Framework

Each country's bureaucracy and public health policy community coalesced around a framing for their regulatory stance for nicotine-containing e-cigarettes. Australia chose to describe their policy as a "precautionary approach". Canada chose to describe its regulatory policy as a "balanced approach". New Zealand describes its policy approach as "risk-proportionate regulation". Policy community participants from each country were in constant contact with one another and were keenly aware of what the others were doing and saying on e-cigarette regulatory matters. Therefore, comparing these framings may be a useful exercise.

The consistency of how each country's policy community defined their approach was perhaps more enlightening than the fact that their framings diverged. Canadians were consistently able to point out that a "balanced approach" to regulating the e-cigarette market meant preserving access to reduced risk products should be preserved for adults, while efforts to decreasing access and

uptake for youth.⁴⁸ The fact that these access goals were in tension with one another was always recognized and brought forwards as an ongoing challenge to policymakers.

New Zealanders were consistently able to define “risk-proportionate regulation” as a strategy of regulatory policies that applied harsher (more contractionist) rules to more dangerous products.⁴⁹ The implementation of a strategy of “risk-proportionate regulation” could differ markedly, however. Tobacco companies preferred that risk-proportionate regulation meant exempting e-cigarettes from the contractionist regulatory policies already in place for tobacco cigarettes. Many in the public health policy community interpreted a risk-proportionate regulation strategy as justifying imposing ever-harsher contractionist regulatory policies on tobacco cigarettes while subjecting e-cigarettes to a modicum of regulatory policies that were harsher than the typical consumer product.

The term “precautionary approach” is consistently used to describe Australian e-cigarette regulatory policy.⁵⁰ This language was agreed upon as an official descriptor of national policy at a November 2017 meeting of the Council of Australian Governments.⁵¹ Attempts to define what the descriptor means beyond the tautological are varied in their results. Some described precautionary policy as simply having a premarket approval system.⁵² Others defined precaution as the concept that novel products with unknown risks merit caution from policymakers, as the classic precautionary principle asks, instead of assuming that novelty implies harm minimization.⁵³ Each definition makes the case that the pre-existing medicines, therapeutics, and consumer goods framework is a precautionary regulatory policy. Medicines require proof of safety and efficacy before receiving pre-market approval. In a related sense, the poisons standard is an even purer application of the precautionary principle because poisons are de-scheduled once safety is established. The precautionary approach was baked into the pre-existing policy framework wherein e-cigarettes were assumed to not be legal for sale instead of being assumed to be legal. Thus, the characterization of premarket approval as the keystone of the policy in the framework seems appropriate. Premarket approval has maintained a prohibitionist stance

⁴⁸ Van Loon, “Canada’s Approach to Vaping Products: Responding to Youth Vaping Rates.”

⁴⁹ “Ministry to Consider Risk-Proportionate Regulation for Vaping and Heated Tobacco Products.”

⁵⁰ Australian Government Department of Health Therapeutic Goods Administration, “Electronic Cigarettes.”

⁵¹ AI @ 30; Australian Department of Health, “E-Cigarettes,” Commonwealth of Australia, October 31, 2017, <https://bit.ly/2xLBnOP>.

⁵² AH @ 34; AL @ 10

⁵³ AJ @ 9

towards nicotine-containing e-cigarettes in Australia because no product has qualified for expansionist treatment under the therapeutic pathway.

The chosen framing of each regulatory approach reflects the philosophy, goals, and fears of each case country. Efforts to avoid making one error (causing an uptake in youth vaping) may outweigh concerns to avoid making a different error (not providing cessation support for adult smokers). Australia's framing purports to avoid making the first error in favor of committing the second. New Zealand's framing attempts to correct for the second error. Canada's framing tries to address both errors at once.

The acknowledgment of the need to help adult smokers quit smoking has never been lost on Australians. The key issue we have learned is that the issue of continued adult smoking is not considered an issue acute enough to address by changing e-cigarette regulation. Australia's general satisfaction with the progress it has made against smoking has caused it to jealously protect those gains. Preserving their progress became the Australian goal.

By contrast, the New Zealand framing belies frustration with tobacco control progress. A belief that the status quo is inadequately serving New Zealand adults, particularly those of Māori descent, drives the need to risk limited youth e-cigarette uptake to expand adult tobacco smoking cessation.⁵⁴ New Zealand is in near full compliance with the tobacco control policy recommendations of the WHO FCTC.⁵⁵ And yet, the country is still seeing tobacco cigarette smoking prevalence in Māori women (36% in 2019) that exceeds anything ever observed in Australian, American, or French women during the height of the popularity of smoking in the 20th century.⁵⁶ The public health policy community felt the need to look for innovative solutions, and risk-proportionate regulation stood apart as the solution they could sell to policymakers.

As no large shift in the language used to describe a regulatory framework has yet occurred in a case country, we cannot know if the framing is antecedent to the taking of a regulatory stance. In Canada, mentions of a balanced approach to e-cigarette regulation only began cropping up after the introduction of Bill S-5.⁵⁷ In New Zealand, the Ministry of Health only began to describe the

⁵⁴ Edwards, "Endgames and Smokefree Aotearoa 2025 Update."

⁵⁵ World Health Organization, *WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2019: Offer Help to Quit Tobacco Use*.

⁵⁶ Forey et al., "International Smoking Statistics: Web Edition"; NZ Ministry of Health, "Indicator: Current Smokers."

⁵⁷ Seidman and Philpott, Issue No. 21 - Evidence - April 12, 2017.

goal for e-cigarette regulation as “risk-proportionate” after the public health policy community lobbied them to adopt such an approach.⁵⁸ A shift in the framing of the goal of regulation in these cases likely belied a shift in intent or strategy that was in progress. Paying attention to framing then can help determine how a regulatory stance is likely to shift, although determinative policy choices may be expressed in the details outside of policymaker’s rhetoric and evaluated through changes in market outcomes.

7.3 EVALI

A Global Focusing Event and a Test of Lessons Learned

In August of 2019, reports of young people who had used e-cigarettes before turning up in the intensive care units of Midwestern US hospitals began spreading through American media.⁵⁹ These young people were suffering from a syndrome of pneumonia-like lung injuries that were not traceable to any microbial source, yet all of them had reported recently using e-cigarettes.⁶⁰ These hospitalizations were shortly followed by reports of the first-ever deaths known to be caused by vaping.⁶¹

In the scramble to identify the cause of the outbreak, a key detail kept on being articulated in an inartful manner to the public; that most of the people falling ill from this new syndrome had been using their e-cigarettes to ingest tetrahydrocannabinol (THC), the primary psychoactive compound in cannabis.⁶² By October, the US Centers for Disease Control and Prevention (CDC)

⁵⁸ Richard Edwards et al., “‘Achieving Smokefree Aotearoa by 2025’: A Response to Critiques,” *Public Health Expert, University of Otago* (blog), October 6, 2017, <https://blogs.otago.ac.nz/pubhealthexpert/2017/10/06/achieving-smokefree-aotearoa-by-2025-a-response-to-critiques/>; “Ministry to Consider Risk-Proportionate Regulation for Vaping and Heated Tobacco Products.”

⁵⁹ Stephen S. Hall, “Who Thought Sucking on a Battery Was a Good Idea?,” *Intelligencer*, February 4, 2020, <https://nymag.com/intelligencer/2020/02/vaping-health-crisis.html>; Isaac Ghinai et al., “E-Cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury — Illinois and Wisconsin, April–September 2019,” *Morbidity and Mortality Weekly Report* 68, no. 39 (October 4, 2019): 865–69, <https://doi.org/10.15585/mmwr.mm6839e2>.

⁶⁰ “2019 Lung Injury Surveillance Primary Case Definitions” (Atlanta, GA: US Centers for Disease Control and Prevention, September 18, 2019), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/assets/2019-Lung-Injury-Surveillance-Case-Definition-508.pdf.

⁶¹ This excludes deaths caused by e-cigarette battery explosions. “First Death Linked to Vaping Reported in US,” *BBC News*, August 24, 2019, sec. US & Canada, <https://www.bbc.com/news/world-us-canada-49452256>.

⁶² Joe Neel, “CDC Says Number Of Possible Cases Of Vaping-Related Lung Illness Has Doubled,” *NPR.org*, September 6, 2019, <https://www.npr.org/sections/health-shots/2019/09/06/758337583/cdc-says-number-of-possible-cases-of-vaping-related-lung-illness-has-doubled>.

had deemed the syndrome, E-cigarette, or Vaping, product use Associated Lung Injury (EVALI), a name that implied that using any e-cigarette product could cause the syndrome.⁶³

A month before the naming of EVALI, questions about the inclusion of a novel additive, Vitamin E Acetate, to illicitly sourced THC cartridges began being bandied about as a supposed cause of the syndrome.⁶⁴ Vitamin E Acetate was added to THC cartridges by cost-cutting manufacturers who would purport that their products contained more THC than they did because Vitamin E Acetate increased the viscosity of the liquid like THC.⁶⁵ Eventually, the CDC came to agree that EVALI could be attributed in almost every case to an illicitly supplied THC product that was laced with Vitamin E Acetate or similar compounds.⁶⁶ In response, the FDA and Drug Enforcement Agency confiscated the websites of retailers who sold Vitamin E Acetate-laced vaping products.⁶⁷ Law enforcement officials at the state and local level seized suspect cartridges from manufacturers and arrested distributors.⁶⁸ These actions would take some time to affect the outbreak.

EVALI cases began to mount as an unnervingly young cohort of patients began turning up at hospitals and being treated for pneumonia-like symptoms.⁶⁹ In response, media attention focused on e-cigarettes in an unprecedented manner. A tally of stories about e-cigarettes in the national media of the case study countries along with the United States is summarized in Figure 15.⁷⁰ We

⁶³ Using a name like NVALI or TVALI to designate which substance, nicotine or THC, was responsible for the outbreak was possible but CDC did not choose that option David A. Siegel, “Update: Interim Guidance for Health Care Providers Evaluating and Caring for Patients with Suspected E-Cigarette, or Vaping, Product Use Associated Lung Injury — United States, October 2019,” *MMWR. Morbidity and Mortality Weekly Report* 68 (2019), <https://doi.org/10.15585/mmwr.mm6841e3>; Michael McGrady, “EVALI and Risk Communication, Explained,” Vaping Post, October 21, 2019, <https://www.vapingpost.com/2019/10/21/evali-and-risk-communication-explained/>.

⁶⁴ David Downs, “Amid Vape Pen Lung Disease Deaths: What Exactly Is Vitamin E Oil?,” *Leafly* (blog), September 11, 2019, <https://www.leafly.com/news/health/vape-pen-lung-disease-vitamin-e-oil-explained>.

⁶⁵ Marissa Wenzke and David Downs, “From ‘Veronica Mars’ to Toxic Vapes: The Rise and Fall of Honey Cut,” *Leafly* (blog), November 8, 2019, <https://www.leafly.com/news/health/toxic-vaping-vapi-evali-lung-injury-rise-and-fall-of-vitamin-e-oil-honey-cut>.

⁶⁶ Kathleen P. Hartnett et al., “Syndromic Surveillance for E-Cigarette, or Vaping, Product Use–Associated Lung Injury,” *New England Journal of Medicine* 0, no. 0 (December 20, 2019): null, <https://doi.org/10.1056/NEJMSr1915313>.

⁶⁷ Office of the Commissioner, “FDA, DEA Seize 44 Websites Advertising Sale of Illicit THC Vaping Cartridges to US Consumers as Part of Operation Vapor Lock,” FDA, December 20, 2019, <http://www.fda.gov/news-events/press-announcements/fda-dea-seize-44-websites-advertising-sale-illicit-thc-vaping-cartridges-us-consumers-part-operation>.

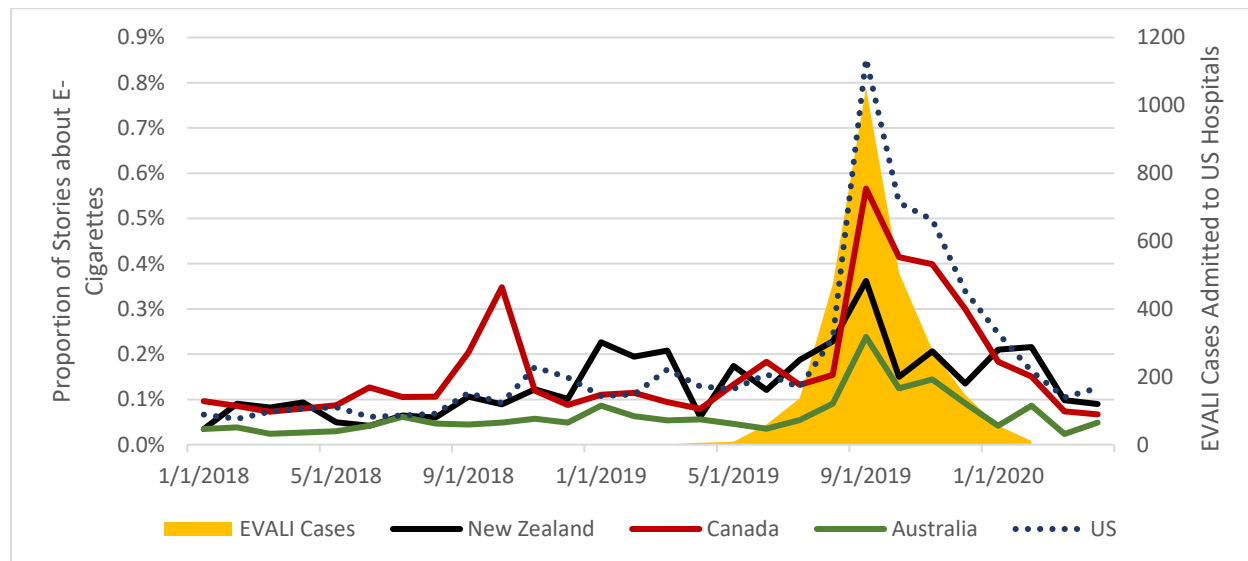
⁶⁸ Joanne Taylor et al., “Characteristics of E-Cigarette, or Vaping, Products Used by Patients with Associated Lung Injury and Products Seized by Law Enforcement — Minnesota, 2018 and 2019,” *Morbidity and Mortality Weekly Report* 68, no. 47 (November 29, 2019): 1096–1100, <https://doi.org/10.15585/mmwr.mm6847e1>.

⁶⁹ Isaac Ghinai, “Characteristics of Persons Who Report Using Only Nicotine-Containing Products Among Interviewed Patients with E-Cigarette, or Vaping, Product Use–Associated Lung Injury — Illinois, August–December 2019,” *MMWR. Morbidity and Mortality Weekly Report* 69 (2020), <https://doi.org/10.15585/mmwr.mm6903e1>.

⁷⁰ Performed using the MediaCloud tool. MIT Center for Civic Media and Berkman Klein Center for Internet & Society, “Media Cloud,” Media Cloud, 2020, <https://mediacloud.org>.

can see that the beginning of the outbreak, September 2019, marked the high-water point for media attention about e-cigarettes in every country. In the US, almost 4500 news stories were written that month about e-cigarettes. Canada, who was suffering a smaller EVALI outbreak than the US saw media interest in e-cigarettes spike nearly as high as the US. Australia and New Zealand paid considerably less attention to the story than the North American countries.

Figure 15: EVALI Hospital Admissions and National Media Attention to e-Cigarettes as a Proportion of all Stories by Country (January 2018 to April 2020)



When the first deaths caused by EVALI began occurring in late August, EVALI had become a problem to which policymakers had to respond.⁷¹ The CDC, Campaign for Tobacco Free-Kids, and many other American public health organizations began leveraging the crisis to push for contractionist regulatory stances towards nicotine e-cigarettes, even though those products were not directly at fault for the injuries and deaths.⁷² Michigan was the first state to move. Governor Whitmer announced that she would be issuing an executive order that temporarily banned the sale of flavored e-cigarettes on September 4th.⁷³ The states of New York, Montana, Washington, Oregon, and New Jersey followed soon afterward issuing executive orders temporarily banning the sale of e-cigarettes with non-tobacco flavors while Massachusetts banned sales of all e-

⁷¹ Matt Richtel and Sheila Kaplan, “First Death in a Spate of Vaping Sicknesses Reported by Health Officials,” *The New York Times*, August 23, 2019, sec. Health, <https://www.nytimes.com/2019/08/23/health/vaping-death-cdc.html>.

⁷² Ronald Bayer et al., “Risk And Reason: Australia, England, And The US E-Cigarette Crisis Of 2019,” *Health Affairs Blog* (blog), April 22, 2020, <https://doi.org/10.1377/hblog20200407.144029>.

⁷³ Angelica LaVito, “Michigan Becomes First State to Ban Sales of Flavored E-Cigarettes,” *CNBC*, September 4, 2019, <https://www.cnn.com/2019/09/04/michigan-bans-sales-of-flavored-e-cigarettes-restricts-vaping-marketing.html>.

cigarettes, regardless of flavoring.⁷⁴ Governors and legislators across the US political spectrum applauded these moves, as majorities of voters in both political parties stated their agreement with a flavored e-cigarette ban.⁷⁵

The President of the United States, Donald Trump, then stepped into the EVALI fray by stating that a federal ban on the sale of flavored e-cigarettes was under consideration on September 11th.⁷⁶ The solution closest at hand, it seems was a replication of the gubernatorial policies banning on the sale of flavored e-cigarettes, even though this solution did little to directly address the problem of tainted THC vaping products. As Trump's policy simply mimicked the actions taken by Governor Whitmer the week prior, the garbage can model of organizational choice (of which Kingdon's Multiple Streams Approach is a close descendant) seems to be a useful metaphor in this instance.⁷⁷ Trump's proposed flavor ban was well-received by American political elites.⁷⁸

Soon after Trump spoke up on the matter, state courts began to strike down several of the executive orders that served as inspiration for the president⁷⁹. Governor Whitmer's order was only in effect for a few weeks as a state judge issued a preliminary injunction against the policy citing the irreparable harm it would do to the state's e-cigarette retailers in October.⁸⁰ The bans

⁷⁴ "US Regulatory Tracker: State Executive Orders Banning Flavours," *ECigIntelligence* (blog), April 16, 2020, <https://ecigintelligence.com/regulatory-tracker-us-state-executive-orders/>.

⁷⁵ Lunna Lopes et al., "Data Note: Public Views on Vaping and E-Cigarettes," *The Henry J. Kaiser Family Foundation* (blog), October 17, 2019, <https://www.kff.org/other/issue-brief/data-note-vaping-and-e-cigarettes/>.

⁷⁶ Audrey McNamara, "Trump Administration Considering Ban on Flavored E-Cigarettes," *The Daily Beast*, September 11, 2019, <https://www.thedailybeast.com/trump-administration-considering-ban-on-flavored-e-cigarettes>.

⁷⁷ Michael D. Cohen, James G. March, and Johan P. Olsen, "A Garbage Can Model of Organizational Choice," *Administrative Science Quarterly* 17, no. 1 (1972): 1–25, <https://doi.org/10.2307/2392088>.

⁷⁸ Nicole Vas, "Lawmakers Applaud Trump's Ban on Flavored e-Cigarettes," *Text, TheHill*, September 11, 2019, <https://thehill.com/policy/healthcare/461017-lawmakers-applaud-trumps-ban-on-flavored-e-cigarettes>.

⁷⁹ Rhode Island's policy became permanent via executive order, while New York and Massachusetts passed legislation codifying bans on the sale of flavored tobacco products (including both tobacco cigarettes and e-cigarettes). NBC 10 NEWS, "RI's Ban on Flavored Vape Products Becomes Permanent," *WJAR*, March 26, 2020, <https://turnto10.com/news/local/ris-ban-on-flavored-e-cigs-becomes-permanent>; Melanie Lekocevic, "State Bans Flavored Vaping Products," *The Daily News*, April 12, 2020, https://www.thedailynewsonline.com/top_story/state-bans-flavored-vaping-products/article_43a406e3-5838-50ee-b5e9-ea36acb3e56b.html; Vanessa Romo, "Massachusetts Governor Signs Law Severely Restricting Flavored Tobacco, Vape Products," *NPR.org*, November 27, 2019, <https://www.npr.org/2019/11/27/783400051/massachusetts-governor-signs-law-severely-restricting-flavored-tobacco-vape-prod>.

⁸⁰ Scott McClallen, "Michigan Supreme Court Declines to Restore Ban on Flavored Nicotine Vaping Products," *Detroit Metro Times*, January 3, 2020, <https://www.metrotimes.com/news-hits/archives/2020/01/03/michigan-supreme-court-declines-to-restore-ban-on-flavored-nicotine-vaping-products>.

in New York and Oregon were also struck down on similar grounds.⁸¹ Only Montana's temporary ban survived court scrutiny.⁸²

By mid-November, President Trump ended up backing off the plan to institute a comprehensive ban on the sale of flavored e-cigarettes, largely in response to a pressure campaign mounted by e-cigarette users, manufacturers, and retailers.⁸³ His administration ended up advancing a much more narrowly tailored policy restricting the sale of flavored e-cigarettes to certain form factors of e-cigarettes (disposable and open systems).⁸⁴ On January 17, 2020, Trump even sent a briefing on the nascent coronavirus outbreak in Wuhan, China from Health and Human Services Secretary Alex Azar off course to excoriate Azar for pushing him to respond to EVALI exclaiming, "I never should have done this f***** vaping thing!"⁸⁵ Trump viewed his administration's actions to advance a contractionist e-cigarette policy as a losing political proposition that antagonized his supporters and rewarded his political opponents.⁸⁶

The combined effects of enforcement actions, public health campaigns warning the public about EVALI, and changing the behavior of THC product manufacturers all contributed to an environment that brought the outbreak to a speedy end. More Americans began to believe that e-cigarettes were more hazardous to one's health than tobacco cigarettes.⁸⁷ By the time the outbreak of illnesses had peaked and then subsided in early 2020, every US state, the District of

⁸¹ Kandra Kent, "Oregon Judge Thwarts Temporary Ban on Flavored Nicotine E-Liquids," KPTV.com, October 17, 2019, https://www.kptv.com/news/oregon-judge-thwarts-temporary-ban-on-flavored-nicotine-e-liquids/article_a5b0a592-f135-11e9-9f2f-cf4c2a60bcb1.html; Brendan J. Lyons, "Judge Strikes down New York's Ban on Flavored Vaping Products," Times Union, January 11, 2020, <https://www.timesunion.com/news/article/Judge-strikes-down-New-York-s-ban-on-flavored-14967736.php>.

⁸² Associated Press, "Judge Approves Temporary Ban on Flavored E-Cigarettes," KECI, December 18, 2019, <https://nbcmontana.com/news/local/judge-approves-temporary-ban-on-flavored-e-cigarettes>.

⁸³ Megan Theilking and Nicholas Florko, "Trump's Stalling on Vaping Issue Raises Fear of Lasting Health Consequences," STAT (blog), November 19, 2019, <https://www.statnews.com/2019/11/19/trumps-stalling-on-flavored-vape-ban-draws-blowback-and-fears-of-lasting-damage-to-american-health/>; Angelica LaVito, "Vape Shop Owners on Edge While Trump Administration Wavers on Banning Flavored E-Cigarettes," CNBC, November 14, 2019, <https://www.cnbc.com/2019/11/14/vape-shop-owners-await-trumps-decision-on-banning-flavored-e-cigarettes.html>.

⁸⁴ Jane Weaver and Lauren Dunn, "FDA Pulls Most Fruity and Minty E-Cigarettes Flavors, but Menthol and DIY Still Available," NBC News, January 2, 2020, <https://www.nbcnews.com/health/vaping/some-flavored-e-cigarette-pods-be-pulled-market-except-menthol-n1109531>.

⁸⁵ Gabriel Sherman, "Inside Donald Trump and Jared Kushner's Two Months of Magical Thinking," Vanity Fair, April 28, 2020, <https://www.vanityfair.com/news/2020/04/donald-trump-jared-kushners-two-months-of-magical-thinking>.

⁸⁶ E. J. Dickson, "The Vaping Industry Is Furious at President Trump -- Could It Cost Him the Election?," *Rolling Stone* (blog), November 11, 2019, <https://www.rollingstone.com/culture/culture-features/vaping-rally-washington-dc-donald-trump-flavors-ban-910474/>.

⁸⁷ Dhaval M Dave et al., "News That Takes Your Breath Away: Risk Perceptions During an Outbreak of Vaping-Related Lung Injuries," Working Paper, Working Paper Series (National Bureau of Economic Research, April 2020), <https://doi.org/10.3386/w26977>.

Columbia, the US Virgin Islands, Puerto Rico, and six Canadian provinces had seen EVALI cases, almost 3000 in total.⁸⁸ As of February 2020, 68 people had died in the EVALI outbreak.⁸⁹

After EVALI had begun to recede, US public health officials began to admit that EVALI had been conflated with a distinctly different health problem of youth e-cigarette use.⁹⁰ Nicotine-containing e-cigarette use among US youth had been rising since the introduction and exponential expansion of the JUUL brand in 2016 and 2017.⁹¹ In 2018 and 2019, the two largest-ever one-year increases in youth substance use in the US were recorded in the Monitoring the Future Survey for nicotine and marijuana vaping.⁹² Young people in the US were using more and more vaping products every year, data confirming this increase in substance use was reported to federal officials at the same moment when EVALI was spiking in the public's attention.⁹³ Removing flavored e-cigarettes from the US market was a much more plausibly connected policy response to youth use than to EVALI. Flavored e-cigarettes have been found to be attractive to youth.⁹⁴ E-cigarette industry-led responses to address sales of favored e-cigarettes have been found to be inadequate to address this issue.⁹⁵ The conflation of the EVALI crisis with a youth e-cigarette usage problem advanced a policy solution that addressed the latter problem instead of the former.

⁸⁸ Krishnasamy, "Update"; Public Health Agency of Canada, "Vaping-Associated Lung Illness," alerts, aem, February 13, 2020, <https://www.canada.ca/en/public-health/services/diseases/vaping-pulmonary-illness.html>.

⁸⁹ CDC's Office on Smoking and Health, "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," Centers for Disease Control and Prevention, February 25, 2020, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

⁹⁰ Brian A. King et al., "The EVALI and Youth Vaping Epidemics — Implications for Public Health," *New England Journal of Medicine*, January 17, 2020, <https://doi.org/10.1056/NEJMp1916171>.

⁹¹ Jidong Huang et al., "Vaping versus JUULing: How the Extraordinary Growth and Marketing of JUUL Transformed the US Retail e-Cigarette Market," *Tobacco Control* 28, no. 2 (March 2019): 146–51, <https://doi.org/10.1136/tobaccocontrol-2018-054382>; David Hammond et al., "Use of JUUL E-Cigarettes Among Youth in the United States," *Nicotine & Tobacco Research* 22, no. 5 (April 21, 2020): 827–32, <https://doi.org/10.1093/ntr/nty237>.

⁹² Nicholas Prieur, "National Adolescent Drug Trends in 2018," Institute for Social Research, December 17, 2018, <https://isr.umich.edu/news-events/news-releases/national-adolescent-drug-trends-in-2018/>; "2019 Monitoring the Future Survey Raises Worries about Teen Marijuana Vaping," National Institute on Drug Abuse, December 18, 2019, <https://www.drugabuse.gov/about-nida/noras-blog/2019/12/2019-monitoring-future-survey-raises-worries-about-teen-marijuana-vaping>.

⁹³ Angelica LaVito, "CDC Says Teen Vaping Surges to More than 1 in 4 High School Students," CNBC, September 12, 2019, <https://www.cnbc.com/2019/09/12/cdc-says-teen-vaping-surges-to-more-than-1-in-4-high-school-students.html>.

⁹⁴ Nicholas I. Goldenson et al., "A Review of the Use and Appeal of Flavored Electronic Cigarettes," *Current Addiction Reports* 6, no. 2 (June 2019): 98–113, <https://doi.org/10.1007/s40429-019-00244-4>; Leventhal et al., "Flavored E-Cigarette Use and Progression of Vaping in Adolescents."

⁹⁵ Alex Liber et al., "Flavored E-Cigarette Sales in the United States Under Self-Regulation From January 2015 Through October 2019," *American Journal of Public Health*, April 16, 2020, e1–3, <https://doi.org/10.2105/AJPH.2020.305667>.

A confluence of problem, vaping-caused illness of mysterious origins and rising youth e-cigarette use, and policy response, removing flavored e-cigarettes from retail, met with receptive politicians who wanted appear to be “doing something” in a policy window to produce scads of new contractionist policies targeted at e-cigarettes in the US. EVALI, more than representing a straightforward extension of regulatory path dependence⁹⁶, served as the impetus for flexing regulatory power by US governors and bureaucrats. EVALI’s effects were concentrated in the US, and to a lesser extent, Canada, but the paths taken by officials represented what was bounded by the solutions available at hand as well as what was perceived to be politically possible. Canada’s experience illustrates how officials tasked with expanded regulatory power leveraged EVALI as a catalyst to flex their newfound regulatory powers to roll back the recent adoption of an expansionist regulatory stance. The experience of New Zealand and Australia with EVALI served to rededicate each country’s bureaucracy to the regulatory stances it was already pursuing. What follows is a short description of how each country reacted to this momentous focusing event that occurred after the completion of the fieldwork for this study.

7.3.1 EVALI in Canada

The Federal Liberal Party of Canada sought re-election in mid-2019 in the aftermath of the SNC-Lavalin affair and reduced enthusiasm about the Prime Minister.⁹⁷ The campaign paid little attention to the matter of e-cigarette regulation as no party manifesto touched on the subject. As the trouble with EVALI began stirring up the political response to e-cigarettes south of the Canadian border, party leaders were asked their opinions on the matter of e-cigarette regulation and none would commit to policy action.⁹⁸ By the 2019 election, NDP voters reported less net support for a ban on flavored e-cigarette sales or a temporary ban on sales of all e-cigarettes than did Liberal or Conservative voters.⁹⁹ The Liberal Party ended up winning a smaller share of seats

⁹⁶ As suggested in Bayer et al., “Risk And Reason.”

⁹⁷ Zack Beauchamp, “Justin Trudeau’s Liberals Won Canada’s Election,” Vox, October 21, 2019, <https://www.vox.com/policy-and-politics/2019/10/21/20926201/canada-election-results-2019-justin-trudeau-wins>.

⁹⁸ Alanna Rizza, “Flavoured E-Cigarette Ban Enters Discussion on Federal Election Campaign Trail,” Federal Election 2019, September 12, 2019, <https://election.ctvnews.ca/flavoured-e-cigarette-ban-enters-discussion-on-federal-election-campaign-trail-1.4590699>.

⁹⁹ Mario Canseco, “Three-in-Four Canadians Back Temporary Ban on Vaping Products,” Research Co., November 13, 2019, <https://researchco.ca/2019/11/13/vaping-canada-2019/>. Net support for flavor ban; Liberal + 43, Conservative +37, NDP +10. Net support for a temporary ban on sales of e-cigarettes (framed as similar to the emergency ban by Massachusetts Governor Charlie Baker in October 2019); Liberal +70, Conservative +64, NDP +55.

than in 2015, enabling Justin Trudeau to form a minority government that had to share power with smaller rivals to advance legislation.¹⁰⁰

The media's portrayal of e-cigarettes soured further as 2019 wore on. In the aftermath of the EVALI scare, some public health activists, like Neil Collishaw of Physicians for a Smoke-Free Canada, began publicly scolding the thinking that led to the passage of Bill S-5 by characterizing the enthusiasm for harm reduction as a "suspension of critical thinking".¹⁰¹ Health Canada, for its part, was measured in its reaction to the EVALI outbreak and simply advised e-cigarette users to monitor their health while using the products.¹⁰²

EVALI news reports likely opened a policy window at the provincial level.¹⁰³ This happened even as Health Canada emphasized that ongoing efforts to change the regulatory stance towards e-cigarettes in the country would not affect the fight against EVALI.¹⁰⁴ As the federal election unfolded, a new round of provincial e-cigarette regulations was adopted to cut down on e-cigarette use among youth. Some bills seemed well-targeted to that purpose like the effort of Prince Edward Island to raise the minimum age of sale for tobacco and vaping products from 19 to 21 years of age.¹⁰⁵ Other legislative efforts, like that announced by British Columbia, seem more poised to contract the size of the e-cigarette market by altering product standards, prices, and the retail environment to make these products into less attractive and effective nicotine sources.¹⁰⁶

¹⁰⁰ Rachel Aiello, "Trudeau Vows to 'fight for All Canadians' as Liberals Win Minority Government," Federal Election 2019, October 21, 2019, <https://election.ctvnews.ca/trudeau-vows-to-fight-for-all-canadians-as-liberals-win-minority-government-1.4647438>.

¹⁰¹ Kelly Crowe, "The Road to Vaping," CBC Longform, December 2, 2019, <https://newsinteractives.cbc.ca/longform/the-road-to-vaping>.

¹⁰² Health Canada, "Information Update - Health Canada Warns of Potential Risk of Pulmonary Illness Associated with Vaping Products," Government of Canada, October 17, 2019, <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70919a-eng.php>.

¹⁰³ CBC News, "'Torrent of Addiction' of Vaping Prompts Canadian Health Groups to Call for Immediate, Effective Regulation," CBC, September 19, 2019, <https://www.cbc.ca/news/health/vaping-thursday-1.5289485>; Eric Stoher, "Health Canada Warns Vaping Carries Risk of Pulmonary Illness," Globalnews.ca, September 5, 2019, <https://globalnews.ca/news/5861425/health-canada-vaping-pulmonary-illness/>; Canadian Press, "Health Canada Confirms 2nd Case of Vaping-Related Illness in Quebec," Global News, October 25, 2019, <https://globalnews.ca/news/6081236/health-canada-vaping-illness-quebec/>.

¹⁰⁴ Public Works and Government Services Canada Government of Canada, "Vaping Products Promotion Regulations."

¹⁰⁵ Kerry Campbell, "Age to Buy Tobacco, Vapes on P.E.I. to Increase March 1," CBC, February 12, 2020, <https://www.cbc.ca/news/canada/prince-edward-island/pei-age-vaping-tobacco-increase-1.5460938>.

¹⁰⁶ Christopher Labos, "British Columbia's Vaping Crackdown Could Offer a Roadmap for the Rest of the World," The Conversation, December 5, 2019, <http://theconversation.com/british-columbias-vaping-crackdown-could-offer-a-roadmap-for-the-rest-of-the-world-128378>.

Enthusiasm to change Canada's regulatory stance towards e-cigarettes into something more contractionist is building, especially at the provincial level.¹⁰⁷ The presence of credible policy entrepreneurs hawking politically acceptable solutions across partisan divides like excise taxes, stricter marketing rules, and more stringent rules around product standards as a solution to the identified problems, leads one to conclude the Canadian regulatory framework for e-cigarettes has not reached an evolutionary endpoint.¹⁰⁸

7.3.2 EVALI in New Zealand

New Zealand was in the middle of writing draft legislation to reform their e-cigarette regulatory stance when EVALI unfolded in the US. The attention garnered by the issue of e-cigarette use in the New Zealand media was significant, even though not a single Kiwi was harmed by the outbreak. Videos of American teenagers sitting in hospital beds stating that they had wished they had never picked up a vape were broadcast in New Zealand.¹⁰⁹

Just before the outbreak came into focus, the Minister of Health was promising to deliver e-cigarette regulatory reform legislation in October 2019 that would eliminate most flavors, cap nicotine levels, and eliminate marketing of e-cigarettes.¹¹⁰ PM Ardern promised in November that legislation that would protect young people from becoming addicted to e-cigarettes was "coming soon".¹¹¹ By the time that the promised e-cigarette regulatory legislation appeared in February 2020, Ardern explained that the delay was attributable to the back-and-forth exercise that her government had engaged in with a bureaucracy that wanted to preserve access to e-cigarettes for adult smokers.¹¹²

¹⁰⁷ Canadian Press, "Here's How Vaping Is Regulated in Each Province," Global News, November 20, 2019, <https://globalnews.ca/news/6194275/vaping-regulations-canada-provinces/>.

¹⁰⁸ Michael Gorman, "Proposed Ban on Flavoured Vape Products Raises Concerns among Users, Industry," CBC, March 5, 2020, <https://www.cbc.ca/news/canada/nova-scotia/vaping-smoking-e-cigarettes-health-care-1.5487385>; Michael Gorman, "Nova Scotia Signs off on Stiffest Vaping Regulations in Canada," CBC, May 11, 2020, <https://www.cbc.ca/news/canada/nova-scotia/health-care-government-regulations-vaping-nicotine-1.5564215>; CBC News, "Province Wants to Discourage Youth from Vaping through 20% Retail Tax," CBC, March 2, 2020, <https://www.cbc.ca/news/canada/edmonton/alberta-20-per-cent-vaping-tax-1.5481923>.

¹⁰⁹ "Vaping Is 'a Real Danger' and Needs Regulation," Stuff, September 14, 2019, <https://www.stuff.co.nz/national/health/115805702/vaping-is-a-real-danger-and-needs-regulation>.

¹¹⁰ "Vaping Flavours, Colours and Marketing in Government's Firing Line"; Vita Molyneux, "US Vaping Death Sparks Fears Kiwis Will Swap E-Cigarettes for Real Ones," *Newshub*, August 26, 2019, sec. NZ, <https://www.newshub.co.nz/home/new-zealand/2019/08/us-vaping-death-sparks-fears-kiwis-will-swap-e-cigarettes-for-real-ones.html>.

¹¹¹ Cheng, "Jacinda Ardern Says Vaping Laws Must Protect Young People."

¹¹² "Jenny Salesa Defends Delay to Release Vaping Legislation."

The policies that were put forward in the Smokefree Environments and Regulated Products (Vaping) Amendment bill of 2020 were less restrictive than the ideas being bandied about in public before the EVALI outbreak.¹¹³ E-cigarettes could be sold in almost any flavor in adult-only vape shops, no cap on nicotine was introduced, and marketing was restricted in almost every manner with a notable exemption of public health campaigns that would encourage smokers to switch.¹¹⁴ That EVALI did not cause a retrenchment towards a more contractionist policy in New Zealand is notable. The policy development process continued behind closed doors in a controlled environment. Bureaucrats did not have to respond to imminent threats to the health of young people and politicians felt no pressure to “do something” about EVALI. Instead, New Zealand acted in a manner that understood EVALI was not caused by nicotine-containing e-cigarettes and that contractionist policies towards that market were unlikely to solve that public problem.

7.3.3 EVALI in Australia

Across the Tasman, September of 2019 provided plenty of fodder for the Australian national media and Commonwealth government to justify its current regulatory stance towards e-cigarettes. The pictures of sick and sad American teenagers swearing they should have never started vaping served to justify that Australia’s precautionary approach had been the right choice all along.¹¹⁵ As in the US, the role of THC-containing products in the EVALI outbreak was not prominently mentioned in Australian media coverage of the outbreak.¹¹⁶ An e-cigarette was an e-cigarette. Heated tobacco was mixed up with nicotine-containing e-cigarettes in the original push for regulatory policy change, and EVALI mixed up the misfortune of THC e-cigarette users with nicotine-containing e-cigarette users. Media framing of the continuing push from THR advocates to ask the government to reconsider its stance on e-cigarette regulation

¹¹³ Salesa, Smokefree Environments and Regulated Products (Vaping) Amendment Bill.

¹¹⁴ Melville, “Smokefree Environments and Regulated Products (Vaping) Amendment Bill 2020.”

¹¹⁵ Conor Duffy, John Mees, and Ryan Chatterjee, “US Vaping Deaths Are on the Rise. Here’s How One Teen Narrowly Survived - ABC News,” ABC, September 21, 2019, <https://www.abc.net.au/news/2019-09-22/how-one-teen-survived-vaping-related-illness/11535282>.

¹¹⁶ Coral Gartner, Billie Bonevski, and Wayne Hall, “Miscommunication about the Causes of the US Outbreak of Lung Diseases in Vapers by Public Health Authorities and the Media,” *Drug and Alcohol Review* 39, no. 1 (2020): 3–6, <https://doi.org/10.1111/dar.13024>.

shifted from cynicism to something more sinister as it was juxtaposed against the EVALI outbreak.¹¹⁷

EVALI further entrenched the negative perception of e-cigarettes by politicians from the left and right-wings of Australian politics.¹¹⁸ A spokesperson for Health Minister Hunt emphasized that the government maintained “a strict commitment to opposing vaping or any liberalization on laws”.¹¹⁹ Hunt directed Australia’s medicines regulator to strengthen its partnership with customs officials to crack down harder on illicit importation of nicotine liquid.¹²⁰ Questions about the relative risk of e-cigarettes compared to tobacco cigarettes evaporated as focus on a condition that could kill in weeks instead of years became the focus of concerned parents and politicians. Mentions of liberalizing e-cigarette regulations disappeared from Parliamentary records in its aftermath. Australia’s public health policy community already viewed its tobacco control issue as being under control before EVALI. After seeing peer countries with legal e-cigarette markets suffer from EVALI, appetites for liberalization in Australia died.

7.3.4 Summary

As a global focusing event on the topic of e-cigarette regulation, EVALI turned out to be a prism through which a country’s concerns about e-cigarettes were reflected. The scary and sudden nature of the outbreak and its choice of victim made the outbreak a salient, negative image for e-cigarette use in each case country. But, the reactions to the outbreak reflected the pre-existing problems that countries believed they needed to address. Canada’s concerns about youth uptake of e-cigarettes, Australia’s concerns about the nefarious nature of e-cigarettes as a product category, and New Zealand’s more staid and technocratic policy conversations all absorbed the EVALI news and produced a policy that was structured by the limiting conditions of each of Kingdom’s stream. Pre-existing regulatory policy, problem definition, political possibility, and policy community decisions structured and limited the scope of action each country could take as

¹¹⁷ Paul Karp, “Climate Change Concern Helped Labor at 2019 Election but Coalition Won on Economy – Survey,” *The Guardian*, December 8, 2019, sec. Australia news, <https://www.theguardian.com/australia-news/2019/dec/09/climate-change-concern-helped-labor-at-2019-election-but-coalition-won-on-economy-survey>.

¹¹⁸ Alison Bevege, “Kevin Rudd Calls for Vaping BAN in Australia Following US Health Fears,” Mail Online, September 13, 2019, <https://www.dailymail.co.uk/news/article-7459017/Kevin-Rudd-calls-vaping-BAN-Australia-health-fears-Trump-set-halt-sales.html>; Martin, “Greg Hunt Digs in on Opposition to E-Cigarettes after Vaping ‘Epidemic.’”

¹¹⁹ Dana McCauley, “Government Launches Border Crackdown on Illegal Vaping Imports,” *The Sydney Morning Herald*, February 28, 2020, <https://www.smh.com.au/politics/federal/government-launches-border-crackdown-on-illegal-vaping-imports-20200227-p544wu.html>.

¹²⁰ McCauley.

EVALI cropped up. The crisis even precipitated a decision by Indian officials who were predisposed to adopting other prohibitionist policies to officially ban the sale of e-cigarettes countrywide.¹²¹ This points to the utility of future scholarly work in this area and others within and beyond comparative regulation that examines the effect of past decisions on future focusing events.¹²²

7.4 Conclusion

This case study has pointed to the utility of the Multiple Streams Approach in breaking down the steps that led to policy change or agenda-setting into their component parts. It has enabled the sketching of a clearer picture of what led to regulatory policy change or stasis in the selected case studies. Problem definition precipitated the events that led to a policy change, wherein the status quo prohibitionist regulatory framework was rejected as being unworkable through a focusing event. The rejection of the regulatory framework enabled the public health policy community to settle on a consensus alternative regulatory policy. That consensus alternative regulatory policy was then shepherded to becoming legislation once left-wing parties came to agree with the change.

The roles that other factors highlighted here, like governmental structure and differences in ideology, might play in determining changes in other cases of regulatory policy debates, should be explored in other case studies. The vast differences in circumstance, history, and structure between jurisdictions points to the necessity of continuing to utilize qualitative comparative techniques to explain the outcomes of regulatory policy. What triggered a change in Canada and New Zealand was highly dependent on factors that are not easily summed up into a set of quantitative variables highlighting whether problem definition caused a bureaucracy to abandon an older regulatory stance. This is an inherently limiting quality of such scholarship, but the important explanatory variables found here should nonetheless be tested in other venues and cases. There are myriad examples of bureaucrats surrendering or standing up for their

¹²¹ Adi Robertson, "India Bans E-Cigarette Sales and Says There's an 'Epidemic' of Kids Vaping," *The Verge*, September 18, 2019, <https://www.theverge.com/2019/9/18/20872967/india-e-cigarette-vaping-ban-epidemic-health-risks>; Radha Sarkar and Amar Sarkar, "Sacred Slaughter: An Analysis of Historical, Communal, and Constitutional Aspects of Beef Bans in India," *Politics, Religion & Ideology* 17, no. 4 (October 1, 2016): 329–51, <https://doi.org/10.1080/21567689.2016.1259108>; "India's Bihar State Bans Alcohol," *BBC News*, April 5, 2016, sec. India, <https://www.bbc.com/news/world-asia-india-35969269>.

¹²² Scott L. Greer, "Chapter 29: John W. Kingdon, Agendas, Alternatives, and Public Policies," in *The Oxford Handbook of Classics in Public Policy and Administration*, ed. Steven J. Balla (Oxford: Oxford Univ. Press, 2015), 417–32, <http://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780199646135.001.0001/oxfordhb-9780199646135-e-18>.

enforcement duties over markets. There are myriad examples of governments failing to live up to their ambitious regulatory policy goals. Policy communities constantly disintegrate into discord or arrive at collective agreement. And politicians always seek power. The effects of these common forces should be explored in other regulatory policy contexts. The details and reasons for changes in policy differed within these cases and are sure to differ in future studies. Collecting detailed accounts of the reasoning for these changes will be a useful exercise for the study of governance and activism alike. If we can better understand why regulatory policies maintain their base of support and how they lose it, we will be better equipped to become effective reformers of broken regulatory frameworks going forward.

Chapter 8 Conclusion

This study makes two key contributions to the social science literature. First, it describes why e-cigarette regulatory policy in Canada and New Zealand changed when Australia stayed put. Second, it describes a useful lens through which regulatory policy can be compared, contrasted, and studied across markets, time, and place. While the previous chapter covers the empirical lessons learned within the narrower confines of the primary case and their immediate extensions, this chapter focuses on why these findings should matter to readers who are not focused on comparative e-cigarette regulatory policy.

Instead of comparing stringency, comprehensiveness, or styles, a regulatory stance should be preferred as a measure for comparative regulation because it focuses on comparing intent. Specifically, it compares the intent of policy to alter the size of a market within an economy in the future compared with the present. The actual stance being taken in any situation can be debated, but a chosen regulatory stance exists in every regulatory policy debate. In cases where governments truly aim to be *laissez-faire* in their regulatory policy, the regulatory stance concept can handle such a decision.¹²³ Clear comparisons can be made once regulatory policy is reduced to a parsimonious outcome variable, like a regulatory stance. Intent is measurable across markets, time, and place, thereby enabling useful comparative studies.

Additionally, the concept of intent to change the size of a market is flexible enough to apply to most regulatory policy debates concerning markets. By applying the concept of a regulatory stance, we can better understand the motive, power dynamics, and logic behind the important regulatory policy choices that shape our world. Being able to assign a regulatory stance towards a market for a given jurisdiction has several distinct benefits. By being so flexible and parsimonious, the regulatory stances concept eases and enables studies across the major dimensions of comparative regulation of jurisdiction, markets, and time.

¹²³ As a permissive stance represents a failure to state a preference for growth, this study makes the case that a neutral stance on this point is evidence of affirmative intent to not alter a market's trajectory.

The use of regulatory stances enables comparisons across markets within a jurisdiction at a point in time by bringing the rationalizations supporting such divergences to the forefront of policy conversations. Policymakers, advocates, and enforcement officials should confront these differences directly and consider why one market is subject to a contractionist stance while another market that causes more damage to consumers is subject to a permissive stance. Further work by social scientists can then be conducted on why certain policies were applied to one market and not another.¹²⁴ As in the current study, regulatory stances can be used to ask and understand why policy convergence and divergence happen within markets and across jurisdictions. Finally, as was the case in this study, a regulatory stance can be used to identify when regulatory policy shifted within a market over time and to ask why such changes occurred within a jurisdiction. The work offered in this study is then, a glimpse of what is possible with a clarifying and useful organizing concept for a complex and messy area of policy.

In the remainder of this concluding chapter, two examples of the utility of the regulatory stances concept are offered. The first case illustrates why a focus on the goal of regulatory policy is preferable to the process of passing so-called comprehensive policies. The regulatory stances concept centers policy discussions around the idea that regulation should correct market failures rather than check boxes. Second, the regulatory stances concept is invoked as a critique of the commercial determinants of health literature. The regulatory stance concept offers a clarifying perspective on a literature that is both Pollyannaish and lacking in ambition. Finally, the chapter concludes with a discussion of the largest unanswered questions raised by this study.

8.1 Powerful Policies over Comprehensive Policies

This study brought to light a certain frustration with the policy advice that is provided to activists and policymakers attempting to contain the tobacco epidemic and public health threats more broadly. In tobacco control, parties to the FCTC have been advised to adopt “comprehensive tobacco control policies”.¹²⁵ This refers to a series of evidence-based best-practices which cover

¹²⁴ For example, determining why the Canadian government has strengthened a contractionist stance towards the tobacco cigarette market while adopting a permissive stance towards the cannabis market would shed light on the different politics of governing each market, but perhaps even more broadly, illustrate how a single government can adopt different regulatory stances to broadly similar markets.

¹²⁵ World Health Organization, *WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2019: Offer Help to Quit Tobacco Use*, 26.

the gamut of policy domains that have been deemed relevant to combatting the tobacco control epidemic.

Each of the countries featured in this comparative case study (Australia, Canada, and New Zealand) has adopted almost every one of the recommended WHO policies and each country dutifully enforces those laws. To highlight a specific example, the FCTC recommends that countries raise excise taxes on tobacco cigarettes to raise prices and decrease the affordability of these products. Specifically, the FCTC recommends that 75% of the price of a pack of cigarettes be made up of taxes and that those taxes should regularly increase.¹²⁶ New Zealand and Australia have taken this recommendation to heart and have increased their cigarette prices to be the highest in the world.¹²⁷ While tobacco tax policy is still effective and is still working in these settings, the implications for health equity have become messy and uncomfortable for health advocates who no longer feel comfortable claiming that cigarettes are normatively too cheap. Despite those significant accomplishments, smoking prevalence rates remain stuck in the mid-teens and disparities within population remain as starkly present as ever.

That result brings the question of why adopting such a comprehensive policy regime remains the state-of-the-art policy advice being doled out by the WHO. We can imagine that policies which would bring smoking prevalence and the size of the tobacco market down faster is possible. Why is finding and utilizing that powerful policy not the recommendation of the WHO? I believe that a reliance on the framing concept of adopting “comprehensive policies” being the goal of regulatory policy towards the tobacco markets and others has prevented the consideration of powerful policies.

Passing individual policies only alters the profit-maximizing behavior of firms to pursue alternative strategies to continue growing sales of their most profitable product lines. This discussion about piecemeal regulation has morphed over time into the pursuit and design of comprehensive policy regimes to regulate markets. I argue that discussion of comprehensive policies is a prelude to discussions of regulatory stances. A regulatory stance is the intended goal

¹²⁶ Heikki Hiilamo and Stanton Glantz, “Limited Implementation of the Framework Convention on Tobacco Control’s Tobacco Tax Provision: Global Comparison,” *BMJ Open* 8, no. 10 (October 1, 2018): e021340, <https://doi.org/10.1136/bmjopen-2017-021340>.

¹²⁷ Money and Keegan, “Evaluation of the Tobacco Excise Increases – Final Report”; Hirono and Smith, “Australia’s \$40 per Pack Cigarette Tax Plans.”

of intervention rather than a checklist of policies to adopt. Utilizing the regulatory stances concept highlights the gap between current regulatory policy recommendations and the less-than-satisfying outcomes by pointing towards the importance of considering and testing powerful, novel policy solutions.

8.1.1 Shortcomings of a Comprehensive Policy

It might behoove activists to ask whether comprehensive policies are the ideal policies they would adopt in a vacuum, free of the considerations of politics. Comprehensive regulatory policies may address isolated market failures in a piecemeal fashion, but they do not directly answer whether the size of a market ought to change. This points to the litany of shortcomings of recommending comprehensive policies instead of recommending regulatory stances to redress market failures.

Recommendations to adopt “comprehensive policies” to regulate markets are an inherently limiting construct. They may be overly prescriptive in telling jurisdictions what actions to take and they may not adapt well to local context or capacity. The evolving definition of a comprehensive policy might frustrate jurisdictions seeking to uphold best practices. Setting comprehensiveness as the defining goal of policy development may limit creativity and experimentation. Essentially, adopting comprehensive, best-practice policies could devolve into a box-checking exercise, devoid of aim beyond fulfilling a promise to be comprehensive and to follow best-practices.

Further, the definition of what comprehensive policy is may not adapt well to different environments. The regulatory tools at the disposal of governments to regulate depends on technical capacity, a path-dependent historical context, and the political environment in which they operate. Available tools vary by jurisdiction and market context, and not every tool can be applied to every market. The best regulatory strategy for a low-capacity anocracy might differ from what is best in a medium-capacity democracy or a high-capacity technocracy. Failing to be sensitive to these differences may be setting up governments to pursue suboptimal regulatory policy on the direction of those seeking to apply a uniform comprehensive policy approach.

For example, Sacks, Swinburn, and Lawrence propose adopting a comprehensive policy framework to address rising levels of obesity by tackling upstream, midstream, and downstream

factors in rising body-mass indices around the world.¹²⁸ While this approach is meaningful in the sense that it wants to address all the causes of the obesity epidemic, it defines comprehensive as a near-exclusive consumer-centric approach to achieving that goal. The authors seek to change consumer behavior by reducing energy intake, increase energy usage, and providing a supportive environment for those behaviors. While this framework would indeed address every major cause of obesity, it disperses the responsibility to act over an entire society, reducing the culpability of parties with concentrated interests in maintaining high levels of caloric intake.

In another case, Kokubo et al., argue that adopting a comprehensive regulatory policy towards sugar-sweetened beverages entails focusing on just five policies. None of these policies seem likely to dramatically cut the size of the sugar sweetened beverage market. They recommend that removing such beverages from school, leveraging an excise tax, restricting marketing, regulating government procurement, and improving product labeling would constitute a comprehensive policy.¹²⁹ These policies have been in place on the tobacco cigarette market for decades in many jurisdictions and have only minimally affected the market's trajectory. While policies would undoubtedly be helpful, they do not speak to the goal of public health activists as directly as possible.

A comprehensive policy regime is made up of many individual policies. The intent of that comprehensive policy regime and the direction it seeks to drive a market is a regulatory stance. A regulatory stance does not function as a checklist of policy milestones that must be ticked off before a market conforms to the whims of the policymaker. A regulatory stance can be shifted by passing just a few policies intent on consequentially changing the character of a market, be it a cap-and-trade system, product standards, or extreme differential excise taxation. A change in a regulatory stance gives a metaphorical 'shove' to markets, fundamentally altering what is profitable and what is not.

¹²⁸ G. Sacks, B. Swinburn, and M. Lawrence, "Obesity Policy Action Framework and Analysis Grids for a Comprehensive Policy Approach to Reducing Obesity," *Obesity Reviews* 10, no. 1 (2009): 76–86, <https://doi.org/10.1111/j.1467-789X.2008.00524.x>.

¹²⁹ Yoshihiro Kokubo et al., "A Comprehensive Policy for Reducing Sugar Beverages for Healthy Life Extension," *Environmental Health and Preventive Medicine* 24 (2019), <https://doi.org/10.1186/s12199-019-0767-y>.

8.1.2 Using Regulatory Stances May Emphasize Powerful Policies

When regulatory policy debates shift focus based on an understanding informed by the regulatory stances concept, the attraction of employing powerful policies to redress market failures may increase. As market failures have an implicit regulatory stance that must be adopted to remedy them, the use of stances might connect the idea that said market failure's effect on market size could be more effectively remedied by the adoption of a powerful policy than a narrowly tailored portion of a comprehensive policy.¹³⁰

In contrast to the more amorphous comprehensive policy concept, a regulatory stance centered on changing the shape of markets would narrowly focus on changing the size of markets for certain desirable or undesirable food products. Whether a market-centric approach would be more effective at achieving say, obesity reduction, remains to be seen, as no jurisdiction has yet decisively decreased obesity prevalence. If a jurisdiction decided it wished to adopt a contractionist stance towards sugar-sweetened beverages, it might write an excise tax policy that aimed to make beverages sweetened with caloric sweeteners multiple times more expensive to purchase than beverages sweetened with non-caloric sweeteners. Such a policy would ramp up demand for the substitute product. This powerful policy could produce larger positive changes in outcomes than any number of components of a comprehensive policy that excluded the use of powerful policies. A powerful policy's focus on remedying the market failure, where for several reasons including poor information and negative externalities, consumption of a sugar-sweetened beverages was too high, by resolving the consequence of the market failure might be more efficient than the alternative comprehensive policy. That comprehensive policy would remedy each market failure in turn in the hopes that the consequence of said market failure would be resolved as a knock-on down-stream effect.

The same can be said for tobacco control policy which could dramatically decrease the sales of tobacco cigarettes by removing nicotine from those products while leaving nicotine for sale in e-cigarettes.¹³¹ Performance-based regulation could provide incentives for grocery stores to sell far

¹³⁰ See 2.1.1 The Regulatory Stance at page 29.

¹³¹ Benjamin J. Apelberg et al., "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," *New England Journal of Medicine* 378, no. 18 (May 3, 2018): 1725–33, <https://doi.org/10.1056/NEJMs1714617>; Kenneth E. Warner and Harold A. Pollack, "The Nicotine Fix" (The Atlantic, November 13, 2014), <http://theatlantic.com/1u5EHfe>.

fewer calories.¹³² Aggressive renewable portfolio standards could crash the energy market for fossil fuels in a couple of years rather than waiting generations.¹³³ When the purpose of regulation becomes centered on shaping the size of markets, the number of potential powerful policies that are possible to consider come into view. The focus shifts from remedying the cause of a market failure to remedying the effect of the market failure. Measuring intent via a regulatory stance allows us to capture the importance of a small number of powerful policies.

More market failures might be successfully resolved under this paradigm. Once powerful policies are under consideration, the conditions by which political actors would agree to their terms can be uncovered. The regulatory stances concept points to the obvious consequences of improperly functioning markets. By focusing on that consequence and asking how best it can be remedied, the development of more effective markets that serve pro-social interests could follow.

8.2 Regulatory Stances as a Critique of the Commercial Determinants of Health

The commercial determinants of health (CDOH) are markets that form the direct interface between health and commerce.¹³⁴ Taken together, tobacco smoking and alcohol use account for one in five deaths in high-income countries.¹³⁵ Adding in the toll of exposures to asbestos, overdoses on legal prescription drugs, results of automobile accidents, unhealthy diets, and on and on yields a total cost of the downsides to consumer goods markets that is higher still. The death toll from the use of these products is not an inevitable consequence of the human condition. Instead, scholars of the commercial determinants of health make the case that market, and political forces produce and enable widespread consumption and the resultant morbidity and mortality that follows. In this way, they have diagnosed a problem, but the commercial determinants of health literature presents fewer effective solutions with less dexterity than the social determinants of health literature it seeks to emulate. Here, I argue that the regulatory

¹³² Stephen D. Sugarman, "Performance-Based Regulation: Enterprise Responsibility for Reducing Death, Injury, and Disease Caused by Consumer Products," *Journal of Health Politics, Policy and Law* 34, no. 6 (December 2009): 1035–77, <https://doi.org/10.1215/03616878-2009-035>.

¹³³ Sanya Carley and Chris J. Miller, "Regulatory Stringency and Policy Drivers: A Reassessment of Renewable Portfolio Standards," *Policy Studies Journal* 40, no. 4 (2012): 730–56, <https://doi.org/10.1111/j.1541-0072.2012.00471.x>.

¹³⁴ Ilona Kickbusch, "Addressing the Interface of the Political and Commercial Determinants of Health," *Health Promotion International* 27, no. 4 (December 1, 2012): 427–28, <https://doi.org/10.1093/heapro/das057>.

¹³⁵ Amanuel Alemu Abajobir et al., "Global, Regional, and National Comparative Risk Assessment of 84 Behavioural, Environmental and Occupational, and Metabolic Risks or Clusters of Risks, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016," *The Lancet* 390, no. 10100 (September 16, 2017): 1345–1422, [https://doi.org/10.1016/S0140-6736\(17\)32366-8](https://doi.org/10.1016/S0140-6736(17)32366-8).

stances concept offers a useful critique and suggests a constructive path forwards that will improve this literature.

In recent years, much more non-communicable disease scholarship and policymaker attention have been explicitly focused on the social rather than on the commercial determinants of health.¹³⁶ The social determinants of health have risen to become a powerful cultural and political force in its own right, focusing attention on the issues that drive systemic inequalities across and within borders.¹³⁷ The comparison in attention is not fair, as the commercial determinants of health is a much newer term (coined in 2013 instead of the first appearance in PubMed in 1961 or the rise to prominence of the social determinants of health concept in the 1986 Ottawa Charter) and they were intended to evoke the social determinants of health in its nomenclature.¹³⁸

Scholars of the social determinants of health have focused their studies on the harms and benefits of structural societal conditions on populations and try to tease apart how these mechanisms cause preventable health inequities. They document gradients in health outcomes across gender, race, socioeconomic status, educational attainment, religion, social class, geography, and access to the essentials of life like food and health care.¹³⁹ Further, they study the interventions that decrease these gaps in outcomes across groups and have worked to integrate their rhetoric and narrative into the political battles to implement their favored policy solutions.¹⁴⁰ Most importantly, the social determinants of health as successfully introduced the idea that social policy is health policy and that such policies should be advanced to remedy health inequities.¹⁴¹

¹³⁶ A. Irwin and E. Scali, “Action on the Social Determinants of Health: A Historical Perspective,” *Global Public Health* 2, no. 3 (July 1, 2007): 235–56, <https://doi.org/10.1080/17441690601106304>.

¹³⁷ Michael Marmot, “Social Determinants of Health Inequalities,” *The Lancet* 365, no. 9464 (March 19, 2005): 1099–1104, [https://doi.org/10.1016/S0140-6736\(05\)71146-6](https://doi.org/10.1016/S0140-6736(05)71146-6); Paula Braveman, Susan Egerter, and David R. Williams, “The Social Determinants of Health: Coming of Age,” *Annual Review of Public Health* 32, no. 1 (2011): 381–98, <https://doi.org/10.1146/annurev-publhealth-031210-101218>.

¹³⁸ Gordon Macgregor, “Social Determinants of Health Practices,” *American Journal of Public Health and the Nations Health* 51, no. 11 (November 1961): 1709–14; Kickbusch, “Addressing the Interface of the Political and Commercial Determinants of Health.”

¹³⁹ Noah Snyder-Mackler et al., “Social Determinants of Health and Survival in Humans and Other Animals,” *Science* 368, no. 6493 (May 22, 2020), <https://doi.org/10.1126/science.aax9553>.

¹⁴⁰ Phillip Baker et al., “What Enables and Constrains the Inclusion of the Social Determinants of Health Inequities in Government Policy Agendas? A Narrative Review,” *International Journal of Health Policy and Management* 7, no. 2 (November 11, 2017): 101–11, <https://doi.org/10.15171/ijhpm.2017.130>.

¹⁴¹ Erik Blas et al., “Addressing Social Determinants of Health Inequities: What Can the State and Civil Society Do?,” *The Lancet* 372, no. 9650 (November 8, 2008): 1684–89, [https://doi.org/10.1016/S0140-6736\(08\)61693-1](https://doi.org/10.1016/S0140-6736(08)61693-1); Raj Chetty, David Cutler, and Michael Stepner, “Effects of Local Health Interventions on Inequality in Life Expectancy: New Publicly Available Data,” *American Journal of Public Health* 106, no. 12 (October 13, 2016): 2154–55, <https://doi.org/10.2105/AJPH.2016.303492>.

The commercial determinants of health literature starts from a similar rhetorical point as the social determinants literature – It points out that the existence of the health inequities it seeks to redress are preventable.¹⁴² The very existence of people living longer and healthier lives when they are at the lower end of exposure to toxic forces implies that the removal of said toxic forces should heal those who are sick.¹⁴³ The commercial determinants of health literature then goes on to propose via analogy to tobacco control that unhealthy markets can be corralled and health inequities caused by said markets may be resolved. I argue that this view is impoverished in several ways and causing the commercial determinants of health to fall short of its potential as a rhetorical and political concept. Further, I propose that the regulatory stances concept advanced in this study provides a healthy way to reframe the debate around the commercial determinants of health in a manner that is both constructive and potent.

8.2.1 The Commercial Determinants of Health is falling short of realizing its potential

In one of the first articles coining the commercial determinants of health concept, Ilona Kickbusch, a former head of Health Promotion at the WHO, claims she would rewrite one of global health’s foundational documents, the Ottawa Charter of 1986.¹⁴⁴ Kickbusch would have the charter focus on five more precise determinants of health rather than the seven less precise factors highlighted in the original (political, economic, social, cultural, environmental, behavioral and biological factors) and proposed dividing the determinants of health into the political, commercial, social, environmental, and behavioral.¹⁴⁵ By fusing the social and economic (along with a dose of the political) determinants of health, Kickbusch pushed for commercial determinants of health to be placed alongside these other factors as the modifiable targets for change. Hundreds of peer-reviewed research articles have since marshaled Kickbusch’s framing to useful ends and have focused attention on the role that, especially, unhealthy commodity industries play in contributing to morbidity and mortality around the world.¹⁴⁶

¹⁴² Ilona Kickbusch, Luke Allen, and Christian Franz, “The Commercial Determinants of Health,” *The Lancet Global Health* 4, no. 12 (December 1, 2016): e895–96, [https://doi.org/10.1016/S2214-109X\(16\)30217-0](https://doi.org/10.1016/S2214-109X(16)30217-0).

¹⁴³ Raj Chetty et al., “The Association Between Income and Life Expectancy in the United States, 2001–2014,” *JAMA* 315, no. 16 (April 26, 2016): 1750–66, <https://doi.org/10.1001/jama.2016.4226>.

¹⁴⁴ “The Ottawa Charter for Health Promotion,” WHO, November 21, 1986, <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>.

¹⁴⁵ Kickbusch, “Addressing the Interface of the Political and Commercial Determinants of Health.”

¹⁴⁶ 484 articles in a search for “commercial” AND “determinants of health” in EBSCOHost on June 4, 2020.

The tenets of the Commercial Determinants of Health literature combines several loosely linked conclusions to push for policy changes that address the issues it highlights; that tobacco companies served as the vector to tobacco-caused disease, that the public health community had successfully fought back and defeated the tobacco, and that other commercial products were causing health harms in a manner similar to the tobacco industry. I argue that only this last clause is entirely true and that to re-evaluate the potential of the commercial determinants of health lens, the first two claims about tobacco must be reconsidered. As originally conceived the commercial determinants of health draws lessons from the experience of tobacco control that is at once too pollyannish and wholly lacking in ambition.

8.2.2 The Commercial Determinants of Health Are a Rebuke to Tobacco Exceptionalism

This push to elevate the commercial determinants of health as a target for concerted intervention stemmed from an implied consensus among the public health community that lessons from tobacco needed to be scaled up and cross-applied to other industries. Around the time of the development of the FCTC, a justification for writing a global health treaty that aimed to confront the harms of a single unhealthy commodity industry began to circulate. This justification, termed “tobacco exceptionalism” contended that the tobacco industry was so inherently harmful and its influence so insidious that tobacco companies should not be allowed to influence regulatory policy over their business.¹⁴⁷ Memorably, a panel of WHO-convened experts quipped, “[T]obacco use is unlike other threats to global health... There are no front groups to promote the spread of cholera. Mosquitoes have no lobbyists.”¹⁴⁸ This observation, while true in the specific cases of mosquitoes and cholera, does not hold up to scrutiny beyond the degree of severity of risk that tobacco poses to its users.

Many unhealthy commodity industries, mentioned before, meet these same criteria.¹⁴⁹ In that sense, the commercial determinants of health were spot on to diagnose a series of issues that sorely lack attention from policymakers, scholars, and the public; Why does the world not address other unhealthy commodity industries as it has done with tobacco? That is the right

¹⁴⁷ Jeff Collin, “Tobacco Control, Global Health Policy and Development: Towards Policy Coherence in Global Governance,” *Tobacco Control* 21, no. 2 (March 2012): 274–80, <https://doi.org/10.1136/tobaccocontrol-2011-050418>.

¹⁴⁸ Thomas Zeltner et al., “Tobacco Company Strategies to Undermine Tobacco Control Activities at the World Health Organization,” Committee of Experts on Tobacco Industry Documents (Geneva: World Health Organization, July 2000), 244, https://www.who.int/tobacco/en/who_inquiry.pdf.

¹⁴⁹ René I. Jahiel and Thomas F. Babor, “Industrial Epidemics, Public Health Advocacy and the Alcohol Industry: Lessons from Other Fields,” *Addiction* 102, no. 9 (2007): 1335–39, <https://doi.org/10.1111/j.1360-0443.2007.01900.x>.

question to ask, but after close examination of the goals, the track record, and the toolkits of tobacco control, I argue that this analogy is not as fully developed as it should be. Additionally, the regulatory stances concept can be invoked to understand why this is the case.

8.2.2.1 The Goal of the Tobacco Control Movement Re-Examined

The well-established public health goal of the tobacco control movement is to reduce the morbidity and mortality of tobacco use.¹⁵⁰ Others invoke the goal is to create a tobacco-free society, where no one has to live as a nicotine addict against their will.¹⁵¹ Others still have sought to make the tobacco industry into a social and economic pariah. The first goal is the noblest, but that it is often justified in an excessively convoluted and roundabout manner. Some invoke the doctrine of tobacco exceptionalism. Others invoke economic models of addiction explaining that smokers are consuming more tobacco than they would ideally consume if they were not addicted to the product.¹⁵² The way the first goal ought to be justified is that morbidity and mortality will decline if tobacco consumption decreases and both will decline faster if tobacco consumption falls faster. This, of course, implies that the goal of tobacco control should be to promote contractionist regulatory stances that are as strong as possible. Policies that do not move expeditiously towards this goal should be re-considered as they do not serve the end goal of efficaciously reducing morbidity and mortality. Instead, policies that decrease tobacco consumption as fast as possible ought to be held up as top policy priorities and the political considerations that block their implementation must be confronted.

8.2.2.2 The Progress of the Tobacco Control Movement Re-Examined

The CDOH literature begins with an assumption that the tobacco control movement has been such a stunning success that the rest of the public health policy must emulate those policies and lessons which have been so successful in tobacco control to other policy areas. The CDOH literature and public health advocates fawn over the adoption of the FCTC and pine for a similar treaty to be established regulating their unhealthy commodity industry of choice.¹⁵³ The CDOH

¹⁵⁰ National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, Reports of the Surgeon General (Atlanta (GA): Centers for Disease Control and Prevention (US), 2014), chap. 16, <http://www.ncbi.nlm.nih.gov/books/NBK179276/>.

¹⁵¹ Deborah Amott, “There’s No Single Endgame,” *Tobacco Control* 22, no. Suppl 1 (May 2013): i38–39, <https://doi.org/10.1136/tobaccocontrol-2012-050823>.

¹⁵² Gary S Becker and Kevin M Murphy, “A Theory of Rational Addiction,” *Journal of Political Economy*, *Journal of Political Economy*, 96, no. 4 (1988): 675–700, <https://doi.org/10.1086/261558>.

¹⁵³ Hannah Abdulla, “WHO Told ‘Tobacco-Style’ Approach Needed for Poor Diets,” *Food Industry News*, November 17, 2014, https://www.just-food.com/news/who-told-tobacco-style-approach-needed-for-poor-diets_id128444.aspx; Allyn L. Taylor and

literature then names a laundry list of tobacco control policies that could be transposed to other policy arenas before saying these would be a good idea to use elsewhere including restrictions on lobbying, marketing, and the levying of excise taxes.¹⁵⁴

These adulations are based on a rosy interpretation of tobacco control’s progress as a movement. I do not go as far as others who propose that the tobacco control movement has been a failure.¹⁵⁵ But, if the goal of tobacco control was to turn the tobacco industry into an unprofitable vestigial pariah of a business, it has only succeeded in making tobacco companies into social pariahs. Table 7 demonstrates that in 2019 even after the effects of global tobacco control policy successes, tobacco companies were still highly profitable, even compared to peers selling consumer staples that are not subject to contractionist regulatory stances.¹⁵⁶ Tobacco companies have thrived, even in what is perceived to be a declining market.

Table 7: Earnings to Revenue Ratios by Large Consumer Staples Companies (Millions USD, 2019)¹⁵⁷

Industry	Company	EBITDA	Revenue	Ratio
Tobacco	British American	13443	33042	40.7%
Alcohol	AB InBev	20828	52329	39.8%
Tobacco	Philip Morris	11495	29805	38.6%
Tobacco	Japan Tobacco	6267	20016	31.3%
Soft Drinks	Coca-Cola	11451	37266	30.7%
Food	Nestle	22957	93469	24.6%
Alcohol	Heineken	6236	26845	23.2%
Cleaning	Unilever	11973	58218	20.6%
Food	Mondelez	4934	25868	19.1%
Soft Drinks	PepsiCo	12723	67161	18.9%
Food	Danone	5129	29113	17.6%
Food	Kraft Heinz	3758	24977	15.0%
Cleaning	Procter & Gamble	8311	67384	12.3%

Ibadat S. Dhillon, “An International Legal Strategy for Alcohol Control: Not a Framework Convention—at Least Not Yet,” *Addiction* 108, no. 3 (March 1, 2013): 450–55, <https://doi.org/10.1111/j.1360-0443.2012.03919.x>.

¹⁵⁴ Becky Freeman and Colin Sindall, “Countering the Commercial Determinants of Health: Strategic Challenges for Public Health,” *Public Health Research & Practice* 29, no. 3 (September 25, 2019), <https://doi.org/10.17061/phrp2931917>.

¹⁵⁵ John B. McKinlay Marceau Lisa D., “Upstream Healthy Public Policy: Lessons from the Battle of Tobacco - John B. McKinlay, Lisa D. Marceau, 2000,” *International Journal of Health Services* 30, no. 1 (June 23, 2016): 49–69, <https://doi.org/10.2190/2V5H-RHBR-FTM1-KGCF>.

¹⁵⁶ Anna B. Gilmore, J. Robert Branston, and David Sweanor, “The Case for OFSMOKE: How Tobacco Price Regulation Is Needed to Promote the Health of Markets, Government Revenue and the Public,” *Tobacco Control* 19, no. 5 (October 2010): 423–30, <https://doi.org/10.1136/tc.2009.034470>.

¹⁵⁷ EBITDA = Earnings Before Interest, Taxes, Depreciation and Amortization. Large companies have annual revenues over US \$20 B. “Macrotrends | The Long Term Perspective on Markets,” accessed May 11, 2020, <https://www.macrotrends.net>.

Even in countries that are supposed tobacco control success stories, like the US, the peak of tobacco company power could be measured in different ways and tell different measures of success. Cigarette use prevalence among US adults peaked in 1965, cigarette sales per capita peaked in 1981, and cigarette sales by inflation-adjusted value did not peak until 2006.¹⁵⁸ Sales in 2018 by real value are equivalent to sales in the late 1990s, an era hardly defined as a nadir of tobacco industry power and influence. There are indeed fewer smokers today, but the companies selling cigarettes are doing well despite the contractionist regulatory stance they have been subject to for the last five decades. The fact that tobacco companies are exploring selling nicotine in novel forms illustrates that they and their shareholders have not been dissuaded of the business case for selling the addictive drug.

The reasons that tobacco companies have been able to squeeze the cigarette market for more and more money are multi-faceted. The products are addictive, contributing to an inelastic demand curve.¹⁵⁹ Tobacco companies have over-shifted tax increases onto consumers, blunting the revenue sting from tax rises.¹⁶⁰ Tobacco companies have managed to shift their marketing into whatever channels remain to replenish their dying consumer base.¹⁶¹ They have even stepped back from diversification strategies outside of their core business of selling nicotine.¹⁶² This was an entirely rational strategy on the part of tobacco companies and it illustrates the difficulty that controlling the CDOH presents.

8.2.2.3 *The Toolkit of the Tobacco Control Movement Re-Examined*

With this sobering realization of the impact that the tobacco control movement has made on the industry it sought to regulate, in hand, why is the tobacco control movement the pinnacle of what the burgeoning commercial determinants of health movement want to achieve? The reason may stem from the public perception that the tobacco control movement has been an unqualified

¹⁵⁸ Orzechowski and Walker, “The Tax Burden on Tobacco, 1970–2018,” *Chronic Disease and Health Promotion Data & Indicators*, June 13, 2019, <https://chronicdata.cdc.gov/Policy/The-Tax-Burden-on-Tobacco-1970-2018/7nwe-3aj9>; Jeffrey Drope et al., “Who’s Still Smoking? Disparities in Adult Cigarette Smoking Prevalence in the United States,” *CA: A Cancer Journal for Clinicians* 68, no. 2 (2018): 106–15, <https://doi.org/10.3322/caac.21444>.

¹⁵⁹ Gary S Becker, Michael Grossman, and Kevin M Murphy, “An Empirical Analysis of Cigarette Addiction,” Working Paper, Working Paper Series (National Bureau of Economic Research, April 1990), <https://doi.org/10.3386/w3322>.

¹⁶⁰ Rosemary Hiscock et al., “Tobacco Industry Strategies Undermine Government Tax Policy: Evidence from Commercial Data,” *Tobacco Control* 27, no. 5 (October 9, 2017): 488–97, <https://doi.org/10.1136/tobaccocontrol-2017-053891>; Rosemary Hiscock et al., “UK Tobacco Price Increases: Driven by Industry or Public Health?,” *Tobacco Control* 28, no. e2 (2019): e148–50, <https://doi.org/10.1136/tobaccocontrol-2019-054969>.

¹⁶¹ Dewhirst, “Price and Tobacco Marketing Strategy.”

¹⁶² Andrade et al., “Hostage to Fortune.”

success, but it may also stem from the fact that tobacco control has proposed solutions to redress the harms caused by an unhealthy commodity industry.¹⁶³ These solutions from tobacco control may have found other problems that they can try to solve.¹⁶⁴ But, this casts the aims of tobacco control and indeed of the entire regulatory apparatus far too narrowly.

Attempts to re-use policies initially created for tobacco control in other unhealthy commodity industries are understandable because these policies have been tried and tested and arrive with a ready-made body of evidence behind them. The attraction of CDOH scholars towards efforts that seek to repeat what is perceived correctly as public health victories in other markets is entirely reasonable. But it may be thinking too small. Tobacco control has not wholly succeeded in stopping tobacco companies from trying to circumvent current contractionist regulatory policies.

The continuing profitability of the tobacco cigarette business indicates that tobacco control has fallen short of its most ambitious goals. It also signals that a more severe contractionist policy is possible. A hypothetical regulatory framework based on a strongly contractionist stance could drive down the size of the cigarette market over a short period. If a government capped nicotine content at non-addictive levels in tobacco cigarettes while allowing companies to still sell addictive levels of the substance in e-cigarettes, we might see such a precipitous decline in tobacco cigarette sales as modelers have forecasted.¹⁶⁵

Is tobacco control then, the success story that the expanded CDOH campaign is trying to replicate? Is this the best-case scenario? Tobacco control has been a qualified success story because it has reversed what was a growing market for tobacco cigarettes and cornered said market into shrinking in size over an extended time horizon. Death and disease have been averted for sure, but changes in corporate economic fortunes have not followed.¹⁶⁶ The reasons that tobacco companies have been able to squeeze the cigarette market for more and more money are multi-faceted. The products are addictive, contributing to an inelastic demand curve.¹⁶⁷

Tobacco companies have over-shifted tax increases onto consumers, blunting the revenue sting

¹⁶³ Gerard Hastings, "Why Corporate Power Is a Public Health Priority," *BMJ* 345, no. aug21 1 (August 21, 2012): e5124, <https://doi.org/10.1136/bmj.e5124>.

¹⁶⁴ Daniel Béland and Michael Howlett, "How Solutions Chase Problems: Instrument Constituencies in the Policy Process," *Governance* 29, no. 3 (2016): 393–409, <https://doi.org/10.1111/gove.12179>.

¹⁶⁵ Apelberg et al., "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States."

¹⁶⁶ Holford TR et al., "Tobacco Control and the Reduction in Smoking-Related Premature Deaths in the United States, 1964–2012," *JAMA* 311, no. 2 (January 8, 2014): 164–71, <https://doi.org/10.1001/jama.2013.285112>.

¹⁶⁷ Becker, Grossman, and Murphy, "An Empirical Analysis of Cigarette Addiction."

from tax rises.¹⁶⁸ Tobacco companies have managed to shift their marketing into whatever channels remain to replenish their dying consumer base.¹⁶⁹ They have even stepped back from diversification strategies outside of their core business of selling nicotine.¹⁷⁰ This was an entirely rational strategy on the part of tobacco companies and it illustrates the difficulty that controlling the CDOH presents. If CDOH scholars and public health advocates want to achieve strongly contractionist policies in tobacco or any other unhealthy commodity industry, then the study at hand offers lessons informed by the range of regulatory stances. These lessons require a rethinking of the regulatory policy toolkit to favor strongly contractionist policies that can carve out as wide a swath of political support as possible.

8.2.3 The Missing Portion of the Commercial Determinants of Health

The social determinants of health literature points to the importance of conditions that both improve and harm health inequities. For example, the provision of quality education, healthcare, as well as political and social rights heals the divides in outcomes. By contrast, the commercial determinants of health literature rarely mentions a positive role for corporate influence over health, when the case can easily be made that not all corporate involvement in markets harms our health. This has limited the concept of the commercial determinants of health to be almost exclusively applied to unhealthy commodity industries selling products that are inherently harmful to health like alcohol, soda, and junk food. But, other products without inherently negative health effects do not fit well into the commercial determinants of health, as currently conceived, like opioids, meat, and e-cigarettes. These products would be health-promoting if they reached certain people and health-harming if they reached others. Further, commercial products with inherently positive health effects like vaccines, renewable energy, and vegetables are almost orthogonally oriented to the commercial determinants of health framework. The underconsumption of beneficial goods causes great harm to societal welfare and public health. As currently conceived, the commercial determinants of health concept has little to offer discussions around how the growth of such markets might be accelerated.

¹⁶⁸ Hiscock et al., “Tobacco Industry Strategies Undermine Government Tax Policy”; Hiscock et al., “UK Tobacco Price Increases.”

¹⁶⁹ Dewhirst, “Price and Tobacco Marketing Strategy.”

¹⁷⁰ Andrade et al., “Hostage to Fortune.”

The trick to understanding all the commercial determinants of health may, therefore, be not to want to eliminate all sources of health harms that stem from the sale of commodities but to understand what policies best control markets to obtain optimal health outcomes. This is where the utility of the regulatory stances concept comes in. If we recognize that every market is subject to a regulatory stance, then we can begin the debate over which markets should be subject to which stance to properly redress the commercial determinants of health.

8.2.4 Regulatory Stances Set the Commercial Determinants of Health Right

Integrating the regulatory stances concept into the conversation over the commercial determinants of health clarifies a useful concept by broadening its application and sharpening its purpose. The commercial determinants of health concept falters when it regards markets with the potential to produce positive or conditional outcomes for health. Therefore, we should assign classifications to various markets based on their effects on health to understand the utility of the commercial determinants of health concept more fully.

I propose classifying markets as having a positive, negative, or conditional effect on health. The commercial determinants literature already points to alcohol and ultra-processed foods as candidates for designation as markets with a negative effect on health. Lencucha and Thow briefly tease their recognition of the role of “healthy commodity industries” in their response to a wide-ranging critique of their investigation into the effect of a neoliberal ideology’s relation to the commercial determinants of health.¹⁷¹ These healthy commodity industry markets like vaccines and vegetables that will produce better health outcomes as they grow in size. In between are conditional products like opioids and e-cigarettes that will produce positive or negative outcomes based on the conditions under which they are sold.

Markets designated as having negative health outcomes require contractionist regulatory stances if public health is to be improved. Markets designated as having positive health outcomes require expansionist regulatory stances if health is to be improved. Markets with conditional health outcomes likely require something in between extremes if public health is to be improved.

¹⁷¹ Raphael Lencucha and Anne Marie Thow, “Developing a Research Agenda for the Analysis of Product Supply: A Response to the Recent Commentaries,” *International Journal of Health Policy and Management*, February 19, 2020, 1, <https://doi.org/10.34172/ijhpm.2020.25>; Raphael Lencucha and Anne Marie Thow, “How Neoliberalism Is Shaping the Supply of Unhealthy Commodities and What This Means for NCD Prevention,” *International Journal of Health Policy and Management* 8, no. 9 (September 1, 2019): 514–20, <https://doi.org/10.15171/ijhpm.2019.56>.

Recognition of harms, benefits, and the relative costs of each can focus regulatory debates on the purpose of regulation. The utility of focusing on the intended size of a market is clarifying and opens up possibilities to advance policy in a manner that might have a broader appeal than the current rhetoric undergirding the commercial determinants of health literature. The regulatory stances concept highlights what necessary corrective action is needed in different markets rather than a blanket solution across markets. Once the goal is identified, we should then seek to apply what was learned from the case studies presented before to propose solutions to reaching political action on redressing the commercial determinants of health.

8.2.5 Cross-Appling the Lessons of this Study

This study found that regulatory stances changed when all actors involved agreed on the alternative regulatory stance. This stance shifted policy from prohibitionist to expansionist, which represented a business opportunity for corporate actors. In circumstances where a pro-public health policy involves shifting towards the contractionist end of the range of regulatory stances, we may not expect to gain cooperation or agreement from business actors so easily.

If we end up agreeing that such actors have a legitimate role at the policymaking table, then we must explore what regulatory stances can be cooperatively developed and adopted that enhance public health while gaining corporate support than opens policy windows to contract markets. Aneurin Bevan, the man charged with establishing the UK's National Health Service, noted that, to broker a deal convincing private-sector physicians to effectively become nationalized, he had to “stuff their mouths with gold”.¹⁷² Bevan persuaded physicians that the loss of autonomy they would suffer would be compensated by enhancing their pocketbooks.¹⁷³ He removed British doctors' incentive to dissent. Lost harmful business opportunities may need to be replaced with new pro-social business opportunities if right-wing pro-business parties are to be co-opted into supporting a contractionist regulatory stance.

Public health does not need to re-create an economic system to serve its image from the ground up to begin to address these issues. Public health, and truly, other interested actors need to understand how the tangled web of regulatory policy serves to contract and expand markets.

¹⁷² Michael Williams, “A Brave New Paradigm?,” *BMJ* 329, no. 7461 (August 5, 2004): 357, <https://doi.org/10.1136/bmj.329.7461.357>.

¹⁷³ Andrew Hindmoor, “The Importance of Being Trusted: Transaction Costs and Policy Network Theory,” *Public Administration* 76, no. 1 (1998): 25–43, <https://doi.org/10.1111/1467-9299.00089>.

Interested pro-social actors can learn how restricting access to capital markets, altering the terms for market entry, and so on affect the trajectory of markets.

Although it offers useful core concepts that deserve to be expounded upon and engaged with seriously, the commercial determinants of health literature can come across as anti-corporate screed. On occasion, the CDOH literature questions the orientation of public policy, industry, capitalism, politics in a manner that could become antithetical to achieving a healthier society. This perspective is impoverished by the narrow view it takes towards the role of corporate influence on health, consistently positing that where corporate influence is involved, profits will win out over health and that public health advocates must convince policymakers that health is either fundamental to growing wealth or that health should outweigh marginal concerns about wealth.

Much of the CDOH literature assumes that the solution to many of the world's health issues is to diminish corporate power.¹⁷⁴ This might be the case, but it might be an unnecessary step beyond the need to shape markets in the interest of health. The literature is often unhelpful to practitioners of politics because it concludes with recommendations that public health advocates essentially participate in the political process by “demanding a seat at the table” or learning how to “mobilize for political action” or asking politicians to “stand up to industry”¹⁷⁵. Transposing advice that “corporate interests should not be involved in the formation of public health policy” into practice will be a tricky matter.¹⁷⁶ These recommendations contain little practical advice to win converts to their side and may thus end up being ineffective. Adulations do not a strategy make.

These debates often offer just three possible solutions to address the CDOH; voluntary self-regulation, public-private partnership, or government regulation.¹⁷⁷ If the idea is to decrease the

¹⁷⁴ Hastings, “Why Corporate Power Is a Public Health Priority”; William H. Wiist, “Public Health and the Anticorporate Movement: Rationale and Recommendations,” *American Journal of Public Health* 96, no. 8 (August 1, 2006): 1370–75, <https://doi.org/10.2105/AJPH.2005.072298>.

¹⁷⁵ Kent Buse and Sarah Hawkes, “Sitting on the FENSA: WHO Engagement with Industry,” *The Lancet* 388, no. 10043 (July 30, 2016): 446–47, [https://doi.org/10.1016/S0140-6736\(16\)31141-2](https://doi.org/10.1016/S0140-6736(16)31141-2); Michael Thorn, “Addressing Power and Politics through Action on the Commercial Determinants of Health,” *Health Promotion Journal of Australia* 29, no. 3 (2018): 225–27, <https://doi.org/10.1002/hpja.216>; Hastings, “Why Corporate Power Is a Public Health Priority.”

¹⁷⁶ Thorn, “Addressing Power and Politics through Action on the Commercial Determinants of Health.”

¹⁷⁷ Kent Buse, Sonja Tanaka, and Sarah Hawkes, “Healthy People and Healthy Profits? Elaborating a Conceptual Framework for Governing the Commercial Determinants of Non-Communicable Diseases and Identifying Options for Reducing Risk Exposure,” *Globalization and Health* 13, no. 1 (June 15, 2017): 34, <https://doi.org/10.1186/s12992-017-0255-3>.

size of unhealthy commodity markets, this is a false choice between solutions. As so many have pointed out, government regulation is necessary to decrease the size of markets because corporations have every incentive to grow their profits.¹⁷⁸ However, if our goal is to increase the size of a market, that does not mean the government must abdicate its role as regulator.

Governments possess a great deal of power to alter the relative profitability of markets and to drive corporate behavior in the desired direction. Markets are not born free, rather they are crafted through institutions and policy and path dependence.¹⁷⁹ Regulation makes markets and pointing that out must be added to the public health policy advocates' toolkit.

Seeking to dismantle the influence of corporate power on politics may be a noble goal and one that could pay dividends was it to succeed. But, focusing on the purpose of the regulation, might help policymakers, advocates, and citizens better recognize why we should care about regulatory policy. We should care because it alters what the economy is composed of. Politics involves setting up coalitions that can stick together to solve collective action problems. What practitioners may take from the study at hand instead is that industry can be co-opted to support contractionist policy if it is linked with an expansionist policy that they plan to support.¹⁸⁰ What may be more consequential than curtailing corporate power writ large is determining how to adopt regulatory stances that serve the interest of public health, even when that redounds to private profit. Focusing on the purpose of regulation might enable us to move faster towards a healthier society.¹⁸¹

8.3 What is still unknown?

As this work centered on a close analysis of three high-income established democracies with a shared heritage of British colonial rule regulating the same novel market, extrapolation of these findings to other environments and cases must be done carefully. While a comparative qualitative research method can increase confidence in the internal validity of a study, there is much that we could not learn because the study design did not allow for it. The conclusions offered here must be explored and picked apart using other research methods and applied in

¹⁷⁸ David Stuckler and Marion Nestle, "Big Food, Food Systems, and Global Health," *PLOS Medicine* 9, no. 6 (June 19, 2012): e1001242, <https://doi.org/10.1371/journal.pmed.1001242>; Buse and Hawkes, "Sitting on the FENSA."

¹⁷⁹ Steven Kent Vogel, *Marketcraft: How Governments Make Markets Work* (New York, NY, United States of America: Oxford University Press, 2018), chap. 1.

¹⁸⁰ See 5.5.3 Issue Linkage with Plain Packaging on page 146.

¹⁸¹ If anyone from the Foundation for a Smoke-Free World is reading this, I invoke this logic not to support pleas to expand 'consumer choice' but to support the gutting of the tobacco cigarette business.

other cases. First, there is the issue of political ideology and form of government, which does not vary enough across the cases at hand to be exploited as an explanatory variable. Second, we have learned very little about the conditions necessary to move towards the contractionist end of the range of regulatory stances. Finally, we know less than is comfortable about what the best practice regulatory stance towards e-cigarettes should be. These questions are the logical follow-ons from this study and the importance of filling in these gaps is explained below.

8.3.1 The Role of Political Ideology and Form of Government

How does political ideology map on to the adoption of regulatory stances towards various markets beyond the current case study? What would have happened to e-cigarette regulation if the Canadian Liberals had not won in the 2015 federal elections? What would have changed in New Zealand had Labour not surged to victory in 2017? What would have happened in Australia had Labor won in 2019? How would a Democratic US President have reacted to the EVALI outbreak? These essential questions remain difficult to answer without a more thoroughgoing exploration of the factors that bound decisionmakers.

The initial analysis suggests that in each case policy windows to change e-cigarette regulatory would have opened in a similar manner to what happened, but the policies that would have passed might have been slightly different. For example, a President Hillary Clinton might have imposed a stronger contractionist policy than did President Donald Trump. A follow-on Conservative Harper government might have passed an even more expansionist e-cigarette regulatory policy in Canada. The former Associate Minister of Health under the last New Zealand National Party government, even submitted what she claimed was the draft e-cigarette regulation bill developed under the old government as a private members bill.¹⁸² That bill was slightly more expansionist towards the e-cigarette market than the bill submitted to New Zealand's Parliament by the Labour government in February 2020.

These scenarios will remain counterfactuals for the time being until rigorous case studies of comparative regulation begin to tackle the conditions necessary for regulatory stances to move in either direction on the range of regulatory stances for e-cigarettes and other markets. Until we closely study right-wing governments passing laws trading prohibitionist for expansionist stances

¹⁸² Wagner, Smoke-free Environments (Regulation of E-Cigarettes) Amendment Bill.

towards e-cigarettes or left-wing governments exchanging expansionist for contractionist policies towards cannabis, we will be without the necessary data to make firm conclusions on these questions.

Asking questions like these may end up creating a classification of different markets that are subject to different regulatory stances under governments led by different ideologies. When the concept of regulatory stances is applied to markets beyond drugs, we could consider why a technocratic competitive authoritarian government in Singapore seeks to spur the development of public housing while crushing demand for cannabis and determine the conditions linking those policy choices. We can consider why the left-leaning government of the state of California chooses to pursue the inverse. Of course, the role of the form of government is an entirely separate issue for comparative regulation that extends well beyond ideology.

Systematized studies of comparative regulation, possibly applied to the range of regulatory stances, holds a great deal of possibility to explain drivers of policy divergence and convergence at a global level. Such studies may point to the strategies that are used to overcome ideological and structural barriers to achieving pro-social or pro-health regulatory policy outcomes. Developing a better understanding of the drivers of change and stasis in regulatory across borders will help develop more effective policy advocates and scholars.

8.3.2 How does a country move towards a prohibitionist or contractionist regulatory stance?

This study focused on two countries who abandoned prohibitionist regulatory stances in favor of expansionist stances towards e-cigarettes. It further learned lessons about the conditions necessary for a country to maintain a prohibitionist regulatory stance. What it explored to a much lesser degree was the conditions necessary to move *towards* a prohibitionist or contractionist policy from an expansionist or permissive policy. This study did not address this question in the realm of e-cigarette regulation beyond the examples of the US and Canadian reactions to EVALI.¹⁸³

In some ways, this question is much more relevant to the studies of unhealthy commodity industries that comparative regulation has tackled before.¹⁸⁴ When a commodity's consumption

¹⁸³ See Section 7.3 EVALI on page 218.

¹⁸⁴ Francesco Duina and Paulette Kurzer, "Smoke in Your Eyes: The Struggle over Tobacco Control in the European Union," *Journal of European Public Policy* 11, no. 1 (January 1, 2004): 57–77, <https://doi.org/10.1080/1350176042000164307>; Kari

is too large, then this will be the practical question to study for scholars and advocates alike. The political dynamics, policy community consensus formation process, and problem definition will be entirely different when moving towards the opposite end of the range. Determining the conditions under which all parties would benefit from a policy change towards the contractionist end of the range of regulatory stances is likely to be a challenge and may even be non-existent. If such circumstances do not exist, then politics of conflict might prove to be more influential for these cases than the politics of consensus were for the case studies here.

8.3.3 Who was right?

This study did not attempt to determine which regulatory stance towards e-cigarettes should be considered best practice. While this question motivates many actors throughout these case studies, it is too early to reach conclusions about what regulatory policy choices will yield the best results in terms of the lowest smoking prevalence or the lowest tobacco-related morbidity and mortality rates. The world has not yet witnessed a country successfully turning back the tide against youth e-cigarette use once those rates began to rise significantly.

Efforts to alter or maintain e-cigarette regulatory frameworks were constantly described as evidence-based policy by actors on all sides of the debate. Evidence around safety, dual use with tobacco cigarettes, youth initiation, clinical cessation trials, and addiction studies were constantly put forward to justify one position or another. Depending upon the local context and who was making the argument to a particular policymaker, it was possible for any number of different conclusions to be reached on the basis of the scientific evidence that was presented and on the identity of the policymakers who was listening. This study did not attempt to resolve the matter of which side was correct.

Even computational modelling efforts that assess which e-cigarette regulatory policies are projected to maximize public health outcomes, do not provide clean answers.¹⁸⁵ The findings of these studies are, of course, reliant on the inputs and assumptions baked into the models. Models

Poikolainen, "The Weakness of Stern Alcohol Control Policies," *Alcohol and Alcoholism (Oxford, Oxfordshire)*, July 6, 2015, <https://doi.org/10.1093/alcalc/agt081>.

¹⁸⁵ Andrew Hill and Oscar M. Camacho, "A System Dynamics Modelling Approach to Assess the Impact of Launching a New Nicotine Product on Population Health Outcomes," *Regulatory Toxicology and Pharmacology* 86 (June 1, 2017): 265–78, <https://doi.org/10.1016/j.yrtph.2017.03.012>; Hayden McRobbie, "Modelling the Population Health Effects of E-Cigarettes Use: Current Data Can Help Guide Future Policy Decisions," *Nicotine & Tobacco Research* 19, no. 2 (February 1, 2017): 131–32, <https://doi.org/10.1093/ntr/ntw387>.

may emphasize different endpoints as most indicative of success. Some will measure cigarette and e-cigarette sales volumes, others will measure changes in product use prevalence, and others will measure rates of morbidity and mortality. The most important endpoints will vary based on the audience they are being presented to and the values that the audience holds. However, until we observe substantial cross-national divergence in these outcomes and can pinpoint which sets of policies caused these figures to diverge, it will be disingenuous to describe any policy as “best practice”.

A recent study pointed out that global tobacco control policy progress may have had only a mixed effect on tobacco cigarette consumption relative to the declines that would have been expected based on prior trends, with developed economies seeing faster declines after policies were passed while developing economies saw no or negative progress.¹⁸⁶ While we are certain that well-implemented individual contractionist policies are effective at decreasing the size of a market, we know that poorly implemented policies achieve far fewer gains. Further, it is less well understood how contractionist policies being adopted in one jurisdiction may affect the strategy of transnational corporations seeking to profit maximize their behaviors in other jurisdictions subject to permissive regulations.¹⁸⁷ No credible public health authority advises countries against adopting contractionist regulatory policies towards tobacco or any other harmful commodity because cross-national comparisons have difficulty finding positive policy outcomes. Instead, such authorities recommend that well-designed studies of policy intervention be conducted as an integrated part of policy implementation.

This study did not begin to tackle the hairy questions about tradeoffs between outcomes, costs, benefits, values, and power that the dilemma of the e-cigarette market’s very existence poses. The questions of how to construct efficacious and just regulatory policy are ahead of us all. The best that studies of comparative regulation can offer in the interim is providing a full account and explanation of the drivers of and barriers to policy change. For now, we will leave it to future scholars to determine the effects of regulatory policy change or stasis.

¹⁸⁶ Steven J. Hoffman et al., “Impact of the WHO Framework Convention on Tobacco Control on Global Cigarette Consumption: Quasi-Experimental Evaluations Using Interrupted Time Series Analysis and in-Sample Forecast Event Modelling,” *BMJ* 365 (June 19, 2019): l2287, <https://doi.org/10.1136/bmj.l2287>; Hoffman et al.

¹⁸⁷ Linda Bauld, “Tobacco Control: New Resources, Existing Treaties, and Emerging Challenges,” *BMJ* 365 (June 19, 2019): l4161, <https://doi.org/10.1136/bmj.l4161>.

8.4 Ending Thoughts

This study closely followed the developments within a relatively small policy subsystem in three countries that combined, have fewer inhabitants than the United Kingdom. Their experiences regulating e-cigarettes reflect their individual histories, governing structures, and current political landscapes. By paying close attention to their experiences navigating a complex, constantly shifting, and contested subject, we learn more about good governance and effective advocacy. By keeping our judgements at bay, we come to understand the motives of actors in this story rather than castigating or lauding them on instinct.

Canada and New Zealand have chosen to expand their e-cigarette markets while Australia has chosen to keep theirs on ice. Just as these countries were good choices for a comparative qualitative study of most similar cases of policy divergence, they will also serve as useful cases by which health and market outcomes can be compared. Continuing to pay attention to how countries with high capacity and expertise regulate markets that affect health can provide guidance to others seeking to learn from their example.

Appendices

Appendix A: Semi-Structured Interview Protocol

- Please tell me a bit of background about you and your current job.
- What have been the effects of the introduction of the e-cigarette in your country/organization?
 - *Probe if primarily listing negatives:* What positive effects have e-cigarettes had?
 - *Probe if primarily listing positives:* What negative effects have e-cigarettes had?
 - *Probe:* Are there subpopulations where e-cigarettes are doing particular good (or harm)?
 - *Probe:* Is a smoker going to lower their risk for disease and death if they switch to an e-cigarette?
 - *Probe:* How should that risk be communicated?
 - *Would NRT be permissible to use for harm reduction?*
 - *What are the similarities between the experience with e-cigarettes and light cigarettes?*
- Is tobacco control working in your country?
- How were these issues brought to the attention of the public and policymakers?
 - *Probe:* Were these issues connected to particular solutions? Tell me more about those.
- What issues does <key bill or regulation> try to address?
 - *Probe:* Are there some issues that were higher priorities than others? Why?
- What political conditions enabled <the key bill or regulation> to come up for consideration?

- *Probe if bill or regulation was stopped: What political conditions prevented the bill from coming up for considerations*
- Which actors were essential to getting <the key bill or regulation> adopted (*or blocked*)?
 - *Probe: Why did those actors support (or block) <the key bill or regulation>?*
- From where did the idea of <the key bill or regulation> originate?
 - *Probe: Explain more about the research or reasoning that underpins the idea of <the key bill or regulation>.*
- Do you believe that the government's policies regarding e-cigarettes slow down or speed up the growth of the market for e-cigarettes, or neither? Why?
 - *Probe: <Re-phrase the prior question as a counterfactual to whether the key bill or regulation had not been adopted>*

Thank you for participating in this interview. I found our conversation to be informative and insightful to understanding the decision-making process around e-cigarette policy in <Country of residence>.

Do you have any final thoughts on subjects we raised you would like to contribute before we finish?

Whom would you recommend I speak to, so that I obtain a fuller picture of this topic?

- Would you serve as a personal reference for me, to help me get in touch with them?

If I need to clarify any information, can I reach out to you again?