

Regulating Risk: The Case of Vapes in Canada

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Abstract

In the midst of rapid technological development and growing concerns around public health, vapes emerged as a device that has produced global polarization. Canada is home to world precedent setting legislation aimed at reducing tobacco consumption and nicotine addiction. Vapes are a product that, in theory, should complement that pursuit. However, there is more than one side to this story. In one perspective, vapes are the holy grail of tobacco reduction – the answer to smoking cessation. From another perspective, they are a product that, in the long run, will result in more tobacco initiation and nicotine addiction.

This study examines the complex process of developing regulatory policy by exploring how vaping advocacy groups and public health advocacy groups interact with Health Canada. A qualitative approach is adopted to determine the factors that drive each respective side of this polarized issue, in pursuit of finding common ground and understanding. The project draws from historical institutionalism and the advocacy coalition framework to describe how path dependency, ideological bias, and advocacy groups influence regulatory decisions. This study offers policy recommendations to support cessation efforts and prevent youth initiation. The findings highlight the importance of transparent decision-making and the need to consider the potential unintended consequences of regulations.

Résumé

Au cœur d'un développement technologique rapide et de problématiques croissantes autour de la santé publique, la cigarette électronique est devenue un dispositif suscitant une polarisation mondiale. Le Canada est le précurseur d'une législation mise en place qui vise à réduire la consommation de tabac et l'addiction à la nicotine. La cigarette électronique est un produit qui, théoriquement, devrait contribuer à cet effet. Cependant, il y a plusieurs approches autour de cette problématique. D'un côté, les cigarettes électroniques sont considérées comme le Saint Graal aidant à faciliter la cessation tabagique – représentant l'ultime réponse au sevrage tabagique. D'un autre côté, elles sont considérées comme un produit qui, à long terme, entraînera plus d'initiation au tabac et de dépendance à la nicotine.

Cette étude examine le processus complexe d'élaboration d'une politique réglementaire en explorant comment les groupes de défense du vapotage et de santé publique interagissent avec Santé Canada. Une approche qualitative est adoptée pour déterminer les facteurs qui animent les deux perspectives à cette question polarisée, dans le but de trouver un terrain d'entente et une compréhension sur le sujet. Ce projet s'appuie sur les approches d'institutionnalisme historique ainsi que sur les groupes de pressions l'*advocacy coalition frameworks* afin de décrire comment les mécanismes de dépendances, les préjugés idéologiques et les groupes de pression influencent les décisions réglementaires. Cette étude propose des recommandations politiques pour soutenir les efforts de cessation tabagique et la prévention de l'initiation des jeunes au tabac. Les résultats soulignent l'importance d'une prise de décision transparente et la nécessité de prendre en compte les conséquences imprévues potentielles de la réglementation.

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1. Introduction

Amid rapid technological development and growing concerns around public health, vapes emerged as a device that has produced global polarization. Canada is home to world precedent setting legislation aimed at reducing tobacco consumption and nicotine addiction. Vapes are a product that, in theory, should complement that pursuit. However, there is more than one side to this story. In one perspective, vapes are the holy grail of tobacco reduction – the answer to smoking cessation. From another perspective, they are a product that – in the long run – will result in more tobacco initiation and nicotine addiction.

Vapes quietly entered the Canadian market as an unregulated product in 2007. Starting in 2009, Health Canada issued a warning to consumers against using vapes (specifically those that contain nicotine), sent “cease and desist” letters to retail outlets, and rejected hundreds of shipments of the devices (House of Commons, 2015). In 2014, the World Health Organization encouraged members to regulate the products, with a focus on preventing youth uptake and misleading health claims (WHO, 2014). By 2018, regulations on vapes were enacted as part of the newly named Tobacco and Vaping Products Act. The regulations, as much as the devices themselves, created polarization in the Canadian public health community.

This study examines the complex process of developing regulatory policy by considering how the perspectives of healthy public policy advocates and vaping advocates influenced vaping regulatory decisions. The primary analysis will employ a qualitative methods approach of semi-structured interviews with public health, policy, advocacy, and medical experts. I adopted this approach to determine the factors that drive each respective side of this polarized issue, in pursuit of finding common ground, understanding, and an effective regulatory approach. The project

draws from historical institutionalism and the advocacy coalition framework to describe how path dependency, ideological bias, and advocacy groups influence regulatory decisions. Through an inductive approach I will evaluate our data in consideration of several external factors (institutional, structural, and ideational factors). This study offers insight into the complex regulatory process for innovative technologies that affect public health, with a focus on policy recommendations that support cessation efforts and prevent youth initiation.

1.1 Vapes

Vapes have become a colloquial term that encompasses a wide range of products that share a common design: a battery-operated device that heats a liquid solution until it becomes vapour and condenses into an aerosol that is inhaled by a user through a mouthpiece (Government of Canada, 2021). The first vaping device was invented in 2003 by Hon Lik, a Chinese Pharmacist who wanted to create an alternative to smoking (Lik, 2003). First known as an electronic cigarette (e-cigarette), vapes can now be referenced as an e-cigarette, vape, electronic nicotine delivery system (ENDS), and by many street or brand names.

Initially, Lik's e-cigarette was very similar in appearance to cigarettes (Fagerström, et al., 2015). The original e-cigarette has expanded far beyond a cigarette replica, disrupting the industry and creating an entirely new market for vapes. Its disruptive nature is threefold, as an alternative to cigarettes, an alternative to government approved Nicotine Replacement Therapies (NRTs), and as an entirely new product that attracts consumers with no history of smoking. Due to this, I use the term vape to encompass the vast and disruptive reach of the devices.

Vapes as a Disruptive Technology

To be considered as disruptive, a device must produce transformations in how the products are marketed and show a significant influence over consumer behaviour (Christensen, 2003), two things vapes have done (Stimson, et al., 2014). In response to the substantial and rapid growth of vapes, tobacco companies have started to purchase or develop their own vape products (Stimson, et al., 2014). Beyond this, vapes represent a challenge for public health and governments as the disruptive nature of vapes, coupled with the everchanging technological innovations, means that reliable scientific data cannot keep up, making it difficult for policymakers to regulate them (Weishaar et al., 2019). As there are debates about what constitutes a disruptive technology, I rely on the following nominal definition: *a product that, due to technological features, gains popularity over a product(s) that previously monopolized the market.*

1.2 The Precautionary Principle

Industries can flood markets with technological innovations at a much faster rate than governments can regulate them. Consequently, governments are compelled to give public justifications for their policies – or lack of policies – around new products, especially ones that affect human health. Prior to putting forward regulations, it is expected that a government will conduct a substantive risk assessment. For Health Canada, this entails evaluating the available scientific data on the product, engaging with interested and affected parties (vaping and health advocacy groups), and involving other experts (policymakers, medical specialists) in the decision-making process (Government of Canada, 2011). For disruptive technologies, the process is complicated due to an asymmetry in information available to regulators, and policy uncertainty in regard to potential unintended consequences of decision-making (Taeihagh, Ramesh, and Howlett, 2021).

To circumvent public health crises, many countries adopt a risk-averse approach by using the precautionary principle to guide their regulatory decisions (Sandin 1999; Steele 2006). Though the precautionary principle was originally established for environmental regulation, for many it has become a fundamental element of public health (Kriebel and Tickner, 2001). However, there is concern that acting in a risk-averse manner can stigmatize an activity or a product before enough scientific evidence can prove or refute health or safety claims (Keeney et al. 2001). For better or for worse, the precautionary principle is cited with increasing frequency in debates regarding disruptive technologies that might impact public health (Martuzzi, 2007; Canadian Association of University Teachers, 2009). Health Canada indicates that they have always exercised precaution when evaluating risks to human health through what they call a “Precautionary Approach” (Government of Canada, 2010; Government of Canada 2011). In light of this, I am interested in the validity of the precautionary principle as a policy-standpoint in Canada and whether it did (or should) inform vaping regulations.

Due to contention over how to define the precautionary principle, I propose the following nominal definition: *adopting a cautious approach towards regulating new disruptive technologies that might impact public health during instances where the scientific evidence is inconclusive.*

1.3 Section outline

To address this policy issue, our analysis proceeds as follows: Section 2 presents an overview of the history of vapes in Canada, data on rates of use, and current policy measures and proposals. In section 3, I break down the literature on this topic and, in section 4, I describe our method. In section 5, I explain the analytical framework that guided the project. Section 6 is dedicated to the

findings from the interviews. Section 8 discusses the implications of our findings and policy recommendations.

2. Overview of Vapes in Canada

This section will provide an overview of vapes in Canada, with a specific focus on how vapes entered the market, how many Canadians are using the products, the current and impending regulations, and the position of the Canadian Council of Medical Officers of Health.

2.1 Vapes on the Canadian Market

In 2007 vapes entered the Canadian market as an unregulated product. Through a prohibitionist approach, Health Canada first addressed vapes in 2009 with a statement banning the sale, advertising and import of vapes, along with a message advising Canadian's against using the products (House of Commons, 2015). In 2013, the federal government began monitoring use of vapes through the Canadian Tobacco, Alcohol and Drugs Survey (Statistics Canada, 2013). The survey results showed that vaping trends would continue to increase. By 2014, international pressure to act was increasing as the WHO encouraged members to regulate the products to prevent youth uptake and misleading health messages (WHO, 2014).

Due to federal inaction, provinces started to produce their own regulations, which often aligned vapes with current tobacco regulations (Canada Vapes, n.d.). At the same time, the Council of Chief Medical Officers of Health (CCMOH) released a statement calling on the federal government to regulate vapes, with an emphasis on equating vapes to cigarettes under current federal regulations (HESA, 2014). In response, the government requested the Standing Committee on Health to prepare a report on vaping. The report offered fourteen recommendations (House of Commons, 2015). Before these recommendations could be

effectively considered, there was an election and change in government that delayed action. During the government transition, Health Canada furtively developed regulations for vaping, which entered the Senate in November of 2016 as Bill S-5, part of the now named Tobacco and Vaping Products Act (TVPA). These regulations received Royal Assent in May of 2018. Through this, Health Canada adopted an expansionist approach, removing the grey area around vapes, making them a legal product in Canada.

The decision to regulate vaping products was received with approval from both vaping and public health advocates as a necessary step in the right direction.¹ However, the contents of the regulations left much to be desired, as neither perspective felt their interests were fully represented or addressed.

2.1 Use Data

This section will discuss the results from two national surveys used to collect data on use rates for vaping products. The Canadian Tobacco and Nicotine Survey (CTNS), previously part of the Canadian Tobacco, Alcohol and Drugs Survey (CTADS), monitors use among Canadians starting at the age of 15 (Statistics Canada, 2019a). The Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) monitors use among Canadian students between grades 7 and 12 (Statistics Canada, 2019b).

The 2013 CTADS was the first national survey that monitored vape use. The results of the survey showed that 9% of Canadians over 15 had tried vapes; this number increases to 20% for youth and young adults. The majority of those who had tried a vape in the past-30-days thought that, to some degree, vapes were less harmful than cigarettes (Statistics Canada, 2013). With

¹ P12 @ 20; P4 @ 22

trends indicating that use would only increase, Statistics Canada included vapes as a permanent part of their national surveys on youth and adults.

Youth Use Data

Canadian youth who have ever tried vaping has doubled since 2016, resulting in 418,000 youth at a higher risk of nicotine addiction and smoking initiation (Statistics Canada, 2019b).² Vaping expanded the nicotine market to an entirely new generation of youth with the potential to encourage dual use with cigarettes, renormalize smoking, and increase tobacco use (Barrington-Trimis, et al., 2016; Farrelly, et al., 2015; Grana, 2013; Leventhal, et al., 2015; Primack, et al., 2015; Wills, et al., 2014). Youth are marginally more likely to experiment with a vape first and then initiate cigarettes (Statistics Canada, 2019b).

There are many reasons youth might start using vape products. Three reasons identified by youth who vaped in the past-30-days are because they were curious about the products, because they enjoy using them, and because using them helps manage stress (Statistics Canada, 2019a). Fruit flavours were cited as the most used flavours by half (51%) of the youth who vaped within the past-30-days (Statistics Canada, 2019a).

Young Adult and Adult Use Data

There are almost four million Canadians over the age of 20 who have ever tried vaping, with the majority of past-30-day users being current or former smokers (Statistics Canada, 2019a). Active users – those who indicated past-30-day use – is significantly lower at just over one million (Statistics Canada, 2019a). Young adults reported using vapes due to curiosity and to try and quit smoking, while adults reported their main intent being smoking cessation and not returning to

² This number increases to one million for youth between 15 and 19 (Statistics Canada, 2019a).

smoking (Statistics Canada, 2019a). Fruit flavours, while popular among all users, are most often used by youth and young adults; tobacco is the second most used flavour by adults (Statistics Canada, 2019a).

2.2 Vape Regulations

The TVPA, which became law on May 23, 2018, governs vaping products in Canada (Government of Canada, 2021). This section will not cover every aspect of vaping regulations³ but rather focus on regulations pertaining to areas that are often debated and questioned in the public health community. While many provinces have enacted their own regulations, I am focusing specifically on the federal regulations; though at times I will reference provincial regulations that informed federal ones.

Nicotine Concentration in Vaping Products

Vaping products containing nicotine were an illicit product in Canada until legalized under the TVPA in 2018. The TVPA allowed for nicotine concentrations of up to 66mg/ml. The regulation received criticism as a permissive vaping policy that enabled mass access to products containing a highly addictive drug (Hammond et al, 2019b). These concerns were confirmed when a study revealed that 90% of Canadian youth who used a vaping product in the past-30-days used one that contained nicotine (Statistics Canada, 2019b). In response, Health Canada started to explore other policy options. After years of development, new regulations came into effect in July 2021⁴ that limit the nicotine concentration in vape products for sale in Canada to 20mg/ml (Canada Gazette, 2021; Health Canada, 2021b).

³ The full TVPA can be accessed from: <https://laws-lois.justice.gc.ca/eng/acts/T-11.5/> and an official summary of key regulations can be accessed from: <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation.html#a2>

⁴ The regulations took effect July 8th for manufacturers and July 23rd for retailers (Canada Gazette, 2021).

Vaping Flavours

There has been a piecemeal approach towards regulating vaping flavours in Canada. The TVPA (2018), in an effort to prevent youth uptake, initially banned the sale of the following flavours: confectionary, dessert, cannabis, soft drink and energy drink.⁵ In addition, many provinces imposed their own regulations on flavours.⁶ Increasingly, research indicates that the availability of most flavours entice youth to experiment with vaping products (Al-Hamdani et al., 2020; Statistics Canada, 2019a; Hammond et al, 2019a; Hammond, et al. 2019b). In light of this, Health Canada has put forward more comprehensive regulations on flavours that will come into effect in 2022, after a public consultation period. These regulations ban the sale of all flavoured vape products, with the exemptions of menthol, mint, and tobacco (Canada Gazette, 2021b; Health Canada, 2021a).

Vaping Products Labelling and Packaging

Canada has set world precedence for its plain packaging regulations for tobacco (Health Canada, 2019b); this standard was not initially met when it comes to vaping product packaging. However, Health Canada is attempting to reconcile this through implementing more robust regulations (Canada Gazette, 2019). The current regulations prohibit advertising in any place youth have access and require health warnings, nicotine/poison warnings, child resistant packaging and standardized ingredient lists⁷ (Canada Gazette, 2021a). It is suggested they improve these

⁵ The full regulations can be accessed here: <https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg2-eng.html>

⁶ Heart & Stroke has an interactive map with vaping policies by region (Heart and Stroke, 2020). Note: the map has not been update since October 2020. Available from: <https://www.heartandstroke.ca/how-you-can-help/advocate/vaping-policies-by-region>; More provinces have since introduced flavour restrictions. You can access an updated timeline for regulations from: <https://smoke-free.ca/resources/>

⁷ A detailed discussion of these regulations can be accessed on: <https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg2-eng.html>

regulations through requiring plain and standardized packaging (Public Health Agency of Canada, 2020).

Vaping Products Promotion

Health Canada, in the TVPA (2018), acted to protect youth through banning advertisements that have the potential to appeal to them (Health Canada, 2018b). These regulations have been strengthened by limiting point of sale promotion in places youth can access and requiring health warnings be included in advertisements (Canada Gazette, 2020). It is encouraged that they further restrict online advertising/promotion through social influencers that attract youth, while allowing online advertising that is directed towards adults and emphasizes the products purpose as a cessation device (Public Health Agency of Canada, 2020).

4. Literature Review: The Vape Debate

This section will discuss some of the key areas of debate in the literature. First, I look at whether the regulations in Canada have been effective, then I examine the debates on the efficacy of vapes as a cessation device and the application of the precautionary principle.

4.1 Effectiveness of Regulations

A study conducted by David Hammond and colleagues (2019a) examined the prevalence of vape use (specifically among youth) between 2017 and 2018. Due to the comparative nature of the study, they used cross-sectional surveys in Canada, England, and the United States to evaluate trends and notable changes. The results showed a significant increase in youth vape use across North America but not in England. Simultaneously, the use of the brand JUUL by youth increased significantly in North America – credited to its development of a novel nicotine salt technology and lifestyle marketing directed at youth. The study found that "between 2017 and 2018, among youth 16 to 19 years old the prevalence of vaping increased in Canada and the US,

as did smoking in Canada, with little change in England" (Hammond et al, 2019a). In 2018, after vapes hit the Canadian mass market, Health Canada introduced policies to regulate the devices. Dr. Hammond and colleagues cite these policies as a cause for the increase in vape use in Canada and the root cause of the Canadian-specific case of youth tobacco initiation during the same period (Hammond et al, 2019a). Based on this study, it appears that the approach adopted by Health Canada towards regulating vapes was not effective; rather than mitigating an issue, they proliferated the consequences.

4.2 Cessation Efficacy

There is clear division in the public health community regarding the efficacy of vapes as a cessation device. Many researchers indicate that any evidence regarding the efficacy of vapes as a cessation device is inconclusive and unreliable (Grana, 2014). Certain studies conclude that vapes do not work as a cessation method and instead might lead to dual use with cigarettes (Terry et al., 2016; Kalkhoran et al., 2016). Other studies remain hesitant to endorse it as a cessation device as the proven effectiveness is currently so low and the supporting evidence very limited (Khoudigian et al. 2016). Conversely, some researchers espouse optimism at the potential of vapes as a cessation device while noting that more in-depth research is required to draw more decisive conclusions (Siegal et al., 2011; Etter and Bullen 2014).

Berry et al. (2019) found that for vapes to be moderately effective as a cessation device, they must be used in a far more frequent manner than one would generally use cigarettes. Recent evidence indicates that vapes can be effective as a prescribed cessation device but should not be sold as a consumer good (Wang, et al., 2021). Overall, the data remains inconclusive. Due to this, I am interested in whether the potential of vapes as an effective cessation device influenced policy decisions.

4.3 Application of the Precautionary Principle

Whether the precautionary principle should be applied to the case of vapes (and health more broadly) is debated. Garnett and Parsons (2017) study how the precautionary principle has been employed in the European Union (EU) and found that the effectiveness of regulations and consistency in application varies greatly by Member State. External factors such as economic considerations and lobbying by impacted industries contribute to weaker regulations when following the precautionary principle (Garnett and Parsons 2017). Additionally, a lack of clarity about how to effectively adopt the precautionary principle creates confusion in developing regulations – even though the EU Commission produced a framework to follow. The research also recognized a trend in which governments require less evidence of harm (to public health or the environment) to introduce strict regulations. These findings show that there are often inconsistencies when applying the precautionary principle. However, they also exhibit a trend of governments in the EU leaning towards implementing stricter regulatory measures. This research helps to understand the positives and negatives of adopting the precautionary principle, as well as the role that industry can have in informing its application.

The literature on vapes is quickly expanding to include more comprehensive studies that will guide our approach towards our research questions and framework. Due to the public health crisis already experienced with cigarettes, some contend that adopting the precautionary principle in the case of vapes is not only justified but necessary (Bush et al., 2016; Green et al., 2018). For some, there should be a presumption of "guilty until proven innocent" - until reliable data proves they are safe, as policymakers need more time to evaluate the political and ethical considerations of regulating vapes (Bush et al., 2016). In terms of addiction, some indicate that the tobacco industry is using vapes to spread nicotine dependency and that governments must act

accordingly by developing policies to protect citizens from a lifetime of addiction to a potentially hazardous product (Glantz and Bareham 2018). In opposition, some advise that vapes are an effective cessation device, and that the precautionary principle is not relevant for developing regulations (Abrams et al. 2018). These opposing perspectives within the literature produce a point of tension. They lead us to ask whether a government can concurrently promote vapes as a cessation device while employing the precautionary principle. This is one of many questions I hope to bring clarity to through this research while also referencing back to ideas established in the literature.

5. An Institutional and Advocacy Coalition Framework

The analytical framework for this project draws from two key theories that help us understand the regulatory process: historical institutionalism and the advocacy coalition framework.

Through using these two frameworks I can evaluate the decision-making process of Health Canada from two complimentary perspectives. The historical institutionalist framework allows us to explore whether past policy decisions, specifically about tobacco, informed Health Canada's approach to vaping. Meanwhile, the advocacy coalition framework enables us to evaluate when and if advocacy groups had a stake in the development of the regulations.

Together, using a combination of these two frameworks provides a clear scope through which I can assess the regulatory process and discern the key factors that affected vaping regulations.

5.1 Historical Institutionalism

In his book, *How to Map Arguments in Political Science* (2007), Craig Parsons describes a typology of explanations frequently used in political science. For this project, I utilize the institutionalist lens (i.e., one focused on institutional explanations) to guide our analysis. An institutionalist approach is defined by how human-made institutions act as determinants of

behaviour due to formal or informal norms, rules, and conventions (Parsons 2007, 70). There are certain policy areas wherein once a precedent is set, it is very hard to diverge from, a reality known as path dependence. For example, a government who mandated health warnings on tobacco products would also require them for vapes. This speaks to the path-dependency of a regulatory process in which earlier policy decisions impact future ones (Hiilamo and Glantz, 2015). I adopt the institutionalist framework to analyse how established norms, past regulatory decisions on cigarettes, and relationships with advocacy groups influenced vaping regulations.

Within the historical institutionalist framework is the concept of increasing returns, which specifies that path dependence occurs for two key reasons – 1) the current path is producing benefits, and 2) there are potential costs associated with diverging (Pierson 2000, 251-2). This analysis is often applied to economics and politics. For the project, I want to use this perspective to evaluate whether a path dependent approach based on increasing returns can be applied to public health regulations. For decades Health Canada has focused on implementing regulations that align with their mission of reducing tobacco consumption. With each regulation Health Canada has moved further down their path and made significant gains in tobacco control. If Health Canada were to diverge from this path, what would the costs be? I am interested if the need to maintain their tobacco control trajectory is what informed the initial vaping regulations. Was it a harm reduction approach aimed at mass cessation?

While the term ‘increasing returns’ instills confidence in the path, the possibility for negative externalities and unintended consequences are still present. In fact, even small events or decisions can lead to considerable long-term consequences (Pierson 2000, 263). Considering this, I am interested in the possible long-term consequences resulting from Health Canada’s

approach to vaping. There are two consequences that I will focus on. The first is the substantial number of youth who are vaping, and the second is the increased potential for tobacco initiation nicotine addiction.

Applying the increasing returns argument to public health regulations presents challenges as the gains and losses are not as easily measured as they are when it comes to economics. However, I suggest that looking at this from a population health level and focusing on the rates of vaping and smoking can enable us to evaluate where gains and losses occurred.

5.2 Advocacy Coalition Framework

Paul Sabatier (1988) developed the advocacy coalition framework, which focuses on the values held by advocacy groups and how they influence policy change. The coalitions can be formed by actors from public, private, and non-governmental organizations who share the same concerns about a policy problem and are acting together to address it (Sabatier 1988, 131-3). For the project, I engage with advocacy groups representing two polarized perspectives, which presents a good opportunity to evaluate how these two competing advocacy coalitions work distinctly to influence policy change.

Researchers in the US applied this framework to evaluate the regulatory process for vapes (Cox, Barry, and Glantz 2016). By adopting this approach, they were able to understand the complex reality of regulating vapes and tobacco. Through their research they found that industry lobbyists can prevent or delay regulations at the federal level and that in general, bottom-up grassroots initiatives are more effective. While their work focused largely on the development of the coalitions, I am specifically interested in the coalitions active engagement in the regulatory process and the results of their efforts. In Canada, researchers have examined how tobacco

control advocacy groups try to influence federal regulations, however, they have not evaluated the impact on policy outcomes (Hastie and Kothari, 2009). For this project, I want to consider the affect that advocacy efforts have on informing regulatory decisions for vapes.

Advocacy coalitions often need to change their strategies and priorities as the regulatory field develops (Sabatier 1988, 133). For vaping, the regulatory process has gone through extensive and expedient changes as regulators were faced with the challenges of regulating a disruptive technology. I will apply this framework to examine how the advocacy groups have adapted to the everchanging policy landscape to advocate for their perspective.

6. Methodology

This section will describe the methodological approach for this project. First, I will explain why Canada is an appropriate choice for study, second, I will detail the document collection procedure, and third, I will discuss our primary data collection through interviews.

6.1 Case Selection

I based my decision to study Canada on four fundamental factors. First, the federal government recently initiated a Regulatory Transparency and Openness Framework that strives to build trust among Canadians toward regulatory decisions (Government of Canada, 2019). This indicates that bureaucrats might be amenable to participate in the project and relevant documents should be accessible. Second, Canada is one of the global leaders for tobacco regulations. Of note, Canada was the first country to introduce graphic health warnings on cigarettes and was one of the first to ban menthol flavoured cigarettes. Third, in 2017, Canada committed to support policy innovation through a Federal, Provincial and Territorial Declaration on Public Sector Innovation (Government of Canada, 2017). Due to this, Canada becomes an interesting case for evaluating

the regulatory process for vapes, a disruptive technology. The fourth reason is due to the expansive advocacy landscape. There are many public health advocacy and vaping advocacy groups that are active and public. This presents a viable opportunity to connect with these organizations. In culmination, all these elements position Canada as a good case study for vaping regulations.

6.2 Document Collection

There are many documents that help to paint the full picture of the vaping situation in Canada. For our project, I collected secondary data from Statistics Canada that detail vape use by Canadians.⁸ These documents are important to help understand how use rates have changed over time and during different regulatory periods. To establish a clear timeline of regulation development, I collected news releases from the Canadian Gazette, speeches in the House of Commons, and meeting minutes between Health Canada and advocacy/industry groups. In addition, I collected articles from Canadian media outlets that covered policy changes. The data collection and interviews were used for the purpose of triangulating the essential moments and rationales that informed the vaping regulations.

6.3 Interviews with Key Actors

This study employs a qualitative approach through semi-structured interviews with 16 key actors. The interviews are the cynosure of the research project. A semi-structured interview guide (appendix I) was developed and used to structure the interviews.⁹ The respondents were selected through a purposive sampling method. As well, at the end of each interview, I asked if the respondents had recommendations of others I should speak with and if they would help make

⁸ There are three main surveys referenced: 1) the Canadian Student Tobacco, Alcohol and Drugs Survey, 2) the Canadian Tobacco Alcohol and Drugs survey, and 3) the Canadian Tobacco and Nicotine Survey.

⁹ Prior to the interview some respondents indicated topics they would not discuss.

the connection. I interviewed respondents until a balanced representation was achieved. The respondents were contacted over email. The interviews took place virtually over an online application¹⁰ in July and August 2021. Interviews ranged from 15 minutes to 66 minutes, with the average interview being 25 minutes.

To protect the confidentiality of respondents, identifying data will not be shared. Based on the informed consent form, respondents have agreed to be referenced by their organization and/or profession. The respondents are part of the following organizations: Health Canada, the Canadian Council of Chief Medical Officers of Health, The Canadian Vaping Association, The Canadian Cancer Society, the World Vaping Alliance, Action on Smoking and Health, Rights4Vapers, Alberta Health Services, and the Centre for Health Law, Policy and Ethics at the University of Ottawa. In addition, I spoke to cessation specialists, tobacco and vaping policy experts, leaders in tobacco and vaping research, and a pediatrician specialized in adolescence and addiction. I interviewed one respondent who had a history of using both vapes and cigarettes.¹¹ The respondents offered a broad range of perspectives on the policy issue. It is important to note that the perspectives shared by respondents are not considered to be the exact perspectives of the organizations they are affiliated with or all members of their organizations.

The interviews were audio recorded and transcribed using Trint, an artificial intelligence software. After the software transcribed the interview, I listened to the audio while following the transcript and corrected any errors, grammar, or inaccuracy. The transcripts were then uploaded to MAXQDA, a software for qualitative analysis. I was not interested in quantifying the data.

¹⁰ I used Webex by CISCO, a platform approved by McGill's Research Ethics Board.

¹¹ I was recommended by respondents to interview someone who had used both vapes and cigarettes that was not associated with industry, advocacy groups or government.

Rather, through open and axial coding I categorized the responses to highlight specific areas of interest.

This project received approval (21-07-002) from McGill Universities Research Ethics Board.

Respondents signed informed consent forms prior to participating. The project presented minimal risk to the respondents. Respondents were not compensated for their time.

7. Research Findings

This section will explore the findings from the interviews, highlighting crucial areas of discussion. There are critical points of divergence between the respondents on these topics. I have divided the respondents into four categories: 1) Health Canada,¹² 2) Vaping Advocacy,¹³ 3) Public Health Advocacy,¹⁴ and 4) Product User.¹⁵

7.1 Vaping Advocacy Arguments

Through our interviews it became evident that vaping advocacy groups are working double time to influence regulatory decisions in Canada. The Canadian Vaping Association proclaims itself as the most active lobby group for any industry in the country.¹⁶ Simultaneously, Rights4Vapers is regarded as one of the most professional and advanced members of the World Vaping Alliance.¹⁷ With vaping considered a healthier alternative on the tobacco risk continuum, these advocates are focused on protecting the rights of adults who are trying to quit smoking over youth who, “just vaped at a party”.¹⁸ Respondents noted that Canada’s membership in the WHO

¹² Respondent 15

¹³ Respondents 7, 9, 11, 12, 13, 14, and 16.

¹⁴ Respondents 1, 2, 3, 4, 6, 8, and 10.

¹⁵ Respondent 5

¹⁶ P13 @ 4

¹⁷ P16 @ 2

¹⁸ P7 @ 8; P7 @ 20

influenced their approach to vapes, to the detriment of smokers. In the following sections I will convey the perspectives of the respondents from the vaping advocacy side.

Youth Use

According to a respondent, the phrase ‘youth vaping epidemic’ has fabricated an unfounded association between vaping and disease, when in their view, vaping should simply be considered a bad habit.¹⁹ Beyond this, it is contended that concern over youth vaping is being used as a false flag, warning that Statistics Canada misrepresents the context in which youth are using the products and that over half of the youth who report past-30-day use are simply “doing vape tricks at a party”.²⁰ The respondents, while maintaining that youth use is an exaggerated problem, did share what youth vaping looks like to them. In reference to the common liability hypothesis, it was suggested that these specific youth were bound experiment with destructive products, whether that be vapes or cigarettes – though “they tend to do both”.²¹ In regard to claims of dual use, a respondent asserted that using both vapes and cigarettes boils down to nicotine experimentation and is no different than youth experimenting with different forms of alcohol.²² In a similar vein, there is agreement from this side that vaping is not a gateway, with one respondent remarking that to say vaping leads to cigarette smoking is as ridiculous as suggesting that Netflix leads to Blockbusters.²³

Flavours

There is great concern from this camp that the imminent flavour regulations will eliminate the option of vaping in Canada.²⁴ Three key concerns were raised in response to the proposed

¹⁹ P9 @ 16

²⁰ P7 @ 21

²¹ P7 @ 18

²² P9 @ 16

²³ P9 @ 18

²⁴ P9 @ 10

flavour ban. The first is that limiting flavours to one's associated with cigarettes will trigger the users; respondents are adamant that those attempting to quit smoking do not want to use flavours reminiscent of cigarettes as they are trying to distance themselves from that association.²⁵ Second, it is argued that years of smoking cigarettes has killed the user's tastebuds and they need the flavours to attract them to the products.²⁶ Third, respondents are confident that the flavour ban will produce a black market as well as lead to dangerous circumstances in which people add flavours on their own.²⁷ In addition to these concerns, respondents highlighted an issue with the motivations of the ban. Health Canada has stated that the flavour ban was developed with the intention of preventing youth from using the products. According to a respondent, there are no flavours that are appealing to only youth – all humans like flavours.²⁸ Instead of attributing youth vaping to flavours, a respondent argued that the true driver of youth vaping was the promotion of the products by social media influencers.²⁹ In contrast to Health Canada's approach, it is recommended to ban flavours that resemble tobacco and menthol, as well as any flavours that – based on toxicology reports – are the most harmful.³⁰

Nicotine

In response to Health Canada's decision to cap nicotine content to 20mg/ml, one respondent said it was, "in a word, insane".³¹ There are two key arguments put forward against the regulation. The first argument questions where 20mg's came from, indicating that such a low limit would exclude heavy smokers from making the switch to vaping.³² The second regarded the contents of

²⁵ P7 @ 24; P12 @ 10

²⁶ P12 @ 10

²⁷ P7 @ 27; P12 @ 15; P13 @ 12

²⁸ P11 @ 9

²⁹ P13 @ 7

³⁰ P7 @ 28

³¹ P11 @ 24

³² P12 @ 5

the vape juice, noting that a stronger nicotine level would be better so that consumers were exposed to less of the other harmful ingredients in the product.³³ Similar to the flavour ban, the nicotine cap was implemented by Health Canada with the intention of preventing youth uptake; a move deemed unnecessary by respondents. Instead of the levels of nicotine being what prompted youth vaping, it is argued to be the mass distribution of the products and ease of access.³⁴ As well, it is noted that when someone is nicotine naïve, they would get a buzz regardless of the concentration, implying 20mg/ml will not affect youth use.³⁵ Due to frustration with the regulation, it was mentioned that members of the vaping community are acting against it by creating informational content regarding how vapers can “legally” get around the nicotine limit.³⁶

Harm Reduction

The respondents from this side were unanimous in their perspective that vaping is an effective harm reduction method. Highlighting that harm reduction is accepted in most areas of public health as a positive measure, but that when it comes to vaping many organizations have opted to villainize it.³⁷ When it comes to vaping, a respondent warned that regulatory decisions need to be made slowly and carefully so the harm reduction potential is not lost.³⁸ It was argued that an important element of vaping harm reduction is acknowledging that users might be addicted to nicotine for the rest of their lives, but that at least this safer form is not going to kill them.³⁹

³³ P7 @ 29

³⁴ P12 @ 7

³⁵ P13 @ 8

³⁶ P9 @ 9

³⁷ P16 @ 15

³⁸ P13 @ 32

³⁹ P9 @ 6

“The Other Side”

There is a high degree of animosity towards those who advocate for vaping regulations that focus on preventing youth uptake. It was suggested that organization’s such as the Heart and Stroke Association are blatantly lying and misleading Health Canada for their own agenda.⁴⁰ One respondent compared advocates from ‘the other side’ to anti-vaxxers and members of a religion who are on a moral quest to protect kids by scaring people.⁴¹ Another referred to them as bootleggers and Baptists who have experienced mission creep; allowed the war on tobacco to morph into a war on nicotine.⁴²

Cessation

The efficacy of vapes as a cessation device is debated even among those who advocate for the products. One respondent recognized that for those who don’t want to quit nicotine, vapes are viewed as an effective substitution but not as a cessation method.⁴³ In that context, the benefit of vapes are their ability to deliver nicotine to consumers without “the tar that kills them”.⁴⁴ In reference to the most effective way to quit smoking, one respondent said that people should try to quit cold turkey first, then use Health Canada approved NRT’s (patches/gum), and as a last resort try vaping.⁴⁵ The prospect of having a prescription vape is not out of the question, with two respondents indicating that they would support the development of a prescription model designed specifically for cessation, while still allowing for a consumer version.⁴⁶ It was

⁴⁰ p9 @ 33

⁴¹ p11 @ 26

⁴² p16 @ 13

⁴³ p7 @ 8

⁴⁴ p9 @ 3

⁴⁵ p9 @ 5

⁴⁶ p9 @ 8

suggested that a prescription model would help decrease stigma felt by those who are using vapes for cessation purposes.⁴⁷

The Precautionary Principle

The application of the precautionary principle to vaping regulations is fervently rejected by this group. One respondent asserted that the precautionary principle is not useful when it comes to developing regulations for medicine and that rather than taking an initially cautious approach, the most important element is post market surveillance.⁴⁸ It was also argued that since we know tobacco kills seven million people a year globally, waiting instead of acting would be worse.⁴⁹ On the same note, another respondent claimed it would be better to deal with unintended consequences of vaping rather than forego the potential gains.⁵⁰ Overall, the perspective is that the precautionary principle is no longer relevant as vapes are proven to be less harmful than cigarettes.⁵¹

Role of Health Canada

Through the interviews it was clear that the respondents hold a Manichean mentality toward the actions of Health Canada. One respondent commented that vapers view Health Canada as an illegitimate body and experts as the enemy.⁵² There are three key reasons this resentment has developed. First, is that vaping advocacy groups maintain that Health Canada does not actually listen to their perspectives but rather occasionally humour them with a meeting and then move on.⁵³ This notion is emphasized as respondents indicate that despite their input during the

⁴⁷ P7 @ 11

⁴⁸ P7 @ 31

⁴⁹ P9 @ 28

⁵⁰ P11 @ 11

⁵¹ P16 @ 17; P14 @ 35

⁵² P11 @ 57

⁵³ P12 @ 27

Gazette process, no changes are ever implemented.⁵⁴ Second is the perception that Health Canada is being influenced by organizations that have an ideological opposition to vaping.⁵⁵

The third cause of resentment is due to the way Health Canada collects and references data. In 2019, 23,000 Canadian's filled out a postcard about their vaping habits and sent them to Health Canada. When developing nicotine regulations, respondents suggest the postcards were considered as 23,000 unique submissions because they indicated that the majority of adult users were using nicotine below 20mg/ml. However, when it came to developing flavour regulations, the postcards, which indicated that the majority of adults use flavoured products, were only (according to respondents) considered as one unique submission. In this case, respondents claim Health Canada considered the postcards as 23,000 unique submissions when it aligned with their objectives and as only one unique submission when they did not.⁵⁶ In a similar manner, respondents are frustrated that Health Canada maintains (without offering evidence) that vaping is only 20% the morbidity and mortality of cigarette smoking, while other jurisdictions and organizations such as Public Health England accept it as 95%.⁵⁷

There is clear concern from the respondents over how Health Canada is regulating vapes, with one claiming they have adopted a draconian approach⁵⁸ while another claims they're committing a public health crime.⁵⁹ The fact that Juul was able to advertise to youth on social media is what one respondent calls, "a complete abdication of responsibility for Health Canada and the Canadian government".⁶⁰

⁵⁴ P13 @ 16

⁵⁵ P12 @ 31

⁵⁶ P14 @ 25; P12 @ 28

⁵⁷ P9 @ 15

⁵⁸ P12 @ 13

⁵⁹ P12 @ 15

⁶⁰ P9 @ 31

7.2 Public Health Advocacy Arguments

Through the interviews it is clear these policy advocacy groups are approaching vaping regulations with the goal of preventing youth uptake. One respondent commented that “the vaping horses are out of the barn, they're running, galloping at full speed toward our kids,” and to protect the youth we must develop effective regulations without delay.⁶¹

Youth Use

When it comes to youth vaping, one of the concerns emphasized is the potential to transition from vaping to cigarettes or engage in dual use. This motivation is supported by claims that youth who vape are at a four times higher risk of tobacco initiation.⁶² As well, one respondent indicated that it takes only one cigarette for 80 percent of youth to become addicted because the product is so well designed.⁶³ Due to this, respondents highlighted five key policy areas that can protect youth. The first is banning all flavours of vape juice except for tobacco to decrease the attractiveness for youth.⁶⁴ The second is removing vaping products from convenience stores where youth can easily access them.⁶⁵ The third is increasing taxes to discourage youth from picking them up.⁶⁶ The fifth is increasing enforcement of current regulations.⁶⁷

According to one respondent, recent evidence indicates there is a huge population health gap regarding cessation versus initiation, as 80 youth will start vaping for each tobacco user who quits by vaping.⁶⁸ Though vaping might offer a safer alternative for adults, a respondent stresses

⁶¹ P8 @ 19

⁶² P2 @ 22

⁶³ P10 @ 7

⁶⁴ P1 @ 7

⁶⁵ P2 @ 15

⁶⁶ P10 @ 19

⁶⁷ P10 @ 5

⁶⁸ P2 @ 22

that, “any benefit has been far overwhelmed by 418,000 youth who are using vaping products at least once every 30 days”.⁶⁹

In response to claims that past-30-day use is an ineffective method to evaluate youth use, a respondent countered that the intention is to identify initiation not necessarily addiction, so it is important to understand how many youth are experimenting with vaping and are at a higher risk of addiction.⁷⁰ It was suggested that while youth smoking rates are continuing to decrease, there is a proliferation of youth nicotine addiction.⁷¹ Another respondent noted that there is more focus on the delivery system versus what is being delivered, which led them to pose a question to Health Canada: “Do you think there's a problem with youth having an addiction?”.⁷²

Flavours

The proposed flavour ban, which exempts tobacco, menthol, and mint flavours, receives criticism from this side, with a respondent noting that to be effective at preventing youth uptake the ban must not exempt menthol and mint.⁷³ It was argued that the US has already demonstrated that youth will gravitate towards any flavour available on the market besides tobacco.⁷⁴ The decision to exempt these flavours indicates that an adults right to consume something flavoured like mint or menthol is more valuable to Health Canada than protecting youth from addiction.⁷⁵ Additionally, a respondent explained that there is no efficacy for menthol or mint when it comes to cessation – only tobacco.⁷⁶ It was also noted that as there is an illicit online market for

⁶⁹ P8 @ 30

⁷⁰ P8 @ 14

⁷¹ P4 @ 22

⁷² P1 @ 15

⁷³ P1 @ 7

⁷⁴ P2 @ 20

⁷⁵ P2 @ 19; P4 @ 12

⁷⁶ P2 @ 26

flavoured products, this ban should be solely focused on reducing the accessibility of any flavoured products to youth.⁷⁷

Nicotine

The nicotine regulations capping the content at 20mg/ml is commended as a step in the right direction.⁷⁸ However, the fact that nicotine was initially allowed in such high concentrations (66mg/ml) is heavily criticized.⁷⁹ A respondent argues that prior to implementing the initial regulations, Health Canada already knew from the tobacco experience how youth react to nicotine and should have introduced lower limitations from the start.⁸⁰ Further, as nicotine is known to have a negative impact on adolescent brain development, greater precautions should have been taken to prevent youth experimentation with nicotine.⁸¹

The expectation for limiting the nicotine concentration is that it will reduce initiation and dependence, sparking a trickle-down effect wherein less youth are experimenting with vaping and transitioning to tobacco.⁸² However, one respondent says a glaring omission is that nicotine salts did not receive unique regulation, which might result in products switching to nicotine salt formulations, so they can meet the 20mg/ml threshold but offer more direct potency to the consumer.⁸³ Beyond this, one respondent highlights that a significant concern is all of the costs associated with vaping and how they can support youth who are experiencing nicotine addiction.⁸⁴

⁷⁷ P1 @ 23

⁷⁸ P4 @ 22

⁷⁹ P1 @ 16

⁸⁰ P2 @ 16

⁸¹ P1 @ 16

⁸² P3 @ 12

⁸³ P8 @ 24

⁸⁴ P1 @ 17

Harm Reduction

It is not disputed that harm reduction is an important element of public health and that shifting people to a safer model of nicotine delivery has its place.⁸⁵ However, there are concerns raised by respondents regarding its application to vaping. The first concern addresses the fact that the harm reduction messaging is being pushed by an industry who has actively targeted youth and non-smokers with their products.⁸⁶ A respondent claims that within investor presentations, the same companies who tout a harm reduction message also tell their investors about the potential to expand nicotine consumption (addiction).⁸⁷ It is argued that the term ‘harm reduction’ has been co-opted by the vaping industry in an effort to vitiate its understanding and application.⁸⁸ One respondent suggests that Health Canada was sucked in by the harm reduction messaging and have now, through good intentions, created unintended consequences.⁸⁹

The overall perspective is that harm reduction does not accurately describe what has taken place with vaping. According to a respondent, Health Canada has actually introduced more potential harm.⁹⁰ It is argued that vaping is not a public health success but rather a trade-off between the health of smokers and youth.⁹¹

“The Other Side”

The vaping industry, according to respondents, is using the same playbook as Big Tobacco.⁹² Further, it is suggested that they are one and the same, with a respondent suggesting that many

⁸⁵ P6 @ 8

⁸⁶ P1 @ 4

⁸⁷ P4 @ 13

⁸⁸ P2 @ 11

⁸⁹ P2 @ 11

⁹⁰ P4 @ 10

⁹¹ P8 @ 29

⁹² P6 @ 6

vaping companies and lobbyist's are funded by Big Tobacco.⁹³ It is argued that the interests of the industry are not aligned with public health objectives nor with the health of youth.⁹⁴ When discussing opposing perspectives, respondents did not refer to the actions or beliefs of individuals but rather the broader motivations of the industry.

Cessation

There is an official process that products must complete to become a Health Canada approved NRT. Currently, no vaping devices have undergone this process and a respondent shared from internal sources that there are no applications in the works.⁹⁵ It is argued that until a vaping device goes through the process and proves its efficacy, it is inappropriate to consider them cessation devices.⁹⁶ While some studies indicate that vapes are as effective or even more effective than NRT products, one respondent emphasized that these studies only indicate efficacy in clinical settings with other behavioural supports, and are not focused on the population level approach.⁹⁷ Further, a respondent says the studies that indicate vaping works for cessation also note that the majority (80%) who are using vapes become long term users.⁹⁸ One respondent, who is a cessation counsellor, recommends that a combination of therapies and counselling is the most effective way to quit smoking.⁹⁹

There is a reason that NRT's are evaluated very carefully before being released, and due to this caution, there have been no youth nicotine gum or lozenge epidemics; if all nicotine products were regulated equally, it is suggested that the rise in youth vaping could have been avoided.¹⁰⁰

⁹³ P3 @ 2; P4 @ 32

⁹⁴ P3 @ 9

⁹⁵ P3 @ 11

⁹⁶ P2 @ 21

⁹⁷ P6 @ 10; P4 @ 16

⁹⁸ P10 @ 14

⁹⁹ P10 @ 14

¹⁰⁰ P8 @ 27

It is argued that vapes should be treated like all other nicotine replacement medications on the market.¹⁰¹

The Precautionary Principle

The problem Health Canada faced once they started developing vaping regulations was the fact that the products were already being consumed. Due to this, it is debated whether the precautionary principle could have been applied. From one side it is argued that the precautionary principle would have been an effective way of approaching vaping, but that it is not the approach adopted by Health Canada.¹⁰² Many organizations recommended Health Canada follow the precautionary principle, which included aligning restrictions on vaping with those for tobacco.¹⁰³ However, despite this, a respondent says that Health Canada “threw precaution to the wind when it came to youth vaping”.¹⁰⁴ It is argued that while there were unknowns regarding the health effects of vapes, there was still substantial enough evidence around nicotine and the dangers of inhaling a volatised aerosol that should have informed stronger regulations.¹⁰⁵ One respondent argued that as enough evidence was available in 2009 for the Therapeutic Drugs Directorate to make vapes illegal, Health Canada should have adopted a more cautious approach.¹⁰⁶ From another perspective, the precautionary principle was not applicable to vapes because the products were already being sold and marketed.¹⁰⁷ However, it is noted that the precautionary principle would have been relevant if applied sooner.¹⁰⁸ In either perspective, it is agreed that Health Canada failed to offer protection to youth.¹⁰⁹

¹⁰¹ P10 @ 23

¹⁰² P3 @ 7; P2 @ 13

¹⁰³ P8 @ 4

¹⁰⁴ P8 @ 18

¹⁰⁵ P1 @ 24; P4 @ 7

¹⁰⁶ P4 @ 7

¹⁰⁷ P6 @ 13; P3 @ 5

¹⁰⁸ P6 @ 13

¹⁰⁹ P1 @ 28

Health Canada's Role

Through the interviews it was evident that the respondents were not pleased with the way Health Canada is regulating vapes. A respondent indicated that instead of learning from the tobacco experience, Health Canada has allowed Canadians to live in a social experiment.¹¹⁰ This happened, according to the respondent, because Health Canada views vaping as a panacea for tobacco control, forgetting that tobacco control gains have been made through strict and intentional regulations.¹¹¹

It is suggested that if Health Canada had taken a more controlled approach, instead of trading the interests of citizens against one another, vaping products could have been accessible for cessation purposes while also preventing youth uptake.¹¹² Respondents are adamant that substantial evidence was shared with Health Canada that would have justified stricter regulations.¹¹³ In addition to this, it is noted that the US experience should have acted as a warning and encouraged a more cautious approach.¹¹⁴ A respondent maintained that it would have been better to walk back from an over-regulatory position than deal with the current situation.¹¹⁵

Health Canada is referred to as a harm reduction apologist after lobbying efforts lead them away from a population health approach.¹¹⁶ There are also criticisms toward the lack of transparency in the development of the regulations, with the proceedings of the advisory council all being

¹¹⁰ P8 @ 6

¹¹¹ P8 @ 36

¹¹² P4 @ 25

¹¹³ P4 @ 26; P8 @ 4; P6 @ 16

¹¹⁴ P2 @ 14; P3 @ 8

¹¹⁵ P8 @ 33

¹¹⁶ P2 @ 7 and 22

secret.¹¹⁷ It is argued that Health Canada, “rolled out the red carpet for Juul and others like them” and reversed tobacco control progress by allowing Big Tobacco funded companies to advertise on television for the first time in 50 years.¹¹⁸ The initial actions of Health Canada are labelled as negligent and their current efforts are considered too little too late.¹¹⁹

7.3 Health Canada’s Arguments

The respondent from Health Canada discussed the important factors they considered while developing regulations, the motivations behind their approach, and future policy considerations. It was emphasized that their focus was on finding a balance between protecting youth and ensuring adults feel attracted enough to vaping that they would switch from smoking.¹²⁰ The respondent noted that developing regulations never works in a straight line and that there are many steps that must be taken to address and define problems.¹²¹ The process becomes increasingly difficult when presented with a lack of evidence or contradictions within the evidence.¹²² For example, the respondent indicated that Health Canada initially allowed some promotions of vaping due to the conflicting evidence presented in the initial hearings in the Senate and the House of Commons Committee.¹²³

The TVPA was designed with the intention of supporting Health Canada in addressing tobacco consumption by assisting adult smokers in switching to vaping.¹²⁴ However, the respondent was

¹¹⁷ P4 @ 31

¹¹⁸ P8 @ 3 and 8

¹¹⁹ P10 @ 20

¹²⁰ P15 @ 22

¹²¹ P15 @ 2

¹²² Ibid

¹²³ P15 @ 12

¹²⁴ P15 @ 20

very clear that Health Canada was always focused on preventing non-users and especially youth from experimenting with vaping or tobacco products.¹²⁵

Youth Use

The main concern highlighted by the respondent is that Health Canada does not want youth who were not already using nicotine-based products to start vaping.¹²⁶ While indicating that they do not like the term “gateway effect”, the respondent did share that Health Canada recognizes recent evidence that suggests a correlation between youth who vape and then smoke afterwards.¹²⁷ Due to this evidence, Health Canada is concerned that vaping might lead to long-term nicotine addiction and tobacco use.¹²⁸

Flavours

Health Canada has opted to ban all flavours of vape juice except for tobacco, mint, and menthol. This decision was particularly interesting as menthol is a flavour that has been banned federally for cigarettes. The respondent explained that they felt there was a need to exempt menthol to make vaping more attractive to adult smokers.¹²⁹ The flavour ban was initiated because Health Canada was aware that flavours were attracting youth.¹³⁰ The respondent acknowledged that regulating in this area is difficult as Health Canada wants to consider what is best for youth as well as smokers seeking an alternative.¹³¹

¹²⁵ P15 @ 21

¹²⁶ P15 @ 19

¹²⁷ Ibid

¹²⁸ Ibid

¹²⁹ P15 @ 22

¹³⁰ P15 @ 8

¹³¹ Ibid

Nicotine

The nicotine cap, similar to the flavour ban, is one step of a series of regulatory initiatives Health Canada is developing to address the youth vaping problem.¹³² The respondent confirmed that the nicotine cap was motivated by youth vaping high concentrations of nicotine for the buzz effect.¹³³ This regulatory decision was informed by similar initiatives in the EU, the UK, and provincial regulations.¹³⁴ The hope is that with the lower concentration levels fewer youth will get a buzz from the product.¹³⁵

Harm Reduction

Harm reduction was not directly addressed but the respondent specified that vaping products are a subset of their tobacco control efforts, and that Health Canada recognizes “public health gains if adults who smoke switch to vaping products”.¹³⁶

Regulation Inspiration

The respondent established that initial vaping regulations were largely informed by the experience of the European Union (EU), the UK, and by the 14 recommendations of the Standing Committee.¹³⁷ Additionally, Health Canada has considered regulations that have come from the provincial level.¹³⁸ According to the respondent, Health Canada would evaluate the regulations in other jurisdiction and decide if they aligned with the goals of the TVPA.¹³⁹

¹³² P15 @ 7

¹³³ P15 @ 8

¹³⁴ P15 @ 13

¹³⁵ P15 @ 8

¹³⁶ P15 @ 22

¹³⁷ P15 @ 13

¹³⁸ Ibid

¹³⁹ Ibid

The Precautionary Principle

The respondent was clear that Health Canada has never directly evoked the precautionary principle when regulating tobacco or vaping products.¹⁴⁰ Instead, the respondent noted that they focus on gathering or building evidence and reliable data to base the regulations on.¹⁴¹ However, while they don't currently use it, the respondent did indicate that the precautionary principle could be used and that they are not opposed to it.¹⁴²

Future Plans

There are plans for future regulations that will continue to address the youth vaping problem. One of those plans involves making it more difficult for youth to access the products.¹⁴³ Additionally, they are considering implementing further restrictions on packaging; the respondent referenced the plain packaging regulation in British Columbia as potential inspiration.¹⁴⁴

7.4 The Product Users Arguments

Early on during the interview process it was suggested by respondents that I speak with someone who has used both vapes and cigarettes. The respondent, who is in their mid-twenties, indicated that they started using grape and peach flavoured prime times while in high school.¹⁴⁵ The decision to switch from cigarettes to vapes in their early twenties was due to perceived harm reduction, the enhanced headrush, and the ability to use the products discreetly.¹⁴⁶ The respondent said vapes were the only cessation method they attempted or even considered, noting

¹⁴⁰ P15 @ 4

¹⁴¹ Ibid

¹⁴² Ibid

¹⁴³ P15 @ 16

¹⁴⁴ Ibid

¹⁴⁵ P5 @ 1

¹⁴⁶ P5 @ 5 and 6

that you are unlikely to see any youth trying to quit with a patch.¹⁴⁷ It was emphasized that vapes were considered more addictive by the respondent because of the immediacy and intensity of the headrush due to the high nicotine concentration.¹⁴⁸ It was suggested that the wide availability of vapes is what drove youth vaping, and that the respondent would have still used vapes as a smoking alternative even if it required a prescription.¹⁴⁹ The respondent shared that while they have quit actively using vapes and cigarettes, they are still a social user and will occasionally share a cigarette or use a friends vape at a party.¹⁵⁰

8. Discussion and Conclusion

This section will discuss the insights gained from the study and highlight the contributions of the findings to the public health and health policy literature. I will also share areas of common ground between the highly polarized sides. Based on the findings of this project I will offer policy recommendations that could conceivably address the concerns that have been raised by both sides of the debate.

8.1 Summary of Research Findings

The findings from this project demonstrate that the combined application of the historical institutionalism and advocacy coalition frameworks generated important insights into the development of vaping regulations in Canada. I gained a fuller perspective of how advocacy groups interact with Health Canada, and how they perceive themselves as an actor in the regulatory process. As well, I now understand how past policy priorities continue to influence the decisions of Health Canada.

¹⁴⁷ P5 @ 14

¹⁴⁸ P5 @ 5 and 11

¹⁴⁹ P5 @ 15 and 23

¹⁵⁰ P5 @ 7

The insights from the vaping advocacy groups revealed a Manichean way of thinking, positioning both public health advocacy groups and Health Canada as their adversary. From their perspective, despite relentless efforts, their recommendations are being overlooked in favour of what they consider a moral quest by those advocating for youth protection. This is a natural response, as there is a propensity toward perceiving the actions (or lack of action) of one's opposition as more hostile and antagonistic than is likely intended (Sabatier, 1988; Sabatier et al. 1987).

One of the key findings that supports this perspective is Health Canada's treatment of the results of a vaping shop led campaign. The campaign resulted in almost 23,000 postcards signed by adult vape users, indicating that most of them use nicotine under 20mg/ml and fruit flavoured vape juice. The respondents suggested that Health Canada considered the postcards as 23,000 unique submissions to support the nicotine regulations, but only counted them as one unique submission for the flavour regulations. Through analysing Gazette publications, I have determined that Health Canada acknowledged the postcards as 23,000 unique submissions for both regulations.¹⁵¹ The respondent's claim, while not accurate, speaks to the distrust that has been established toward Health Canada. In the future, such misunderstandings could be mitigated with a clearer and more transparent process in which Health Canada acknowledges receipt and consideration of input by advocates.

From the public health advocacy interviews, the key findings reflect the importance of developing regulations with youth in mind. The respondents, much like those from the vaping

¹⁵¹ Health Canada references the 23,000 postcard submissions in a Gazette on nicotine and flavours, which can be accessed here: <https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html> <https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg2-eng.html>

advocacy side, also felt that Health Canada did not initially heed their recommendations.

However, with the revisited regulations on promotions, the recent nicotine cap, and the flavour ban proposal, there is optimism that the focus has shifted towards the youth impact. The insights revealed that public health advocates tend to recognize the difficulty in developing regulations and understand that it might take years to achieve their objectives. Due to this, their frustration is largely directed towards the vaping industry who they credit with persuading Health Canada that vapes were a panacea to tobacco control. The findings have demonstrated that there has been a transition in the focus of this advocacy coalition from purely tobacco reduction to reducing potential for nicotine addiction. I suggest that this change is a natural occurrence based on changing government decisions and the introduction of new information (Sabatier 1988, 133).

The polarization of this issue might at times feel unreconcilable. Fortunately, the findings have enabled me to determine a few key areas in which respondents from vaping advocacy groups and public health advocacy groups share similar stances. There is widespread agreement from both sides that while vaping is a healthier alternative to smoking, it still presents risks to users and it would be ideal if users could transition off vapes in the long-term.¹⁵² Enforcement is an area that was highlighted by both sides as an issue, with respondents noting that current regulations need to be more effectively enforced.¹⁵³ There is also amenability from both sides to have products removed from convenience stores and made available strictly in specialty shops.¹⁵⁴ Even the nicotine cap, while not favoured, is deemed as a decision that respondents can “live with”.¹⁵⁵ As well, the way that companies advertised to youth is considered unacceptable.¹⁵⁶ While these two

¹⁵² P6 @ 8; P16 @ 14

¹⁵³ P12 @ 19; P10 @ 5

¹⁵⁴ P12 @ 19; P1 @ 30

¹⁵⁵ P9 @ 9

¹⁵⁶ P4 2 29; P9 @ 32

groups might not always agree on the content of regulations, it is acknowledged by both that vaping regulations are necessary.¹⁵⁷ It is also agreed that while vaping does help some people quit, it also presents a danger to youth.¹⁵⁸ It is natural that each of these groups perceive the problem and its solutions through their own conception of beliefs, though it is encouraging that there is an overlap between these perceptions (Sabatier, 2005). All these areas offer hope that the division between these groups might one day lessen.

The findings indicate that there is no simple answer as to whether the precautionary principle should have been applied in this context. However, they clearly demonstrate that Health Canada did not adopt the approach towards vaping regulations. I suggest that the precautionary principle, based on the evidence that was available prior to 2018 and the knowledge around nicotine addiction, would have been an appropriate way to initially approach vaping. Though at this juncture, a precautionary approach is no longer applicable due to the large body of evidence that has been established. Health Canada is now able to confidently base decisions on scientific evidence and the experiences of other jurisdictions.

It is clear from the findings that Health Canada initially produced vaping regulations with the intention of making the product widely available for adults who want to quit smoking. From a historical institutionalist perspective, this action seemingly aligns with their regulatory history of trying to reduce tobacco consumption. However, there have been unintended policy consequences, resulting in rampant youth uptake of vaping and the potential for increased tobacco use. These consequences can be difficult to reverse and create a moment of critical importance in which Health Canada must decide how to approach the problem (Pierson 2000,

¹⁵⁷ P9 @ 18

¹⁵⁸ P8 @ 30; P9 @ 18

251). The youth vaping epidemic created what I consider a critical juncture, in which Health Canada has needed to re-evaluate their regulatory path. I suggest that Health Canada has not diverted from their path and are still acting in the interest of reducing tobacco consumption whilst simultaneously addressing the youth vaping problem. As institutions are not amenable to change, it is cogent that Health Canada is attempting to merge their interests so as not to divert further (Pierson 2000, 256).

Policy Recommendations

The findings establish areas in which there is a need for regulatory action. Based on this, I offer the following policy recommendations that I suggest address the need for reasonable access to vapes for adults while minimizing the potential for youth experimentation. The first is on nicotine, I recommend that Health Canada includes a specific regulation for nicotine salts that reflects the higher potency of the products. The second is on packaging, I recommend that Health Canada refers to their regulations for global precedent setting tobacco packaging and follow those same guidelines to implement plain packaging measures for vapes, vape accessories, and vape juices. The third recommends that vapes are included under federal (and provincial) regulations for smoke-free restrictions to prevent exposure to second-hand vapour and the potential for the renormalization of smoking. The fourth recommendation is for provincial governments to restrict vape products to specialty stores. The fifth is a recommendation to develop a retailer training program specific to vaping. The sixth recommendation is to maintain the current proposal for a flavour ban, as it provides options for adult users while limiting the appeal to youth. Overall, my recommendations are that Health Canada and provincial governments align their vaping regulations with already established tobacco regulations. The

introduction of these regulations would not impede an adult's ability to access the products, but they would decrease the attractiveness and availability of the products for youth.

8.2 Contribution to the Literature

This paper has taken a direct step in addressing the impact that advocacy groups have on regulations in Canada, while looking specifically at the development of vaping regulations. I have focused on the interplay between opposing advocacy perspectives and Health Canada to elucidate how problems are defined and the procedures to address them. There is a great need for further research in this area. Currently, the literature on vaping is largely focused on use rates, and health benefits and risks. The work of Hastie and Kothari (2009) has looked at how coalitions advocate for tobacco regulations in Canada, though their focus was not on the policy outcomes. In this paper, I have begun to address the need for research on this topic by examining the dynamics at play in this regulatory area.

This study offers critical insights into the perception of Health Canada as a regulator, which is valuable as it offers an explanation on where misunderstandings take place and how antipathy develops. I presented regulatory options that address the concerns of both those who are advocating for the rights of adults and protection of youth. This area requires future research specifically focused on which policies can most effectively support both groups. In terms of the advocacy coalition framework, the findings demonstrate that the foundations and motivation of each group is based in their own ideologies and value systems (Sabatier, 1988). Future research that focuses more in-depth on one advocacy coalition would offer more insight into this process.

There is a significant amount of literature that debates the applicability of the precautionary principle to vaping regulations. I have contributed to this literature by getting a clear-cut answer

from Health Canada that they did not reference this principle and have also never used it to guide regulatory decisions for tobacco. I suggest that the debate over the precautionary principle is only relevant in terms of discussing whether it was applied and not if it should be applied now. Based on the available and emerging literature on vaping, there is no need to act in a manner that is not based on scientific and reliable evidence.

Though there were several limitations with this project, the hope is that taking the step to study this important regulatory area will stimulate further research focused on the specific areas highlighted above.

8.3 Conclusion

This thesis has argued that advocacy groups are able to effectively inform regulatory outcomes, though the process is not always assured to generate the desired results. Additionally, when there are opposing advocacy perspectives, it becomes increasingly difficult for both needs to be satisfied. Further, the historical decisions of Health Canada and its policy priorities will often outweigh the evidence offered by advocacy groups. Health Canada's path dependence is deep rooted in long-term objectives to reduce tobacco consumption and increase public health gains (Pierson 2000, 262).

The limitations of this project have been discussed above, though there are three more to highlight. The first is that as I interviewed groups who are driven by personal values and beliefs, it is possible that the findings have been influenced by this. To mitigate such an effect, I evaluated and fact checked claims that were made by respondents. The second is that there were topics that were off limits with certain respondents, which made it difficult to gain a fully balanced perspective. To compensate for this, I tried to fill the gaps through secondary sources.

The third is that there was only one respondent from Health Canada. With such an organization there is a high degree of cohesion among its members regarding the organization's public positions, though it is important to emphasize that this one respondent cannot be tasked with comprehensively representing the perspective of an entire organization.

This project sought to find common ground between the polarized perspectives with the intention of recommending regulations that can satisfy the objectives of both groups. The analysis undertaken has endeavoured to explicate the areas in which these groups objectives meet, while offering recommendation on adequate regulations. I have indicated several areas that future research should focus on to improve our understanding of this regulatory field.

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Appendix I - Interview Guide

- When referring to vapes, e-cigarettes, ENDS, is there a term that you prefer to use?¹⁵⁹
 - Probe: why do you prefer that term?
- What is your involvement with the ___ community? How does your work address vaping?
- Are you familiar with the precautionary principle? It stipulates that governments should use caution when developing regulations for products that might impact public health. Do you think this principle is relevant to regulating vapes?
 - *Probe:* Do you think Health Canada considered this principle when developing regulations?
 - *Probe:* What are the benefits or potential negatives effects of basing policy decisions on the precautionary principle?
- What steps do you think Health Canada took to evaluate the risk of vapes?
- Do you think there is a connection between youth vaping and tobacco initiation?
 - *Probe if response is negative:* Do you have any concerns around youth vaping?
 - *Probe if response if positive:* How can Health Canada approach this issue?
- Health Canada has just proposed a ban on all flavours for vapes except tobacco, menthol, and mint. What are your thoughts on this?
 - *Probe:* There is a federal ban on menthol for tobacco. Why do you think they differed from this stance when it comes to vapes?
 - *Probe:* is there a version of a flavour ban that you would support?
- Health Canada recently implemented a cap on nicotine content at 20mg/ml. What is your perspective on this decision?
- The efficacy of vapes as a cessation device is still debated. What is your perspective?
 - *Potential Probe:* Should vapes be offered as an official Nicotine Replacement Therapy instead of as a consumer good?
 - *Potential Probe:* What is your perspective on vapes as a prescription device?
- Interest groups, lobbyists and advocacy groups often influence health policy. Do you think any of those groups had an impact on vapes regulations?

¹⁵⁹ Based on the response, I will use that term throughout the interview.

- *Probe:* Do you think your or your organization have been able to influence Health Canada's position?
 - *Probe:* Can you speak on information sharing with Health Canada?
- Health Canada has been trying to reduce tobacco consumption for decades. How (if at all) do you think tobacco control efforts informed vaping regulations?
- Do you have any final comments that you would like to share based on the topics we have covered?
- Is there someone you recommend I speak to in order to gain a fuller perspective on this topic?
 - *Probe:* Would you help me connect with them?
- Can I reach out to you in the future if I need to clarify anything that we discussed?

*The interview is semi-structured. This is only a guiding template.