

To smoke or to vape? E-cigarette regulation in the US, the UK, and Canada

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Abstract

E-cigarettes are hailed by some as a positive development in the war against smoking and reviled by others as a weapon used to addict a new generation to nicotine. This dichotomy highlights an important debate about e-cigarette risk trade-offs: how can governments strike a balance between promoting e-cigarettes as a smoking cessation aid / reduced harm alternative for adult smokers and ensuring that e-cigarettes don't act as "gateway drugs" to smoking for adolescents and other non-smokers?

To this end, this thesis will specifically examine how the US, the UK, and Canada are regulating e-cigarettes. This thesis will show that policymakers often must grapple with risk trade-offs, even if they do not explicitly say as much. I also show that at least in the case of e-cigarette regulation, policymakers focus more on scientific evidence when business interests are fractured. Due to a lack of explicit risk trade-off analyses, however, their assessments of risks vary based on society-specific concerns, which then contributes to great variations in regulation. These variations thus emphasize the need for better cost-benefit analyses of risk-risk trade-offs.

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Introduction

Widely seen as a healthier alternative to cigarettes, electronic cigarettes, or e-cigarettes, have exploded in popularity since their creation in 2003. The term electronic cigarette encompasses a wide variety of products that contain a heating element that produces an aerosol from a liquid that consumers can inhale through a mouthpiece. The liquid (called e-liquid) typically contains nicotine (although non-nicotine e-liquids exist), flavorings, and humectants (to retain moisture). The primary humectants used in e-liquid are propylene glycol, glycerol, or a combination of the two (The National Academies of Sciences, Engineering, and Medicine, 2018). Between 2014 and 2015, sales of traditional cigarettes declined by 1.4% in the US, while sales of e-cigarettes jumped by 14.4% in the same year (Trilling, 2017). Since 2012, worldwide e-cigarette sales have swelled from around \$500 million USD in 2012 to \$7.1 billion in 2016; industry analysts forecast the market will reach \$50 billion USD by 2025.

Many tobacco companies have begun developing and selling their own versions of e-cigarettes as an investment in a future where more and more people avoid smoking due to health concerns. Over the past 50 years, the smoking rate in the US has declined precipitously as Americans have grown increasingly aware of the negative health effects of smoking. According to data from the Centers for Disease Control and Prevention (CDC), 42.4% of Americans smoked in 1965 (The Washington Post, 2015). Although that number had dropped to 15.1% by 2015 (Centers for Disease Control and Prevention, 2017), more than 16 million Americans live with a disease caused by smoking. Every year, smoking is responsible for more than 480,000 deaths in the US— including more than 41,000 deaths resulting from secondhand smoke exposure – and more than 6 million deaths worldwide (Centers for Disease Control and Prevention, 2018).

In light of these sobering statistics, it is unsurprising that many governments have initiated studies on the health effects of e-cigarettes and instituted stricter regulation of the newer nicotine products. Unfortunately, as e-cigarettes were created in 2003, no longitudinal health studies exist. This thesis will therefore analyze how governments monitor and legislate e-cigarettes in light of this uncertainty. As of November 2016, 68 different countries regulate e-cigarettes using a range of policies. Common policies include a minimum-age-of-purchase, public indoor-use bans, and marketing restrictions; to this point, few countries tax e-cigarettes (Kennedy, Awopegba, De Léon, & Cohen, 2017). This paper will also explore key factors that help explain why these governments have chosen different approaches to e-cigarette regulation.

Many scholars have grappled with risk trade-off analysis (RTA) in contexts ranging from food safety to national defense and RTA has become increasingly prevalent in regulatory decision-making (Graham & Wiener, 1995). According to Kip Viscusi, an expert on the economics of risk and uncertainty, risk reduction policies involve inherent uncertainties. As a result, policymakers face the challenge of adopting the policies that will yield the greatest *expected* net societal benefits (Viscusi, 1994). These scientific uncertainties permeate a variety of regulatory areas; one such example lies in chemical regulation and the lack of studies on alternatives to substances that possibly disrupt the endocrine system. Another example in drug regulation that regularly arises is the accelerated approval of promising drugs after one year of clinical trials in lieu of the standard two years – a situation in which US Food and Drug Administration (FDA) regulators sacrifice more clinical data in order to potentially help patients more quickly (Lofstedt & Schlag, 2016).

Given that risk trade-offs occur in such a variety of distinct and consequential contexts, many scholars already work to create more systematic and rigorous methods to evaluate and resolve risk

trade-offs (Graham & Wiener, 1995; Viscusi, 1994). This thesis will *not* seek to build on those efforts; rather, I will focus on the political dynamics and policy implications surrounding risk regulation under conditions of scientific uncertainty. The inherently speculative nature of risk regulation necessitates a better understanding of how policymakers currently choose courses of action and the factors that influence such regulatory decision-making.

To this end, this thesis will specifically examine how the US, the UK, and Canada regulate e-cigarettes. After a brief explanation of the focus on these three countries, I provide a framework to evaluate risks and use that framework to analyze the risks that e-cigarettes pose and highlight the tensions that regulation seeks to resolve. The thesis will then delve into essential background information, including the historical legacies of tobacco regulation and the evolution of e-cigarette regulation in each of the three countries. I then shift to a review of e-cigarette risk perceptions from both scientific and societal perspectives as well as the general regulatory process in each country, before moving on to examine the role that key interest groups and advocacy coalitions play in shaping regulatory decision-making. A conclusion highlights key takeaways for e-cigarette regulation, as well as priorities for further health and social science research.

This thesis will show that policymakers often must grapple with risk trade-offs, even if they do not explicitly say as much. I also show that at least in the case of e-cigarette regulation, policymakers focus more on scientific evidence when business interests are fractured. Due to a lack of explicit risk trade-off analyses, however, their assessments of risks vary based on society-specific concerns, which then contributes to great variations in regulation. These variations thus emphasize the need for better cost-benefit analyses of risk-risk trade-offs.

Why the US, the UK, and Canada?

Although Asia has the largest number of e-cigarette users, many countries in that region have either few regulations or outright bans and so do not highlight contentious policy trade-offs. With the exception of South Africa, usage of e-cigarettes in Africa is likely very low. Similarly, South America sees very low usage of e-cigarettes as well. There are relatively few smokers and vapers in Australia, although rates are closer to that of North America and Europe than Asia. Finally, Mexico has implemented extremely strict restrictions, which makes for a relatively straightforward case study.

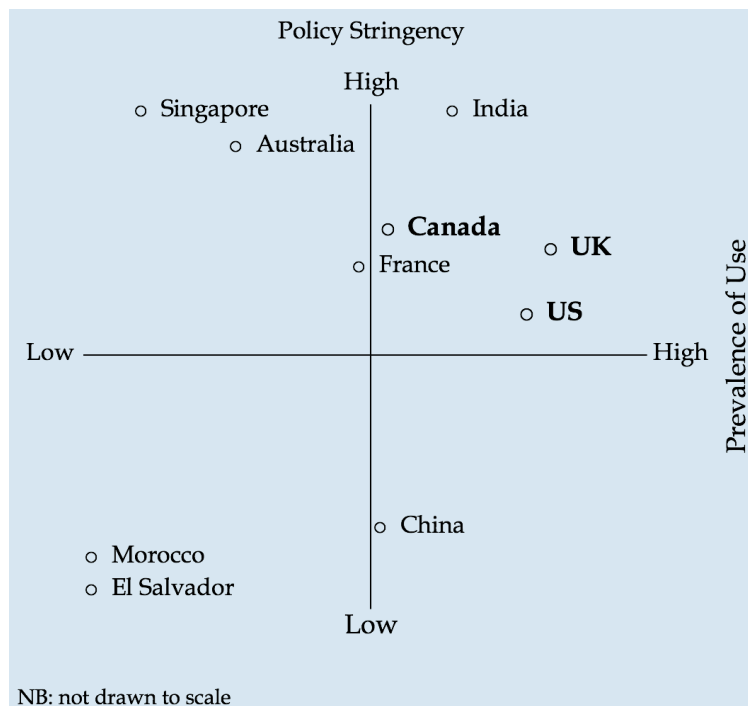


Figure 1: E-cigarette policy stringencies and prevalence of use

As the image above shows, the US, UK, and Canada all have relatively high levels of e-cigarette use.

In addition, these countries' moderate policy stringencies avoid the extremes of few or no regulations and outright bans and thus highlight risk-risk trade-off debates. In 2016, the US and

Europe were the two largest e-cigarette markets, respectively, and accounted for over 75% of the global market. Until recently, e-cigarettes containing nicotine were prohibited in Canada. In May 2018, the Canadian parliament passed a landmark bill that recognized the risk trade-offs that e-cigarettes pose – that although vaping could help current smokers quit, it could also encourage teens to start smoking. The varied e-cigarette regulatory histories of these countries therefore tell a complex and dynamic story of how governments regulate in the face of scientific uncertainty and learn from the successes, mistakes, and unintended consequences of the policies of other countries.

The US constitutes the world's largest vape market. According to estimates from the Center for Disease Control and Prevention (CDC), 3.7% of American adults used e-cigarettes either every day or on some days in 2014 (Schoenborn & Gindi, 2015). This figure translates to over 9 million users who spend over \$3.4 billion per year on related products, accounting for around 43% of the \$8 billion market in 2015 (Schleicher, 2016). Among youth, an estimated 27.1% of adolescents (7.3 million) had tried e-cigarettes as of 2015. Among middle school students, 5.3% were current users and 0.6% used them frequently. For high school students, those numbers were 15.5% and 2.5%, respectively (Office of the Surgeon General, 2016).

The highest growth e-cigarette market in Europe remains the UK with around 2.9 million users as of 2017 – a four-fold increase from 2012. In addition, over half of e-cigarette users (1.5 million people) are ex-smokers and the “main reason people offered for their use of e-cigarettes was to stop smoking” (Action on Smoking and Health, 2017). Among youth, 10% admit to having used them no more than once a month, and 2% use them at least monthly, including 1% that use them more than once a week (Action on Smoking and Health, 2016). The UK also has the strictest anti-smoking policies in Europe (Action on Smoking and Health, 2016), including some of the highest taxes –

policies that could then extend to e-cigarettes or conversely allow for a greater shift from conventional cigarettes to e-cigarettes.

Until 2018, the Canadian national government retained prohibitions against the manufacture and sale of nicotine-containing e-cigarettes. Due to lack of enforcement, however, both nicotine and non-nicotine e-cigarettes were widely available throughout the country. Statistically, e-cigarette use in Canada has similar characteristics to both the US and the UK. According to the 2017 Canadian Tobacco, Alcohol, and Drugs Survey, 15% of Canadians aged 15 and older (4.6 million people) had tried an e-cigarette. Most Canadians who had used an e-cigarette in the past 30 days were current (65%) or former smokers (20%). 32% of current or former smokers reported using e-cigarettes as a smoking cessation aid. On the other hand, youth and young adults (aged 15-24) had the highest rate of trying e-cigarettes compared to other age groups, and an additional 23% of middle and high school students reported having tried a vaping product. Most students who had tried e-cigarettes had also tried tobacco cigarettes (Health Canada, 2018).

E-Cigarette Risk Analysis:

The complexity of e-cigarette regulation stems from its multi-stakeholder implications. Users are of all ages, come from all backgrounds, and require different regulatory approaches. An e-cigarette risk analysis demands a two-pronged approach: a theoretical framework to outline any and all potential risks, as well as empirical research to determine the degree of risk and to understand the actual and expected risk trends.

Risk-Risk Trade-Offs

Any understanding of e-cigarette policy-making requires attention to the more general dynamics of risk regulation. Regulations can affect the very activity they are trying to police and create additional, unintended risks (and potentially additional benefits). When government agencies propose new regulation, they should do so only after a sensible effort to weigh all effects of a regulation (Graham & Wiener, 1995). This analysis, called a risk-risk analysis, ensures that policies and regulations advance society's best interests and do more good than harm (Viscusi, 1994). The first and perhaps most explicit risk-risk trade-off emerges when both action and inaction could cause harm, which is called a risk substitution. For example, taking aspirin for a headache can irritate the stomach lining and eventually cause stomach ulcers (Graham & Wiener, 1995). A second type of risk-risk tradeoff, called a risk offset, comes from behavioral change elicited by a new policy (Viscusi, 1994). People could increase risky behavior if the risk of that behavior is reduced, thereby offsetting the risk reduction. A third type involves a "risk transfer". Here, action taken to reduce a risk simply transfers the risk to a different population. Finally, a fourth type of risk-risk trade-off occurs when action taken to reduce a risk in one population causes a different kind of risk in a different population. For example, banning DDT (a long-lasting, but relatively mild toxic pesticide) to protect wildlife

increases health risks to farmers who now have to handle other pesticides that tend to be less persistent, but more toxic. Scholars have dubbed this process a “risk transformation” (Graham & Wiener, 1995).

For e-cigarettes, risk substitutions, offsets, and transformations all loom as possibilities. Risk substitution might occur because both e-cigarettes and conventional cigarettes can cause harm. Although scientists have generally found e-cigarettes to be safer than conventional cigarettes (Farsalinos & Polosa, 2014; Hajek, Etter, Benowitz, Eissenberg, & McRobbie, 2014; Wills, Sargent, Knight, Pagano, & Gibbons, 2016) because they are a non-combustible product, we lack studies on the long-term impacts of inhaling the particular chemicals found in e-cigarettes. Some e-cigarettes have been found to contain a variety of toxins and carcinogens (Gilmore & Hartwell, 2014) and studies have found that at high voltage levels, concentrations of certain chemicals such as formaldehydes can reach levels found in traditional cigarettes (Kosmider, et al., 2014). Insofar as consumers shift from traditional cigarettes to e-cigarettes, one can trace an explicit trade-off between the risks posed by cigarette smoke and the risks posed by e-cigarette vapor, although at this stage a significant majority of experts agree that the risks posed by e-cigarette vapor are likely to be smaller than those of cigarette smoke.

A risk offset could arise to the extent that consumers perceive e-cigarettes as posing lower risks than traditional cigarettes. For many smokers, e-cigarettes are the most similar to cigarettes out of all of the many alternative nicotine delivery systems (including patches, gum, etc.), in part due to the speed of uptake of nicotine and similar method of intake (Gilmore 2014). E-cigarettes can therefore provide a safer alternative to cigarettes and perhaps even act as smoking cessation aids, as some studies have associated e-cigarette use with a higher rate of quitting smoking (Zhuang, Cummins,

Sun, & Zhu, 2016; Zhu, Zhang, Wong, Cummins, & Tedeschi, 2017). This low-risk perception, however, could potentially lead to greater e-cigarette use among smokers and therefore a higher exposure to nicotine (and e-liquid chemicals) than if they smoked conventional cigarettes.

Adolescents and non-smokers, who now smoke at lower rates, but use alternative tobacco products at higher rates (e-cigarettes, hookah, etc.) (Bunnell, et al., 2014; Giovacchini, Pacek, McClernon, & Que, 2017; Jamal, et al., 2017) confront even greater risks. Due to low risk perception, these groups could be more likely to experiment with e-cigarettes (Giovacchini, Pacek, McClernon, & Que, 2017), which could act as “gateways” to conventional cigarettes (Bunnell, et al., 2014; Wills, Sargent, Knight, Pagano, & Gibbons, 2016). Risk perceptions of e-cigarettes will decrease as agencies relax regulations.

Finally, perhaps the most troubling risk-risk trade-off for e-cigarettes lies with the possibility of a risk transformation. Targeting the risk that e-cigarettes pose to adolescents by restricting access to e-cigarettes could create the countervailing risk that smokers would not use them and would continue to smoke conventional cigarettes and all of the accompanying toxins instead. In regulating e-cigarettes, policymakers will have to find a balance between the potential benefits of e-cigarettes as a potential smoking cessation aid and even as a reduced toxicity alternative to cigarettes and the potential risk that e-cigarettes could lead non-smokers to conventional cigarettes and nicotine addiction. Below I offer a summary of risk-risk trade-offs and how they pertain to e-cigarettes:

Risk-Risk Trade-Off	Relationship to E-Cigarettes
Risk Substitution: actions to reduce risk cause harm	e-cigarette vapors can also cause harm
Risk Offset: specific risk reduction increases frequency of risk behavior	perception of e-cigarettes as less harmful might increase use
Risk Transfer: reduction transfers risks to a different population	N/A
Risk Transformation: reduction for one population generates new risks for another	restricting access to protect youth could limit shift to vaping by adult smokers

Figure 2: Potential e-cigarette risk-risk trade-offs

What Does the Science Say?

On the whole, e-cigarettes are becoming increasingly popular (particularly among current smokers), act as smoking cessation aids for many, and have become widely available throughout North America and Europe (Glasser, et al., 2017). Scientific discussion on e-cigarette safety has evolved throughout the years. A 2014 meta-analysis of 76 articles found that because of severe methodological issues, relatively few and small studies, and inconsistent and contradictory findings, the authors could make no firm conclusions on e-cigarette safety. However, the authors simultaneously emphasized that e-cigarettes could “hardly be considered harmless” (Pisinger & Døssing, 2014). In contrast, a 2017 meta-analysis on 687 articles found that e-cigarettes “pose

substantially less harm to smokers than cigarettes” (Glasser, et al., 2017). Although the 2017 analysis also noted that “more longitudinal studies and controlled trials are needed to evaluate the impact of ENDS on population-level tobacco use and determine the health effects of longer-term vaping,” these analyses differ in significant ways. Even though the long-term health impacts remain unknown, the 2017 analysis importantly views e-cigarettes through a relative, harm-reductionist lens whereas the 2014 analysis regards harm as absolute. For the most part, scientists and public health experts now agree with the findings of the 2017 meta-analysis – that while e-cigarettes are not harmless, they are substantially less harmful than conventional cigarettes. Experts generally publish and refer to studies and reports that support this view, although the specific documents that are mentioned most often differ by country.

Evolution of E-Cigarette Regulation

Despite relative scientific consensus, e-cigarette regulations in the US, UK, and Canada vary widely. Whereas policymakers in the US and Canada have had to concentrate on adolescent use, British regulators have fixated on promoting e-cigarettes as smoking cessation aids. The arc of regulation in all three countries has also followed different paths; whereas American regulations follow a more or less natural progression, current British and Canadian regulations diverge drastically from their initial policies. These differences in e-cigarette regulation form the foundations of the forthcoming case studies.

United States:

On September 28th, 2018, the FDA conducted a surprise inspection of JUUL Labs headquarters and seized more than a thousand documents related to the company's sales and marketing practices. (Hoffman, 2018). Two weeks earlier, on September 12th, 2018, FDA Commissioner Scott Gottlieb announced the launch of a comprehensive plan using posters and ads on digital and social media sites to warn kids of the dangers of e-cigarette use. The agency also issued more than 1,300 warning letters and fines to retailers who illegally sold e-cigarette products to minors, as well as letters to the five largest e-cigarette manufacturers that asked them to submit plans to the FDA within sixty days detailing how they would curb youth access and use of their products. These five manufacturers – JUUL, Vuse, MarkTen, blu, and Logic – together comprise 97% of the US e-cigarette market. The FDA warned that failure to comply or adequately address these concerns could result in orders to prohibit sale of their flavored products. The FDA's current policy allows these products to remain on the market without a marketing order from the agency (U.S. Food and Drug Administration,

2018), and there are few regulations apart from a requirement that e-cigarettes conform to existing child poisoning prevention packaging standards (114th Congress, 2016).

These regulations build on previous policies. In late 2006, manufacturers introduced e-cigarettes to the US market (NY Times, 2011). In March 2009, the FDA temporarily banned the importation of e-cigarettes on the grounds that they constituted an unapproved drug delivery device, but the Court of Appeals for the DC circuit ruled in December 2010 that the FDA only had grounds to regulate e-cigarettes as a tobacco product unless suppliers claimed therapeutic benefits. In April 2011, the FDA announced it would comply with the ruling (NY Times, 2011). As the 2009 Tobacco Control Act granted the FDA authority over anything they consider to fit the definition of a tobacco product, the next step for the FDA was to create a rule deeming e-cigarettes a tobacco product; in April 2014, the FDA released a proposal aiming to accomplish just that (NY Times, 2014). Members of Congress also expressed concerns over the safety of e-cigarettes; in December 2015, Congress passed the Child Nicotine Poisoning Prevention Act which subjected the packaging of “liquid nicotine containers” to existing child poisoning prevention packaging standards (114th Congress, 2016).

In May 2016, the FDA finalized the rule bringing e-cigarettes under their regulatory authority. The rule, effective August 8, 2016, also prohibited the sale of e-cigarettes to minors and required producers to register with the FDA and apply for a permit to sell (Food and Drug Administration, 2016). Following the 2016 election and Trump’s subsequent appointment of Dr. Scott Gottlieb as the new head of the FDA, e-cigarette regulatory action accelerated. In July 2017, the FDA announced a comprehensive plan for tobacco and nicotine regulation that extended the new products application deadline for any e-cigarette introduced to the market after February 15, 2007 from 2018 to 2022. Simultaneously, the FDA also announced that it would start considering

regulations to lower the nicotine levels in combustible cigarettes (Food and Drug Administration, 2017). Finally, in March 2018, the FDA released an Advanced Notice of Proposed Rule Making (ANPRM) on the topic, announcing that it would consider over-the-counter regulation for e-cigarettes, and in April 2018, began cracking down on retailers who sold to minors. Thus, the FDA's recent crackdown on youth use emerges as a natural extension of its previous actions.

United Kingdom:

As a member of the EU, the UK currently must abide by EU regulations regarding e-cigarettes. The 2014 Tobacco Products Directive (TPD) (2014/40/EU) allows e-cigarettes to be marketed without a medicines license if their nicotine concentration does not exceed 20 mg/ml. The directive not only brought e-cigarettes under the EU's tobacco regulatory scheme, but also implemented comprehensive e-cigarette regulations, including:

- 10ml per bottle limit on refill volume and 2ml for vaporizer specific cartridges
- bans on coloring, vitamins/health additives, caffeine, taurine
- requirements that e-cigarettes and refills must be child- and tamper-proof and must deliver nicotine at consistent levels
- bans on advertising on TV, radio, print, and sponsorship (although it left the regulation of passive forms of advertising, such as billboards, under the discretion of individual countries)

In August 2018 however, Members of Parliament (MPs) on the science and technology committee released a report endorsing the promotion of e-cigarettes as an alternative to traditional cigarettes.

The committee recommended lowering taxes on e-cigarettes, allowing vaping in some places where smoking is banned, and importantly, loosening EU advertising and labeling restrictions, which will become possible once Britain leaves the EU in March 2019 (Jennings, 2018).

These policies represent a departure from the UK's initial approach. Manufacturers introduced e-cigarettes in Europe at the same time as the US, in 2006. They were initially subject to general consumer protection laws and only Trading Standards officers had any authority to regulate them on general safety standards (Action on Smoking and Health, 2009). In 2009, however, Action on Smoking and Health (ASH-UK), a public interest group, expressed their support for reduced harm alternatives to cigarettes and recognized e-cigarettes as one potential alternative, but stressed that those attempting to quit should still use conventional nicotine replacement therapies (NRTs); two years later in 2011, the British Cabinet's Office's Behavioural Insights Team (BIT) arrived at the same conclusion. After a three-year consultation process, the MRHA announced in June 2013 that the British government would license e-cigarettes as over-the-counter medicines.

However, the 2014 EU Tobacco Products Directive (TPD) upended these plans, as the directive allowed e-cigarettes to be marketed without a medicines license if their nicotine concentration does not exceed 20 mg/ml, as previously mentioned. In late 2015, British American Tobacco's e-Voke vape became the first e-cigarette to receive a license to be sold as a smoking cessation aid. A few months later in February 2016, the National Centre for Smoking Cessation and Training issued a guide for those wanting to use e-cigarettes as a smoking cessation aid and in April 2016, the Royal College of Physicians issued a report, "Nicotine without smoke: tobacco harm reduction," noting that e-cigarettes are much safer than smoking.

In the same month, the UK passed the Tobacco and Related Products Regulations, which implemented the TPD. The minimum safety and quality standards in the TPD went into effect in May 2016, while the stricter standards took effect a year later in May 2017. The UK's version of the TPD were even stricter; the UK also required all e-cigarettes and e-liquids to be reported to the

MRHA before their introduction to the market and banned the sale of half-packs (packs of 10 cigarettes). Finally, in March 2018, Public Health England (PHE), another executive agency of the Department of Health and Social Care, advised doctors to encourage smokers to switch to vaping (Public Health England, 2018).

Canada:

In May 2018, the Canadian federal government passed the Tobacco and Vaping Products Act (TVPA), which provided extensive legislation regulating e-cigarettes, including:

- banning vaping product sales to persons under 18;
- granting regulatory power over how many vaping devices and how much e-liquid a package can contain;
- banning sales via vending machines;
- requiring age verification for online sales;
- banning the use of ingredients that suggest health benefits (such as caffeine or taurine);
- and, most importantly, banning the advertising of vaping products where specific ingredients or flavor categories are used or where there is any indication of a flavor that could be appealing to young persons.

The TVPA also limited other kinds of advertising, including appealing to youth, lifestyle advertising, and promoting vaping products by using tobacco brands. The TVPA does allow for brand preference advertising that complies with applicable regulations and the use of approved statements regarding the relative health risks of vaping products in comparison with tobacco products.

Like the UK, these new regulations deviate from early policies. E-cigarettes first arrived in the Canadian market around the same time as in the US and the UK and have existed in a regulatory gray area ever since. In 2009, Health Canada advised Canadians not to use e-cigarettes, as they “may pose health risks and have not been fully evaluated for safety, quality and efficacy by Health Canada”

(Ottawa Citizen, 2014). Since Health Canada has not given any company market authorization to sell nicotine e-cigarettes, the sale and advertising of nicotine e-cigarettes remained technically illegal (The Globe and Mail, 2014). In practice, however, the enforcement of this ban was spotty at best and nicotine e-cigarettes were widely available. Since 2009, non-nicotine e-cigarettes have been neither approved nor banned in Canada, and could also be found nationwide (Ottawa Citizen, 2014).

While eight of the ten provincial governments, including British Columbia, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward’s Island, and Newfoundland and Labrador, passed legislation regulating e-cigarettes between 2015 and 2016, the federal government did not take any additional steps until May 2018, when it passed the TVPA. Below is a summary of the evolution of e-cigarette regulation in all three countries (see Appendix A for a timeline):

	Past Regulation	Current State of Regulation
US	2015: Congress mandates child-proof packaging. 2016: FDA claims regulatory authority. 2017: FDA extends new products application deadline to 2022.	FDA pre-approval not required. FDA action to curb youth vaping (fine on retailers who sell to minors).
UK	2013: MRHA decides to license as OTC medicines. 2014: EU Tobacco Products Directive (TPD) supersedes MRHA 2016: Parliament implements TPD	EU regulations: strict product restrictions, bans on coloring and additives, bans on advertising
Canada	2009: Technically illegal, but widely available. 2018: Parliament passes TVPA which legalizes and regulates e-cigarettes.	Bans on sales to minors, advertising of flavors that could appeal to youth, and additives.

Figure 3: Evolution of e-cigarette regulation

History of Tobacco Regulation

An assessment of the history of e-cigarette regulation is incomplete without an exploration of the foundation on which it rests – tobacco regulation. That history involves a decades-long efforts of tobacco companies to mislead the public about the dangers of smoking. As courts have ordered tobacco companies to pay billions of dollars in damages as recently as 2017 for hiding evidence from the public (Orlando Sentinel, 2017), e-cigarette manufacturers have clearly taken care to not repeat Big Tobacco’s past mistakes. In addition, tobacco regulation in each of these countries is stringent in comparison to emerging economies, reflecting societal norms in industrialized democracies that increasingly reject smoking and general tobacco use. These cultural attitudes will also undoubtedly shape attitudes towards vaping. Appendix B shows a timeline of cigarette regulation in the US, UK, and Canada.

United States:

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which gave regulatory power over tobacco products to the FDA, also:

- prohibited the advertising of cigarettes as “light,” “low,” “mild,” or similar descriptors without an FDA order;
- banned sponsorship of sports, entertainment, and other social and cultural events;
- required graphic warning labels for cigarettes and larger text labels for smokeless tobacco;
- required tobacco companies to submit research on health, toxicological, behavioral, or physiological effects of tobacco use;
- allowed the FDA to conduct compliance checks and issue fines and potential no-tobacco sale order;
- prohibited flavoring in regular cigarettes;
- authorized the FDA to regulate tobacco product content including tar, nicotine, and other harmful components;
- and required manufacturers to get an order/exemption from FDA before introducing new tobacco products (111th Congress, 2009).

Although federal cigarette legislation is fairly extensive, Congress has not attempted to pass any federal smoking bans; Executive Order 13058 issued by President Clinton restricted smoking in all federal buildings as of January 1979. As of 2017, 25 states have enacted statewide bans on smoking in all enclosed workplaces and 11 other states have enacted statewide smoking bans but with exceptions made for certain establishments such as casinos, cigar bars, and private clubs (American Nonsmokers' Rights Foundation, 2018).

United Kingdom:

UK cigarette laws are similarly comprehensive. Although in many cases, UK regulation predated EU tobacco directives, certain directives impacted cigarette regulation in the UK. In June of 1998, the EU attempted to pass a directive banning all forms of tobacco advertising and sponsorship.

Although the European Court of Justice annulled this directive in 2001 and forced the EU to pass a more limited ban (which they did in 2003 with Directive 2003/33/EC – the Tobacco Advertising Directive), this prompted the British government to pass the Tobacco Advertising and Promotion Act in 2002. This act comprehensively banned all forms of tobacco advertising, including billboards, print media, direct mail, and sponsorship (Parliament, 2002). In 2003, EU Directive 2001/37/EC also implemented new, larger health warning labels on cigarette packs (EUR-Lex, 2014).

Canada:

Canadian laws provide as broad protections as those in the US and the UK. One notable aspect is that the tobacco industry preemptively withdrew radio and TV advertising and placed weak health warnings beginning in 1972. Although this tactic worked over a decade, the Tobacco Products Control Act of 1989 gave the government authority to ban all forms of advertising and phase out promotional activities and sponsorships — the first legislation to do so in any of these three

countries — although this legislation was later deemed unconstitutional by the Supreme Court as a violation of free expression. In response to the Supreme Court’s decision, Parliament passed the Tobacco Act, which:

- required health and toxic content warnings in English and French;
- imposed a federal age limit of 18;
- prohibited the use of terms such as “light” or “mild;”
- imposed ignition propensity regulations so that unwatched cigarettes became less likely to cause a fire;
- and prohibited or phased out advertising, sponsorship, testimonials, points-of-sale displays, and branding on accessories (Canadian Legal Information Institute, 1997).

Analysis:

In regulating tobacco, none of these three countries is consistently more stringent. Each country has been the first to regulate certain areas and each now regulates some areas more rigorously than the other. Out of the three, the US required health warnings first, but the UK banned advertising on TV earlier. The UK also prohibited the sale of tobacco to youths before the US tackled the issue, but the US started to regulate smoking in public spaces earlier than the UK, as the restriction on smoking in federal buildings began in the late 70s.

With regard to many regulatory issues, Canada has lagged slightly behind the other two countries. A notable exception is the regulation of advertising and sponsorship; although the Tobacco Products Control Act of 1989 was eventually deemed unconstitutional, it represents one of the rare instances in which Canadian tobacco legislation outpaced that of the US or the UK. In addition, Canada was the first country to adopt pictorial health warnings in 2001, years ahead of both the UK, which followed suit in 2007, and the US, which has yet to successfully do so. The UK currently remains the only country of the three to have adopted plain packaging for cigarettes cartons, although Health

Canada announced in June 2018 that it would consider implementing this measure as well. Although the US has led the charge in passing strict cigarette legislation in the past, it has arguably fallen behind in recent years. When the FDA passed a rule requiring pictorial health warnings in 2011, tobacco companies challenged the rule in court, which was then vacated by the US Court of Appeals (U.S. Food and Drug Administration, 2018). Nevertheless, we can generally consider cigarette regulations in all three countries, including the US, to be stringent – especially in comparison to policy in emerging economics.

As each country has implemented relatively strong cigarette regulations, we cannot consider this to be a particularly important cause of the diversity of e-cigarette policies. The evolution of e-cigarette regulation, however, does reveal salient aspects, such as the fact that regulations changed drastically at distinct turning points in the UK and Canada, and accelerated fairly recently in the US. More salient contributors to variations in e-cigarette regulations between the three countries will be further explored in the case studies.

Case Studies

Several factors contribute to the variations in these countries' approaches to e-cigarette regulation.

The most important include the structure of the policymaking process in each country, the degree of consensus around scientific studies and their influence on decision-makers, country-specific vaping trends, and the role of interest groups, advocacy coalitions, and political macro narratives. Other less important but relevant determinants involve the history of cigarette and e-cigarette regulation, as well as outcomes in partisan politics.

The regulatory processes of the three countries share key characteristics. Parliament retains the authority to establish policies that are then carried out by health agencies or departments in the UK and Canada. This process diverges slightly in the US since the Food and Drug Administration (FDA), an independent regulatory agency, decides and implements e-cigarette regulation. However, the FDA wields authority only because Congress has delegated it (and has the power to revoke it); despite superficial differences, the regulatory processes of each country thus converge to a large degree.

The precautionary principle, which is the idea that precautionary measures should be taken if an activity threatens harm to human health or the environment (Science & Environmental Health Network, 1998), guides regulation in the face of scientific uncertainty. Some countries, including the EU (EUR-Lex, 2016), explicitly follow the principle. Even so, reactionary regulation that responds to societal needs is more crucial than precautionary regulation. As a result, vaping trends are therefore some of the most, if not the most, significant determinants of policy.

Another important aspect to consider is the role and strength of various advocacy coalitions. Policymakers do not exist in a vacuum; they are not all-knowing and they need to rely on experts and serve constituents. Certain groups and points of view will inevitably be more influential than others, and their perspectives will be more likely to color policy.

For e-cigarette regulation, the most relevant interest groups have turned out to be medical organizations and the business lobby, including tobacco companies and pharmaceutical companies that produce smoking cessation aids that could be threatened by e-cigarettes. In addition, libertarian think tanks and other interest groups actively participate in the e-cigarette regulation debate. One might imagine that convenience stores, bars, nightclubs, and restaurants would lobby against e-cigarette regulation, since they benefit from e-cigarette sales; various non-profit anti-smoking organizations have attained especial prominence or hold particular sway in their respective countries.

Influence will partly rely on how successfully interest groups can manipulate political narratives to attract support for their views. In addition to the explicit narratives they utilize, political meta-narratives will also determine their success. These meta-narratives are often unconscious ideologies that citizens internalize as they seek to understand the events around them (Mayer, 2014). Political meta-narratives wield political ideologies to promote or legitimize viewpoints, policy positions, and perspectives. It is therefore likely that narratives that support these subconscious values will also exert more influence.

United States

Regulatory Process:

The Food and Drug Administration (FDA), an independent regulatory agency (IRA), is responsible for e-cigarette regulation. Congress was in charge of cigarette regulation until the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave regulatory authority over tobacco products to the FDA in 2009. This act did not explicitly give the FDA regulatory power over e-cigarettes since they are not strictly a tobacco product, so the FDA finalized a rule in May 2016 that deemed e-cigarettes as meeting the statutory definition of tobacco products, which therefore extended the FDA’s authority to cover e-cigarettes. This diagram shows the process the FDA must undertake to create new regulation:

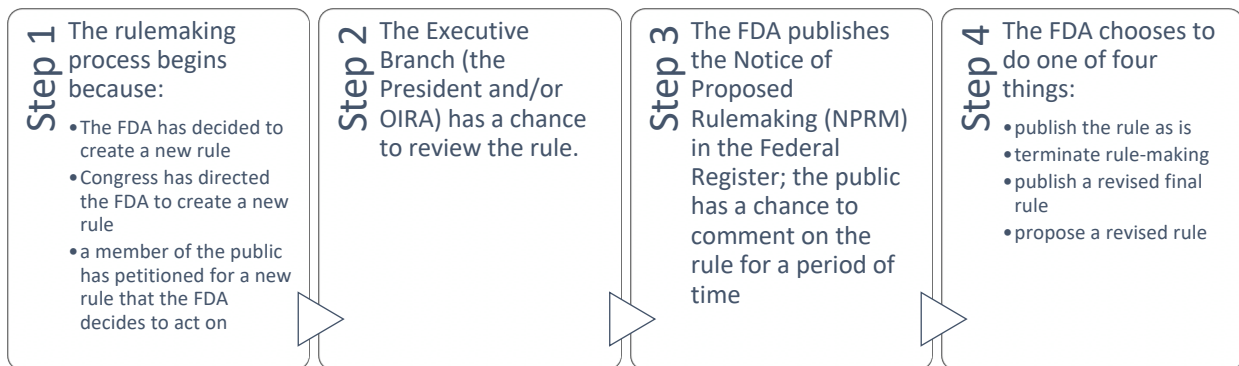


Figure 4: FDA rulemaking process

In the preliminary stages, the FDA can also publish an “Advance Notice of Proposed Rulemaking” (ANPRM), a formal invitation that starts the notice-and-comment process. Interested parties can respond to the ANPRM. Before the public comment period, the executive branch can also review the rule (Office of the Federal Register, 2011). The Office of Information & Regulatory Affairs (OIRA) is in charge of reviewing proposed rules that have a “significant” effect, including rules that

have an annual effect of \$100 million or more on the economy or has an adverse effect “in a material way” on anything related to the economy; rules that interfere with the actual or planned actions of another agency; rules that materially alter the budgetary impacts of entitlements, grants, user fees, etc.; and rules that raise new legal and policy issues (Office of Information & Regulatory Affairs, 2017).

The public is allowed a comment period that generally ranges from 30 to 60 days depending on the complexity of the rule, but the FDA can lengthen the period to up to 180 days or more, or shorten the comment period if justified. The FDA can also extend or re-open the comment period if comments are low-quality or if they raise new issues the agency has not previously considered. The FDA can also hold public hearings and meetings during this time. These comments are not votes; at the end of the process, the FDA must base its final regulations on the rulemaking record, which consists of the comments, scientific data, expert opinions, and facts gathered during the rulemaking process. The FDA must conclude that the rule will help accomplish the goals set out and must also consider alternative solutions.

As an IRA, it is possible that the FDA can move more quickly than traditional lawmaking. On the other hand, it is perhaps less accountable to the public and its actions could depend on the priorities of its commissioner and consequently, the president who appointed said commissioner.

Scientific Reports:

To the extent that scientific studies in the US converge, one can trace the evolution of scientific knowledge since the invention of the e-cigarette. The two major systematic reviews of available studies on the health and societal effects of e-cigarettes arrive at completely different conclusions.

These meta-analyses are the 2016 report from the Surgeon General titled “E-Cigarette Use Among Youth and Young Adults” and the 2018 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) on the “Public Health Consequences of E-Cigarettes.”

The US Department of Health and Human Services prepared the 2016 report under the general direction of the CDC’s Office on Smoking and Health. As the title suggests, the report primarily discussed the effect of e-cigarette use on youths; the first sentence of the foreword stated that “tobacco use among youth and young adults in any form, including e-cigarettes, is not safe.” The foreword sets the tone for the rest of the report, which strongly supported additional regulations to protect “a new generation of Americans who are at risk of nicotine addiction.” The report focused on the potential harms of the e-cigarette; there is no mention of potential benefits except when looking at the marketing claims of e-cigarette producers and even then, the report did not attempt to verify the truthfulness of those claims. The report did mention that “although e-cigarettes generally emit fewer toxicants than combustible tobacco products, we know that aerosol from e-cigarettes is not harmless” (Surgeon General, 2016). Even when the report admitted potential benefits, the focus was always on the risks that e-cigarettes pose.

The 2018 NASEM report, which Congress ordered the FDA to commission, adopted a markedly different tone. Unlike the 2016 report, it acknowledged that e-cigarettes reduce harm and did not qualify the fact that “e-cigarettes appear to pose less risk to an individual than combustible cigarettes.” While it reported “substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults,” it carefully avoided stating that e-cigarettes leads to long-term smoking among never-smokers and also recognized “limited evidence that e-cigarettes may be effective aids to promote smoking cessation.” The report called for

additional studies “to help clarify whether e-cigarettes will prove to reduce harm – or induce harm – at the individual and population levels” (The National Academies of Sciences, Engineering, and Medicine, 2018).

Although the FDA never released a statement regarding the FDA-commissioned NASEM report, FDA Commissioner Gottlieb exclusively cited the report in his June 2018 speech, “FDA’s Nicotine and Tobacco Regulation and the Key Role of Regulatory Science,” at the Tobacco Regulatory Science Program Meeting (U.S. Food and Drug Administration, 2018). Similar to the views expressed in the report, Dr. Gottlieb stated that he believed that “fully transitioning smokers to ENDS can reduce the morbidity and mortality associated with tobacco use,” but that “we must make sure that kids aren’t being initiated on, and becoming addicted to these products.”

Vaping Trends:

The FDA’s recent actions directly respond to the JUUL’s dramatic growth in popularity in recent years, especially among youth and young adults. According to data from Wells Fargo, its stunning rise has helped it capture over 70% of the US e-cigarette market. In addition, more high schoolers vape than smoke (11.7% vs. 7.6%), according to the CDC’s 2017 National Youth Tobacco Survey (LaVito, 2018); an additional 3.3% of middle schoolers also vape for a total of around 2.1 million youth vapers. Data from the 2017 Monitoring the Future survey (MTF) shows that nearly 30% of high school seniors reported past year use of vaping products. The JUUL phenomenon has spurred multiple articles puzzling over its popularity (Barshad, 2018; Bellafante, 2018; Richtel & Kaplan, 2018; Zernike, 2018).

This is not to say that only adolescents vape; according to a 2016 survey, 10.8 million adults in the US use e-cigarettes (Mirbolouk, et al., 2016). However, the proportion of teens who vape (11.7%) is staggeringly high, particular in comparison to other countries (Action on Smoking and Health, 2018; Health Canada, 2018). See Appendix C for a table on how these numbers compare. In addition, the proportion of teens who vape is nearly triple that of adult e-cigarette users (4.5%). The FDA’s April 2018 crackdown on retailers who sold to minors and September 2018 warning to manufacturers to create a plan to stop youth use reveal that it is focusing on and responding to exactly this trend. In his September 18th news release, FDA Commissioner Gottlieb also explicitly stated that his belief that “youth use of e-cigarettes is reaching epidemic proportions”... “is based on a number of factors, including the agency’s mounting enforcement actions, recent sales trends, news coverage, increased concerns among kids, parents and educators, as well as preliminary data that will be finalized and released in the coming months” (U.S. Food and Drug Administration, 2018).

Interest Groups, Advocacy Coalitions, and Political Meta-Narratives:

The FDA’s crackdown on youth vaping aligns with the views of the leading medical organizations in the US. The American Lung Association’s (ALA) July 2017 “Statement on E-cigarettes,” expressed concerns “about the potential health consequences of electronic cigarettes (e-cigarettes), as well as what it described as unproven claims that they can be used to help smokers quit. The statement further detailed concerns over secondhand emissions as well as e-cigarettes acting as a “gateway to regular cigarettes, especially in light of the aggressive industry marketing tactics aimed at youth.” The statement also emphasized the harmful effects of nicotine “on fetal development and adolescent brain development” – “an issue of paramount concern to the Lung Association” (American Lung Association, 2015).

Since the ALA statement predates NASEM's 2018 report, it only cited the 2016 Surgeon General report, which as previously discussed, was far less favorable to e-cigarettes than the 2018 NASEM report. Overall, the policy position illustrates the unfavorable view the ALA has taken towards e-cigarettes. The ALA reiterated this position in two separate September 2018 statements; one "commends the FDA for adding e-cigarette counter-marketing to its highly successful 'The Real Cost' smoking prevention campaign" (American Lung Association, 2018) and the other urged the FDA "to take meaningful action – including requiring all e-cigarettes and other newly deemed tobacco products to go through the pre-market review process required in the Tobacco Control Act, and removing all flavored tobacco products from the marketplace" to protect kids from e-cigarettes (American Lung Association, 2018).

Similarly, both the American Cancer Society (ACS) and American Academy of Pediatrics' (AAP) focus on adolescent use. The ACS "strongly recommends that every effort be made to prevent the initiation of e-cigarettes by youth" and calls on the FDA to regulate "all tobacco products, including e-cigarettes" (American Cancer Society, 2018). Unlike the ALA and the AAP however, the ACS has acknowledged that e-cigarettes are less harmful and endorses encouraging smokers who are not looking to quit to switch exclusively to e-cigarettes. The fact that children's pulmonary function can suffer from nicotine exposure, while primarily adults suffer from lung cancer, could help explain this discrepancy between these two organizations. Since children and babies are more affected by nicotine's impact on the pulmonary system, the ALA's greater concern over secondhand exposure makes sense. Conversely, it takes much more exposure to carcinogens to develop cancer, which affords the ACS latitude to encourage e-cigarettes as a harm reduction alternative to tobacco.

As one might expect, the American Academy of Pediatrics' (AAP) advocates for laws to prevent youth initiation of e-cigarettes. Its November 2015 e-cigarette policy statement advised pediatricians not to recommend e-cigarettes “as a treatment product for tobacco dependence” and to recommend “parents, caregivers, and adolescents who use ENDS...tobacco cessation counseling.” The statement also called for a ban on the sale of e-cigarettes to youth younger than 21 years old, internet sales, all flavors, advertising in places that can be viewed by youth, and vaping in public spaces to protect “youth and other nonusers” from secondhand exposure. Furthermore, the AAP recommends limiting the depiction of e-cigarettes in movies, TV shows, and video games and requiring an adult rating for any that do so (American Academy of Pediatrics, 2015).

One reason why these medical organizations hold such sway over regulation is that there is no organized business lobby fighting for the other side (see Appendix D for a breakdown of all interest groups in each country). Pharmaceutical companies such as British manufacturer GlaxoSmithKline (GSK) and its American counterpart Pfizer, the primary manufacturers of nicotine replacement therapies (NRTs) such as Nicorette gum (GSK) and NICOTROL inhaler (Pfizer), promote e-cigarette regulation. Since these companies make the leading NRT products in the US, UK, and Canada and stand to lose market share if e-cigarettes become popular smoking cessation aids, one might presume that these companies would lobby against these products. Although there are scant traces of overt public lobbying by these companies, they are at least aware of the potential threat. Intriguingly, the American Lung Association, which expressed its support for the FDA's e-cigarette deeming rule in May 2016, accepts money from both GSK and Pfizer (Lipton, 2016).

Statements, articles, and reports on these companies' websites offer good indicators of their policy views. A July 2016 Pfizer report called “Value of Medicines: Smoking Cessation” stated that e-

cigarettes’ “effectiveness as a smoking cessation product and their long-term effects on public health are not yet known” (Pfizer, 2016). This language echoed that of a 2014 GSK statement on “FDA’s Proposed Regulation of Electronic Cigarettes and Other Nicotine-Delivering Products,” which asserted that “e-cigarettes have not been proven to help smokers quit” and that “GSK intends to submit written comments to the FDA public docket” (GlaxoSmithKline, 2014). In their comment, GSK made a distinction between “therapeutic and recreational nicotine” to justify what they claim is a need for “regulatory clarification.” GSK further argued that “the most effective way to mitigate electronic cigarettes’ potential as a gateway product and help reverse the renormalization of smoking that they are causing is to regulate them in a similar to combustible cigarettes.” Such regulations include restrictions on advertising, bans on flavors, and online controls regarding taxation, shipping, and age verification (GlaxoSmithKline Consumer Healthcare, 2014).

Pfizer’s comments on the FDA’s proposed deeming rule diverged from those of GSK. They did not recommend substantive policy changes but rather focused on labelling and implementation aspects of the FDA’s rule, such as addiction warnings and implementation timelines. Overall the comment showed Pfizer supported the rule and wanted the FDA “to complete the final rule and begin implementation as soon as possible” (Pfizer, 2014). Another article on Pfizer Canada’s website reported the results of a self-sponsored survey that shows smokers who also use e-cigarettes still smoke 13 cigarettes per day on average (Pfizer Canada, 2015). Neither Pfizer’s UK website nor GSK’s UK or Canada website includes any discussion of e-cigarettes. According to a 2015 Guardian article, GSK also explored the idea of entering the e-cigarette market, but ultimately decided not to because e-cigarettes were “just too controversial.” Even though the CEO admitted e-cigarettes have gained market share, he also said that “there’s a lot of competition in that space anyway” (Kelland, 2015). Overall, these pharmaceutical companies evidently see e-cigarettes as a competing product to

their NRTs. As a result, they have a clear incentive to emphasize the fact that e-cigarettes have not been proven to help people smoking.

In addition, some tobacco companies also favor e-cigarette regulation, albeit selectively. Although e-cigarettes directly compete with traditional cigarettes, many tobacco companies have entered the e-cigarette market with their own products. Altria Group, Inc., formerly known as Philip Morris, is the largest America-focused tobacco company. As smoking rates in the US decline, Altria and other large tobacco companies, including R.J. Reynolds and Lorillard which represent the second- and third-largest American tobacco companies respectively, have shifted their focus to smoke-free alternatives and other reduced-harm nicotine products. Altria acquired smokeless tobacco company UST in 2008 and was the last of the major American tobacco companies to enter the e-cigarette market in August 2013 (CNBC, 2013). To that end, Altria has lobbied extensively to prevent strict regulation. Even before the FDA deeming rule became final, Altria drafted a bill in April 2015 – which was introduced verbatim by Representative Tom Cole (R-OK) two weeks later – eliminating the FDA requirement that the agency retroactively evaluate e-cigarettes already on the market. The bill never made it out of committee; Rep. Cole reintroduced it in 2017, but the bill again stalled in committee. According to the Center for Responsive Politics, Altria annually spends around \$10 million in lobbying since 2010 and focuses most of their efforts on this bill based on the “number of reports and specific issues” in 2017 (Center for Responsive Politics, 2018).

On the other hand, Altria does generally support other regulation. Its website states that “policymakers at all levels of government should adopt a policy framework that allows the FDA to lead a tobacco harm reduction strategy and implement regulatory policies that differentiate among tobacco products.” The company asserts that they “actively supported” laws that “make it illegal for

kids to buy e-vapor products before FDA extended its regulatory authority over these products” (Altria, 2018).

Another important factor is the prominence of and degree to which anti-tobacco organizations in the US focus specifically on reducing adolescent initiation. Unlike the UK and Canada, the preeminent anti-smoking non-profit organizations in the US, Campaign for Tobacco-Free Kids (CTFK), focuses on preventing youth tobacco use. Then President-elect Barack Obama tapped the former executive director of CTFK to be the number two official at the Department of Health and Human Services (Pear, 2009). The president of the organization has also spoken at the biannual E-Cigarette Summit in the past, which is held twice per year in Washington, D.C. and London, and commented on the FDA’s 2014 proposed deeming rule. In its comment, CTFK recognized that e-cigarettes “substantially reduce a cigarette smoker’s risk of death and disease” but emphasized that only cigarette smokers who switch exclusively to e-cigarettes will reap these benefits. The CTFK also called for “strong regulatory [incentives] not to market tobacco products in ways that appeal to adolescents” (Campaign for Tobacco-Free Kids, 2014). Some examples CTFK cites are celebrity advertising, promoting at sporting events or concerts, and using sexual innuendo or cartoons. On its website, the CTFK further elaborates that “the FDA should prohibit all flavorings...given the evidence that flavors play a key role in youth initiation and continued use of tobacco products” (Campaign for Tobacco-Free Kids, 2018).

Thanks to its strength and diversity, the advocacy coalition pushing for regulation to prevent youth use has dominated the conversation around e-cigarettes in the US. On the other side, libertarian think tanks, vaping trade associations, and convenience stores simply cannot compete. Both the Cato Institute and the Heritage Foundation, the two leading libertarian think tanks in the US, have

published several articles on e-cigarettes. Although the arguments differ slightly from article to article, the basic premise remains the same: government should regulate e-cigarettes minimally. These think tanks argue that regulation would block the creation of products that are better for health than smoking and help people stop smoking (Bakst, Congress Needs to Stop FDA Attack on E-Cigarettes, 2016; Marlow, 2014), reduce consumer choice (Bakst & Stier, Rethinking Tobacco Policy: The Federal Government Should Stop Blocking Alternatives to Smoking, 2017; Marlow, 2014), hurt smaller manufacturers and suppress innovation (Bakst & Stier, Rethinking Tobacco Policy: The Federal Government Should Stop Blocking Alternatives to Smoking, 2017; Burrus, 2016; Marlow, 2014), and unfairly burden low-income Americans (Calder, 2018). While each think tank has published only a handful of articles on the topic, the Cato Institute has printed two of these articles in its quarterly magazine and the Heritage Foundation has hosted a March 2018 event on the issue called “Rethinking Tobacco Control in an Era of E-Cigarettes.”

As for vaping trade associations, the US perhaps suffers from too many disparate groups (see Appendix E). Of the nearly 80,000 public comments on the FDA’s 2014 proposed deeming rule for e-cigarettes, many associations were mentioned in fewer than or around 100-150 distinct comments. One association, however, particularly stands out; more than 1,500 comments mention the Consumer Advocates for Smoke-Free Alternatives Association (CASAA), which also directly submitted a comment. This analysis will focus on CASAA’s views, although other trade associations also submitted comments. CASAA’s comment on the proposed deeming rule primarily argued that the paperwork of the application process would be unduly burdensome for the vast majority of e-cigarette manufacturers. CASAA asserted that only the “major traditional tobacco companies...have the resources to comply with the paperwork burdens.” The comment went on to note that thousands of products will exit the market due to the burden of the approval process, which “will

create all the obvious costs for commerce...but much more important in this case is the enormous loss inflicted on consumers” (Phillips, 2014).

Of the various trade associations for convenience stores, bars, restaurants, and nightclubs, only the National Association of Convenience Stores (NACS) left a public comment on the FDA’s 2014 proposed deeming rule. In its comment, the NACS supported the requirement that retailers be required to ensure potential buyers are at least 18 years old, as well as similarly comprehensive enforcement of online and tribal sales. It also opposed restrictions on point-of-sale advertisements because “retailers must be able to inform their customers what products are available in a store” and proposed an effective date of 120 days after the final rule is published in order to give retailers time to “adjust employee training material, raise awareness of the new requirements, and train and educate employees to ensure proper compliance” (National Association of Convenience Stores, 2014).

Given this striking imbalance in the engagement with the FDA regulatory process, one might find it surprising that the US has not implemented more regulations. This is where partisan politics and political meta-narratives come into play. The embrace of libertarian capitalism by the Republican Party is primarily responsible for this trajectory of regulation, as exemplified by Dr. Gottlieb’s decision to keep products on the market as the FDA studied the risks and benefits of e-cigarettes. This decision is diametrically opposed to Canada’s position, which required premarket approval before allowing manufacturers to legally sell e-cigarettes. Although a lack of enforcement in Canada ultimately led to roughly the same result, the FDA’s policies reveal a pro-business, free-market streak that contrasts with Canada’s precautionary stance. In his July 2017 statement announcing application submission deadlines, Dr. Gottlieb cited a desire to make the process “more efficient, predictable,

and transparent for manufacturers” (U.S. Food and Drug Administration, 2017). Even when announcing that youth use has risen to epidemic proportions, he insisted on “the power of American ingenuity to solve a lot of problems, including this one” (U.S. Food and Drug Administration, 2018).

The embrace of libertarian ideals of freedom also suffuses the ads that e-cigarette companies, like Blu, air. Although organizations like Campaign for Tobacco-Free Kids have accused the company of using tactics that appeal to kids because of celebrity endorsements from actor Stephen Dorff and Jenny McCarthy, messages like “take back your freedom” and “rise from the ashes” suggest that Blu’s ads target adult smokers. The majority of adolescents probably do not know who Stephen Dorff or Jenny McCarthy are; in addition, these messages evoke a strain of libertarianism that likely resonates more with an older audience. Other ads in Blu’s campaign feature older adults and generally do not convey the sense that they are trying to appeal to youth. This particular ad below conjures images of 1950’s cultural icon James Dean, as shown further below in Figure 6.



Figure 5: Blu e-cigarette ad (Mashable, 2014)

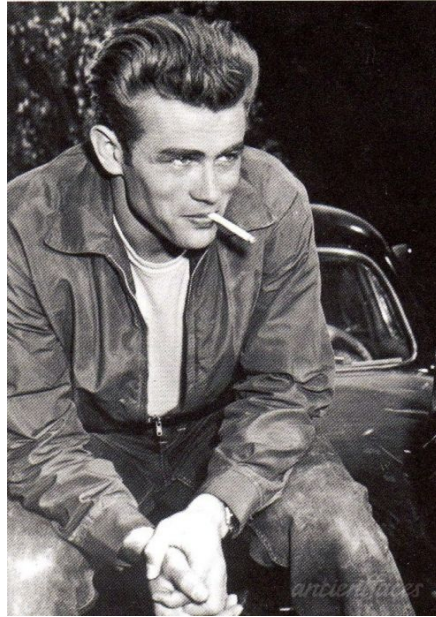


Figure 6: James Dean smoking a cigarette in *Rebel Without a Cause* (Warner Bros., 2018)

Although Dean is a famous symbol of teenage disillusionment, the ad's evocation of the *Rebel Without a Cause* star arguably targets an older audience that is more likely to be familiar with him and more likely to be receptive to this kind of marketing that was popular with cigarette companies when they were coming of age.



Figure 7: 1962 Marlboro cigarette ad (Hornung, 1962)

Not all e-cigarette companies have used these same tactics. JUUL ads in particular seem to be aimed at a younger audience. With its bright colors and noticeably younger models, the 2015 JUUL ad campaign highlights its sleek, high-tech design.

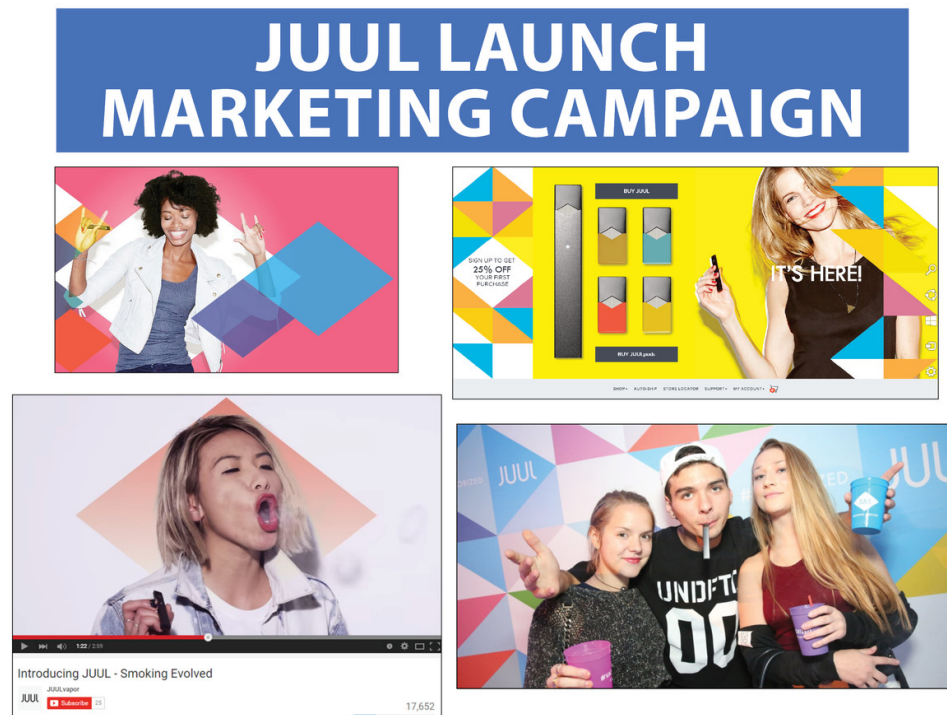


Figure 8: 2015 JUUL e-cigarette ad (Becker, 2018)

By early 2017, the company realized that teens were using its products and decided that all models in JUUL ads should be over 35 years old to “better [align] with a mission of focusing on adult smokers” (Richtel & Kaplan, 2018). Since then, their marketing campaigns have become more adult-oriented (see Figure 9 below). Although it is difficult to read the text, this new ad’s muted colors mirror those of Blu’s e-cigarette ads. Its message, “Simply Satisfying,” reassures adult smokers that the JUUL will satisfy their nicotine cravings as well as a cigarette could.



Figure 9: 2017 JUUL e-cigarette ad in store window (Jason Henry for the New York Times, 2018)

However, other e-cigarette companies still use JUUL’s original tricks to entice youth. To combat this messaging, the FDA’s “The Real Cost” campaign targets all forms of adolescent nicotine use by appealing directly to youth. Regarding vaping, the campaign primarily highlights how a) flavors can contain harmful chemicals and that b) many e-cigarettes contain nicotine, which is addictive and can harm brain development. A message from the Surgeon General similarly highlights that nicotine can be dangerous to adolescent brain development, although the video targets parents rather than teens.



Figure 10: FDA’s teen vaping public health campaign (Food and Drug Administration, 2018)

The fact that teen vaping is a bigger problem in the US creates higher possibilities of risk transformations and affects the calculus of risk-risk trade-offs for FDA regulators. As the FDA's recent actions to curb youth vaping reveal, policymakers have sought to respond to this heightened danger of e-cigarette risk transformations – thus acting in line with the recommendations of medical organizations. This regulatory action seems to be facilitated by the division of the business lobby, which has not demonstrated a unified stance on e-cigarette regulation.

This phenomenon is due in part to the fact that pharmaceutical companies and tobacco companies actually benefit from e-cigarette regulation, to varying degrees. Another salient aspect is tobacco companies' not-so-distant history of lying to the public about the dangers of smoking (Hilts, 1994). This shameful legacy might restrain tobacco companies and e-cigarette manufacturers' natural instinct to play regulatory offense.

United Kingdom

Regulatory Process:

In the UK, where there are more levels of authority than the US, an executive agency called the Medicines and Healthcare Products Regulatory Agency (MHRA) oversees the implementation of e-cigarette regulation. The MHRA does not decide policy; rather the Department of Health and Social Care (DHSC), the Cabinet department that oversees the MHRA, has authority over policy-making (HM Government, 2012). However, the MHRA decides what is considered a medicine or a medical device. The UK Government, composed of the Prime Minister and other ministers of the Cabinet, is the supreme policy-making committee.

A policy created by the Government is called delegated legislation, or a statutory instrument; although the government must present legislation to both houses of Parliament, they can only approve or vote down legislation. Only in very rare cases can Parliament amend a delegated legislation. The elected House of Commons last defeated an instrument in 1979. The House of Lords, which is appointed by the monarch on advice of the Prime Minister, last defeated an instrument in 2015, but this is an uncommon occurrence; the House of Lords rarely annuls instruments and usually expresses discontent in two other ways. First, a Lord can move a motion regretting an aspect of a statutory instrument without requiring the government to take action. This motion to regret provides an opportunity for critical views to appear in the public record. A Lord can also move a motion calling for the government to take a specific action, which serves as an indirect amendment. This motion helps the House avoid the need to vote on the instrument itself (UK Parliament, 2007).

As a member of the EU, the UK must also comply with EU directives. Until Brexit occurs in 2019, the European Commission, the institution of the European Union (EU) that is responsible for writing new laws, therefore also has authority over e-cigarette policy in the UK. Directives dictate that member states must achieve a certain outcome without mandating any particular procedure. Member states must comply with the directive, but have the discretion to implement additional measures. Thus, the UK, as well as its political component parts, has the right to create stronger regulations than the EU directive requires. While England does not have its own separate parliament, Scotland, Wales, and Northern Ireland all have devolved governments who have authority over some domestic policy issues. Below is a diagram of the regulatory process in the UK:

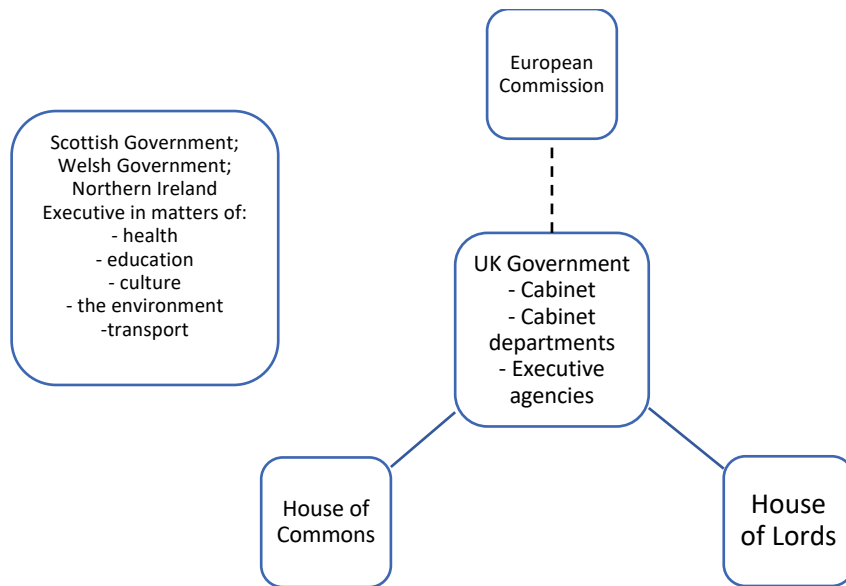


Figure 11: UK government structure

Scientific Reports:

As early as 2011, the UK Behavioural Insights Team, an office within the government, endorsed a harm reduction strategy for nicotine addiction. Although the team’s report does not specifically mention e-cigarettes, it argues that “if more alternative and safe nicotine products can be developed which are attractive enough to substitute people away from traditional cigarettes, they could have the potential to save tens of thousands of lives a year” (Behavioural Insights Team, 2011). A 2014 systematic analysis commissioned by PHE found that studies have shown that e-cigarettes “are moderately effective as smoking cessation and harm reduction aids” (Britton & Bogdanovica, 2014) and an update in 2015 concluded that “e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit” (Public Health England, 2015).

In 2015, Public Health England and 12 other UK health organizations including the Royal College of Physicians released a joint statement stating, “We all agree that e-cigarettes are significantly less

harmful than smoking...And yet, millions of smokers have the impression that e-cigarettes are at least as harmful as tobacco...It is our duty to provide reassurance for the 1.1 million e-cigarette users who have completely stopped smoking to prevent their relapse” (Public Health England, 2015). A 2016 statement by the Royal College of Physicians reiterated that sentiment, and a 2018 PHE update of their 2015 report, released just a few weeks after the NASEM report, states that “the evidence does not support the concern that e-cigarettes are a route into smoking among young people (youth smoking rates in the UK continue to decline, regular use is rare and is almost entirely confined to those who have smoked)” (Public Health England, 2018).

In August 2018, Parliament’s Science and Technology Committee published a report, “E-cigarettes.” The report strikingly reviews the current evidence on the harmfulness of e-cigarettes compared to conventional cigarettes – thus demonstrating an implicit harm-reductionist approach – as well as the current policies on e-cigarettes (Parliament, 2018). While the vast majority of cited sources originated in the UK, including the aforementioned 2015 PHE report, the report did briefly mention reports from other countries. For example, the report cites the 2016 US Surgeon General report to demonstrate the lack of evidence on long-term health effects, as well as the Australian policy to ban e-cigarettes. The report, however, immediately rebutted the precautionary approach favored in these examples and generally dismissed them as examples of what *not* to do. The report ultimately recommended that the Government should maintain an annual evidence review, support long-term research, allow e-cigarette use in mental health facilities, and ensure that e-cigarette taxes remain the lowest of all smoking-related products (Science and Technology Committee, 2018).

Vaping Trends:

In comparison with the US, e-cigarette usage trends are completely reversed in the UK (see Appendix C). Whereas the rate of teen use is more than double that of adult use in the US, the rate of adult use is more than triple the rate of teen use in the UK. According to Action on Smoking and Health (ASH), 52% of e-cigarette users are ex-smokers and there are more ex-smokers who use e-cigarettes (1.7 million) than current smokers (1.4 million) (Action on Smoking and Health, 2018). Given these statistics, UK policymakers' focus on encouraging e-cigarettes as smoking cessation aids is understandable. The rate of regular teen use remains so low that the potential benefits of e-cigarettes outweigh the potential harms, as things stands. Indeed, one conclusion in the Committee on Science and Technology's report expresses this sentiment explicitly:

“An estimated 2.9 million people in the UK are using e-cigarettes, and tens of thousands are using them to successfully quit smoking each year. Concerns about the risk of e-cigarettes potentially providing a ‘gateway’ into conventional smoking have not materialised to any significant degree. Similarly, the risk of the variety and type of flavours being attractive to young non-smokers, who would be drawn into e-cigarette use, also appears to be negligible” (Science and Technology Committee, 2018).

Many other health organizations, including ASH, Public Health England, the British Lung Foundation, and Cancer Research UK, publicly endorse this view. As a Times (UK) article states, “the big sell of vaping [is] that it saves lives. And the UK, more than almost any country, is on board” (Bhattacharya, 2018). This view could be challenged, however, by JUUL's recent July 2018 launch in the UK market, which “met with anticipation and trepidation in equal measure” (Bhattacharya, 2018). Although JUULs conform to UK regulations, including the nicotine

concentration limit, regulators will be watching to see if the US teen vaping phenomenon emerges in the UK as well.

Interest Groups, Advocacy Coalitions, and Political Meta-Narratives:

The vast majority of the relevant interest groups support the liberalization of e-cigarette regulation, thus creating a powerful advocacy coalition. Like the US, regulators promote the views of medical organizations. However, UK health groups endorse regulations diametrically opposed to those favored by American regulators (see Appendix D). For example, the British Lung Foundation (BLF) promotes the e-cigarette as a potential “stop smoking treatment” (British Lung Foundation, 2016). At the same time, the BLF emphasizes that e-cigarettes are not harmless; indeed, they funded a study that “found some evidence that e-cigarettes might be damaging lung cells in a similar way to that observed in people with chronic obstructive pulmonary disease (COPD).” The BLF views e-cigarettes as “an important tool in bringing down the number of active smokers, but they should not be mistaken as a long-term replacement for smoking cigarettes, or as a harm-free alternative to taking up smoking” (British Lung Foundation, 2018).

Like the BLF, Cancer Research UK (CRUK) accepts e-cigarettes as a smoking cessation aid. In a July 2018 policy position briefing, CRUK asserts that “it is important that regulation does not stifle the development of e-cigarettes or make accessing these products more difficult for smokers.” To promote e-cigarette use as a cessation aid, CRUK also sees no justification “based on the evidence currently available[,]...for an indoor ban on e-cigarettes,” further elaborating that “unnecessary regulation risks sending the message that e-cigarettes are as harmful as tobacco and this could deter quitting.” The statement does add that “it is important that adequate protections exist to stop the promotion of e-cigarettes to young people” (Cancer Research UK, 2018). This policy brief closely

tracks a November 2016 version (Cancer Research UK, 2016), demonstrating the consistency of CRUK's view that e-cigarettes should be used as smoking cessation aids. The changes between the documents are minor updates and edits rather than major revisions – for example, CRUK added information about a 2018 study looking at whether any association between e-cigarette use and future smoking in young people could be causal. The results were inconclusive, partly because the study could not control for many of the possible confounding factors (Cancer Research UK, 2018).

The UK's Royal College of Paediatrics and Child Health (RCPCH) has very little to say on e-cigarettes, in stark contrast to American Academy of Pediatrics. The RCPCH buried two sentences about e-cigarettes in two separate documents: a policy response for England on the State of Child Health report, and an archived subject guide on smoking. The subject guide simply says that “despite it being illegal to sell tobacco or e-cigarettes to under-18s, two thirds of smokers start before the age of 18” (Royal College of Paediatrics and Child Health, 2018). The January 2017 policy statement, modified in September 2018, only said this about e-cigarettes: “Government should prohibit all forms of marketing of e-cigarettes for non-medicinal use” (Royal College of Paediatrics and Child Health, 2018).

Other interest groups that push for greater regulation in the US either are not as active in the UK or hold differing views. It was difficult to uncover the activities of GSK and Pfizer in the UK, but British tobacco companies appear to behave similarly to their American counterparts, although they push for even more selective regulation. Like Altria, British American Tobacco (BAT), the largest British tobacco company, has expanded into the e-cigarette and other reduced-risk products market. Although it was the first ever company to be granted a license to sell its Voke “nicotine inhaler” as a smoking cessation aid in the UK, BAT decided to focus on consumer products like e-cigarettes after

manufacturing issues delayed the release of the Voke (Geller, 2017). Although it abandoned the Voke, BAT recently attempted to “win public health contracts so that its e-cigarettes can be promoted as smoking cessation aids” (Doward, 2018). According to a September 2018 Guardian article, emails revealed that BAT and the Birmingham city council were piloting a program to promote BAT’s products to smokers looking to quit. These revelations angered health officials, including public health Minister Steve Brine, who called the project a “disgrace” (Doward, 2018).

Unlike Altria, BAT actively pushes for liberalization. For example, BAT’s website emphasizes “marketing freedoms”: the company strongly believes that plain packaging regulation “is disproportionate, will not deliver its intended results and significantly erodes [their] intellectual property rights” by not allowing them to use their trademarks (British American Tobacco, 2018). The company concedes the need for many specific regulations, including “quality and safety standards,” “responsible marketing to adults only,” and “appropriate taxes and excise.” More generally, it calls for public/private collaboration, innovation, and “sensible regulation that works.”

Lastly, the most prominent anti-smoking organization in the UK, Action on Smoking and Health (ASH), also agrees with the general British consensus that e-cigarettes pose far fewer risks than cigarettes. ASH UK should not be confused with other organizations of the same name operating in other countries, including the US and Canada, as they are autonomous groups rather than different chapters of the same organization. The executive director of ASH UK, Deborah Arnott, consistently depicts e-cigarettes as valuable smoking cessation and harm reduction aids. She regularly comments on new e-cigarette developments in the media and has testified in front of Parliament promoting e-cigarettes as “cheap products that are highly effective in helping smokers quit” (Science and Technology Committee, 2018). She has also regularly spoken at the biannual ‘E-Cigarette Summit’

since its 2013 inception. Although ASH does not have an explicit policy position on e-cigarettes on its website, issues ASH raised with the Committee on Science and Technology included the “potential to further increase uptake of e-cigarettes among smokers through reviewing the process for medicinal licencing and ensuring products can be made available as licenced medications on prescription.” In addition, ASH also asserted a “pressing need to improve public understanding of the relative risk from vaping compared to smoking,” by which they mean that vaping is less harmful than smoking (Action on Smoking and Health, 2018).

In conjunction with these respected organizations, groups that push for deregulation in the US such as libertarian think tanks and vaping trade associations tend to wield similar influence and hold comparable views in the UK. For example, the Adam Smith Institute (ASI) and the Institute for Economic Affairs (IEA), UK-based neoliberal and free-market think tanks, respectively, have also each published several articles and reports on e-cigarettes. Like their US counterparts, the ASI and IEA argue for liberalizing e-cigarette regulation to improve health outcomes, encourage innovation, and give consumers choice (Pryor, 2018; Snowden, 2017). Although the ASI only has few articles on e-cigarettes, it published a June 2018 report on the topic and endorsed the Committee on Science and Technology’s post-Brexit recommendations and the IEA’s *Vaping Solutions: An easy Brexit win*, published in November 2017. The IEA, on the other hand, has published far more articles than the ASI and American think tanks that directly and indirectly mention e-cigarettes. The IEA indirectly mentions e-cigarettes in many of its articles on the Nanny State Index, as well as discussions on free market solutions in public health. In terms of articles published on their website that are explicitly on e-cigarettes, the IEA remains the most prolific publisher.

British e-cigarette trade associations similarly push for deregulation. Both the Independent British Vape Trade Association (IBVTA) and the UK Vaping Industry Association (UKVIA), the only two active bodies in the Britain, gave evidence before the Science and Technology Committee for their 2018 “E-cigarettes” report. While both testified in front of parliament, UKVIA constitutes the “largest trade body representing the vaping sector by market share” (UK Vaping Industry Association, 2018), while IBVTA represents independent manufacturers, distributors, vendors, etc. The policy positions of the two associations largely overlap; both advocate for the lifting of advertising restrictions to give smokers access to information about e-cigarettes and of nicotine strength and tank size limits (Independent British Vape Trade Association, 2018; UK Vaping Industry Association, 2018). The UKVIA also maintains that flavors “are a core part of the appeal of vaping products to smokers seeking to switch” – “all steps must be taken to ensure products are not marketed towards under-18s or non-smokers, but it is vital that product choice is maintained” (UK Vaping Industry Association, 2018). The UKVIA also notes that Brexit presents an opportunity to reform the TPD and negotiate free trade customs and excise arrangements.

No trade associations for restaurants, bars, etc. gave evidence in front of Parliament. However, the Nottinghamshire Healthcare NHS Foundation Trust testified on behalf of mental health facilities and Public Sector Prisons South (PSPS) also gave testimony on e-cigarette use in prison. In 2017, the Prison and Probation Service rolled out a smoking ban in all closed prisons in England and Wales; later that same year, the Ministry of Justice made e-cigarettes available in all prisons. The executive director of PSPS testified in front of Parliament that the policy was working well. Like in prisons, smoking is banned in all 50 English NHS mental health trusts. However, only a few mental health facilities allowed e-cigarette use. After hearing evidence that restricting vaping to specific areas within facilities could be counterproductive and further isolate patients who are heavy

smokers, the Committee recommended that all mental health facilities establish “a default of allowing e-cigarette use by patients unless an NHS trust can show reasons for not doing so which are demonstrably evidence-based” (Science and Technology Committee, 2018).

Public health officials further use political meta-narratives to push e-cigarettes as smoking cessation aids. Public health ads in the UK focus on busting myths that make adult smokers reluctant to switch to e-cigarettes. A February 2018 blog post by Public Health England focuses on these six myths: e-cigarettes give you popcorn lung; e-cigarettes are unregulated and we do not know what is in them; e-cigarettes must be harmful since they contain nicotine; secondhand vapor exposure is dangerous; e-cigarettes will lead young people into smoking; and e-cigarettes are being used as a Trojan horse so that the tobacco industry can keep people smoking. PHE’s aim is to emphasize that “e-cigarettes aren’t completely risk free but carry a fraction of the risk of smoking and are helping thousands of smokers to quit and stay smokefree” (Dockrell, 2018).

Since the UK bans tobacco and e-cigarette ads on TV and in print media, there are few online examples of e-cigarette ad campaigns online. However, this consensus, with its emphasis on deregulation and free-market economics, reflects traditional conservatism, the dominant political ideology in the UK over the ascendant political force in Britain since the Conservative Party’s retaking of Parliament in 2010 (BBC News, 2010).

The high proportion of adult vapers, in conjunction with a consistently low adolescent usage rate, creates lower chances of e-cigarette risk transformations; thus, the costs and risks associated with e-cigarettes are accordingly lower in the eyes of British regulators than for their American counterparts. Given the benefits that e-cigarettes therefore present for the UK, as well as the

strength of the advocacy coalition pushing for regulatory liberalization and the fact that deregulation fits well with the dominant political macro-narrative, the UK has developed a strong consensus to adopt and promote e-cigarettes as smoking cessation aids.

Canada

Regulatory Process:

Canada has a federal, parliamentary government. The central government shares power with ten provincial governments responsible for areas such as education, health care, some natural resources, and road regulations. For some important areas such as education and health care, the provinces share responsibility with the federal government (Parliament of Canada).

The Government of Canada, consisting of a Cabinet of Ministers of the Crown chaired by the Prime Minister, has ultimately authority over policy-making. Health Canada, the ministry department of the Government responsible for national public health, has the authority to regulate tobacco products. Similarly to the FDA, Health Canada administers many pieces of legislation enacted by the Canadian Parliament and develops and enforces regulations under such legislation that impact public health.

Bills are generally introduced by Ministers, who draft and present legislation to the Cabinet. If approved, bills then go to Parliament. Although the government usually chooses to introduce bills in the House of Commons, it can also introduce proposed legislation in the Senate unless the subject matter involves spending or taxation. Each Chamber of Parliament reads the bills three times – the first reading takes place at the same time as the introduction of the bill; during the second reading, members debate and vote on the principle of the bill and can refer it to a committee to be amended;

once the committee has studied the issue and made amendments, it reports the bill back to the House (or Senate), where members can then debate and offer additional amendments; during the third reading, members debate and vote on the bill as amended. After three readings, the bill is then sent to the other chamber. Once both Chambers have passed the bill in the same form, the Governor General or a deputy gives the bill Royal Assent on behalf of the Queen, at which point the bill becomes an Act of Parliament. No modern Canadian viceroy has withheld Royal Assent.

This diagram shows how a Government bill becomes law:

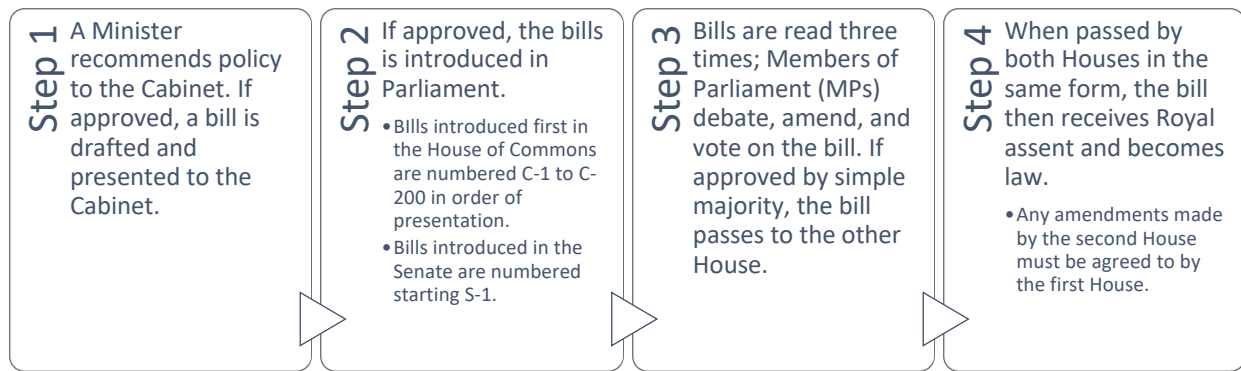


Figure 12: Canadian regulatory process

Scientific Reports:

Since the Canadian government only recently legalized e-cigarettes, Canada does not have any major scientific reports or studies like the United States and the United Kingdom; the previous illegality of e-cigarettes could have similarly hampered independent scientific research into the subject.

Canadians have produced two systematic analyses of evidence on the risks and benefits of e-cigarettes, both highlighted in a March 2018 policy statement by the Canadian Public Health Association (CPHA), a non-profit public health organization. The first comes from the Ontario Tobacco Research Unit's (OTRU) systematic analysis, which includes evidence published up to August 2015; the second was produced by the University of Victoria's Clearing the Air Project

(CAP), which includes evidence published up to April 2016 (Canadian Public Health Association, 2018). Figure 13 presents highlights of the studies:

	OTRU (2015)	CAP (2016)
SMOKING CESSATION	no evidence	no evidence
GATEWAY EFFECT	insufficient evidence	no such effect
HEALTH	less harmful; long-term effects unknown	less harmful
YOUTH USE	increased acceptability and use	low

Figure 13: Summary of Canadian e-cigarette systematic analyses

These reports are relatively dated, so there may have been limited evidence at the time these studies were conducted. However, the fact that these systematic reviews conflict in so many areas aligns with other meta-analyses. In a span of three years from 2014 to 2017, US systematic reviews found very different conclusions as well.

The lack of a comprehensive government report on e-cigarettes has forced Canadian policymakers to rely more on expert witnesses who often cite a multitude of specific studies. This is evident in government documents; for example, the 2015 Standing Committee on Health’s report on e-cigarettes noted that “data on youth experimentation with electronic cigarettes were provided by witnesses” (Standing Committee on Health, 2015). Similarly, during the House debate on whether to pass Bill S-5, one MP noted that “quite a number of studies were presented to us by the Canadian Cancer Society.” Interestingly, several MPs cited the UK’s 2015 PHE study, and one mentions a

University of North Carolina School of Medicine report that concluded that e-cigarette aerosol could cause “bodily harm” (Parliament, 2018).

Vaping Trends:

Despite the fact that Health Canada had not approved the sale of any e-cigarettes, Canadians could buy e-cigarettes throughout the country before the legalization of vaping products in 2018 (Ottawa Citizen, 2014). In the House of Commons debate about Bill S-5, one Member of Parliament (MP) complained that there were “a lot of stores that have sprung up all over the place, but there is no governance or oversight.” Due to this lack of enforcement, the vaping industry had established a strong presence in the country. This state of affairs precipitated the practical need to regulate the industry. Other circumstances have shaped the substance of this regulation.

Canadian trends generally reflect what is happening in the US. Although Appendix C shows that the rates of teen and adult use of e-cigarettes in Canada are lower than those of the US, the rate of teen use is more than double that of adult use, just like in the US. On the other hand, the proportion of adult vapers who have never smoked cigarettes is especially low, even in comparison to the UK. This trend mirrors the rate of adult vaping in Canada in general, which is the lowest among the three countries.

Policymakers perceived both trends; provisions of Bill S-5 sought to address these competing concerns, which guided the consultation process. As MP Bill Blair described during the House debate, “Bill S-5 strikes the right balance between protecting Canadians and recognizing the potential benefits of vaping as an alternative to smoking.” He noted that he shared concerns “about

the effects of tobacco use on the long-term health of our kids” and the bill “has been strengthened to better protect youth, particularly since its review by the Standing Committee on Health.”

The final bill, with its unprecedented ban on the advertising of flavoring, strongly reflected concerns about youth vaping. We do not yet know the societal effects of the bill at this time, nor whether the Canadian government intends to pursue a more forceful enforcement strategy. Thus, it remains to be seen whether the government will continue in the direction that the US has gone in and focus on youth use, or follow the UK’s example and start promoting vaping as a smoking cessation aid.

Interest Groups, Advocacy Coalitions, and Political Meta-Narratives:

The views of Canadian medical organizations fall somewhere in between those of their American and British counterparts. For example, the Canadian Lung Association’s (CLA) policy statement acknowledged that Health Canada legalized e-cigarettes to provide another option for smokers looking to quit, but primarily emphasized that “e-cigarettes should not be used by youth, by non-smokers, or by ex-smokers who have quit altogether.” They reluctantly endorsed e-cigarettes as a last resort for people “who have tried other methods to quit but have not succeeded” but promoted “behavioural support and/or cessation aids” (Canadian Lung Association, 2018).

Similarities between the Canadian Cancer Society’s (CCS) and CLA’s position statements suggest that they were adopted from a template statement, most likely originating from Health Canada. Sentences that are identical word-for-word include “Health Canada has legalized the sale of e-cigarettes with nicotine so that e-cigarettes would be accessible as an option for smokers looking to quit,” “e-cigarettes are less harmful than conventional cigarettes, but e-cigarettes remain harmful,” “the best approach would be to quit altogether, with behavioural support or cessation aids or both

increasing the chance of success,” and “E-cigarettes should not be used by youth, by non-smokers, or by ex-smokers who have quit altogether”. Both sites also included links to “find out more about Health Canada’s perspective on e-cigarettes.” However, the CCS also stated that smokers “unable to quit completely would be better off from a health perspective to use e-cigarettes on a longer-term basis, if needed” (Canadian Cancer Society, 2018) – language that did not appear in the CLA’s policy statement.

The Canadian Paediatric Society (CPS) developed a comprehensive policy statement in March 2015, later affirmed in February 2018. Like the American Academy of Pediatrics, the CPS “calls on the federal government to curb and control the e-cigarette industry” by expanding regulations such as maximum nicotine concentrations, labelling and warning requirements, child-proof packaging, bans on advertising to youth and in ways that specifically attract youth. The statement also called for restricting internet sales only to “individuals identifiable as adults,” prohibiting manufacturers and retailers from making positive health claims until Health Canada has reviewed and approved such claims, and banning the sale and possession of e-cigarettes by “anyone under the current federally established legal age to purchase conventional tobacco products” (in other words, anyone under 18) (Canadian Paediatric Society, 2018).

Just like American and British regulators, Canadian policymakers have adopted the views of medical organizations. Once again, business interests have not coalesced around a single organized business lobby. Like in the UK, it is difficult to ascertain the activities of pharmaceutical companies, but tobacco companies in Canada have adopted the same strategies as tobacco companies in the US and the UK. This is unsurprising since the two largest Canadian tobacco companies are subsidiaries of

Philip Morris International (PMI), which is a spin-off of Altria, and British American Tobacco (BAT).

With nearly 50% of market share, Imperial Tobacco Canada, a wholly-owned subsidiary of BAT, is the largest Canadian tobacco company. Along with the second-largest Canadian tobacco company Rothman, Benson & Hedges, Inc. (RBH), Imperial Tobacco Canada pushed for regulation in order to legally enter the e-cigarette market. As Imperial Tobacco Canada's head of corporate and regulatory affairs Eric Gagnon said in July 2017, "There needs to be a regulatory framework in place as soon as possible" (Krashinsky Robertson, 2017). Soon after Bill S-5 received royal assent on May 23rd, 2018, Imperial Tobacco Canada unveiled its Vype vaping product against the backdrop of World No Tobacco Day on May 31st (Ubelacker, 2018).

Like its parent company BAT, Imperial Tobacco Canada's policy recommendations focus on "product standards, responsible marketing, collaboration, innovation, and appropriate taxes" (Imperial Tobacco Canada, 2018). As a subsidiary of PMI, RBH's published policy statement shares language with Altria. It focuses on product and policy innovation "to shift the tobacco and nicotine market towards a future in which cigarettes are replaced by less harmful, yet satisfying, smoke-free alternatives" and calls for "sensible, risk-based regulation of smoke-free products" (Philip Morris International, 2018).

Surprisingly, the leading anti-tobacco organization in Canada aligns more with the views of ASH UK. Although the Non-Smokers' Rights Association (NSRA) did not testify in front of Parliament, it did submit a brief, which anyone can do, even if not called to testify. The process differs from the FDA comment period in the US; whereas nearly 80,000 comments were submitted to the FDA,

Parliament has only published 31 briefs, which includes many from witnesses (although it is unclear if there are any unpublished briefs). In its brief, the NSRA lamented that “much of the opposition to reduced risk options for Canadian smokers is focused on theoretical risks to young people rather than very real and deadly risks to smokers if they are not given the means to get off cigarettes.” The letter further asserted that “current evidence shows that youth are mostly experimenting with e-cigarettes” and also called on the government to allow statements on the relative risks of products (Non-Smokers' Rights Association, 2018).

Other groups pushing for less regulation hold moderate positions, compared to their counterparts in the US and the UK. Top neoliberal think tanks in Canada including the Fraser Institute, C.D. Howe Institute, and the Macdonald-Laurier Institute have not published anything on e-cigarettes. The Atlantic Institute for Market Studies has published just one article dating back to 2014, but the Montreal Economic Institute (MEI) is the only top neoliberal think tank in Canada that has written multiple articles on e-cigarettes. Like other neoliberal think tanks, the MEI argues that regulation harms public health (Guénette, 2017) and restricts consumer choice (Irvine, 2015). These articles tend to invoke principles of “freedom, dignity, and personal responsibility” (Guénette, 2017) rather than free-market ideals, and notably omit the argument that regulation stifles innovation.

Of the handful of Canadian vaping trade associations, Parliament called only the Canadian Vaping Association (CVA) as a witness for Bill S-5. Indeed, in its comments to the Senate, the CVA called itself “the national voice for the industry.” Although the CVA welcomed the bill as a “national framework” to standardize regulation across the country, agreed with age restrictions, and “[conceded] that restricting [e-cigarettes] use in public spaces is inevitable,” the CVA also argued that the bill’s prohibition on advertising and flavoring reduces the industry’s “ability to maximize the

public health benefits of encouraging cigarette smokers to less harmful e-cigarette technologies” (The Canadian Vaping Association, 2017). Many of its policy positions are similar to other industry views, including that e-cigarettes should not be regulated as a tobacco product. However, one interesting aspect to note is that the CVA calls for regulators to classify e-cigarettes “as a tobacco harm reduction product not a smoking cessation device” (The Canadian Vaping Association, 2018).

Parliament called the Canadian Convenience Stores Association (CCSA) and the Consumers’ Association of Canada (CAC) to testify on Bill S-5. In its brief to the Standing Committee on Health, CCSA iterated full support for regulation, because convenience stores and distributors “have followed Health Canada’s directive to refrain from selling vape products with nicotine, while illegal vape shops have been allowed to pop-up [sic] on street corners in every community” (Canadian Convenience Stores Association, 2014). CCSA also argued for “limited, substantiated communication by convenience retailers about alternative nicotine products including electronic cigarette” to acknowledge the growing consensus that vaping is less harmful than e-cigarettes – in other words, point-of-sale advertising. Although one might think that the CAC, a consumer’s rights organization, would applaud regulation to legalize e-cigarettes – thereby increasing consumer choice – the CAC’s brief contained absolutely no mention of e-cigarettes, but focused primarily on plain packaging (Consumers’ Association of Canada, 2018). See Appendix D for a summary of advocacy coalitions.

The relative weakness of the Canadian advocacy coalition pushing for less regulation helps explain the comparative stringency of Canada’s e-cigarette regulation. One explanation for why all interest groups seem relatively more comfortable with greater regulation lies in Canadian political ideology. Unlike the US and the UK, liberalism (along with its acceptance of greater government intervention)

has dominated the political landscape since the 1960s (Clarkson, 2014). Pierre Trudeau's 1968 campaign charismatically swept the nation at a time of rising Canadian nationalism. Indeed, political parties focused their attention on a "pan-Canadian mission." Trudeau's tenure as prime minister included successes such as the patriation of the Constitution and the institution of official bilingualism – hallmarks of a political agenda aimed at constructing a national identity and, more importantly for the topic at hand, social cohesion through Medicare, pensions, and other social security measures (Clarkson, 2014). These policies reinforced a dominant liberal ideology that is in play in other aspects of Canada's e-cigarette policies.

For example, Health Canada is currently in the process of developing a national e-cigarette public health campaign that will include "social media influencers" to whom teens might be more likely to listen. There are currently no restrictions on where ads can appear, although they cannot appeal to kids or advertise a lifestyle (Dickson, 2018). However, it is very difficult to find any ads through an internet search.

Despite this fairly liberal advertising policy, Canada's precautionary stance remains evident. Rob Cunningham, senior policy advisor at the Canadian Cancer Society (CCS), has expressed concerns that "there is the potential for youth to be exposed to substantial ads." As a result, the CCS supports "stronger regulations for the advertising component of the act, something Health Canada is considering through consultations" (Sharkey, 2018). This revelation also lends credence to the possibility that Health Canada is organizing medical organizations throughout Canada. This article was published just one day before the CCS posted its policy statement online – a statement that made no mention of advertising restrictions.

Like their American counterparts, Canadian policymakers are evidently more concerned about the risks that e-cigarettes pose rather than potential benefits. One likely reason for this is that Canada's relatively high rate of youth vaping, especially in comparison to the Canadian adult vaping rate, implies a risk transformation calculus like that of the US. Other factors explored above, such as a dominant political macro-narrative that accepts greater regulatory action, also help explain why Canada adopted such groundbreaking e-cigarette legislation.

Explaining the Range of E-Cigarette Regulations

Analysis reveals that some of the factors mentioned in each case study contribute more to the large variations in e-cigarette regulation between these three countries than others. On its own, a discrepancy among these three countries in the structure of the policymaking process cannot account for differences in policy. However, the fact that e-cigarettes are regulated by Parliament and elected heads of departments in the UK and Canada and by unelected officials in the US could influence the impact of scientific studies on policymakers and the role of advocacy coalitions, among other things.

Scientific studies also cannot explain variations in regulation. It is important to note that the strength of the evidence for what scientific studies influence policymakers varies since regulators could omit certain studies in their public comments. FDA Commissioner Gottlieb has only made one speech citing a specific report or study; his statements tend to cite general data. The UK reports, on the other hand, detail the studies they use and therefore provide stronger evidence for what scientific studies influence UK policymakers. Since the US and the UK have government-affiliated systematic reviews, it stands to reason that US and UK policymakers rely on the documents from their own

countries, which generally focuses on data and studies from the home country. That being said, these systematic reviews often mention studies from other countries in various contexts, so regulators do pay some attention to findings elsewhere. Regulators in Canada, in contrast, have no major Canada-focused study on which to rely. As the comments of the parliamentary members show, they are forced to lean more heavily on individual studies, which can lead to a more piecemeal understanding of the scientific data among regulators. It is unclear to what extent this lack of a major systematic review contributes to a greater reliance on studies from other countries, as it is possible this phenomenon arises from a relative paucity of studies in Canada.

Crucially, policymakers in all three countries have primarily responded to the current situation in their respective countries. Although they all recognize the theoretical potential harms and benefits of e-cigarettes, they naturally focus on the most pressing concerns. Although British regulators cannot currently do much because they have to abide by EU regulations for the time being, they have the luxury of being able to focus on the e-cigarette's potential as a smoking cessation aid because the UK does not as yet have a problem with youth vaping. American and Canadian regulators, on the other hand, must address youth vaping – even if it comes at the expense of adult vapers – because the rate of youth use is comparatively very high.

This pattern of course does not mean that policymakers remain ignorant of developments in other countries. For example, JUUL has only launched in three other markets besides the US – the UK, Israel, and most recently, Canada. JUUL entered the Israeli market in May 2018 (The Times of Israel, 2018); Israel, which did not previously have nicotine concentration limits, nevertheless banned imports and sales in late August due to “grave” public health concerns that its nicotine concentration exceeded 20 mg/ml (Reuters, 2018). The Israeli government allowed JUUL to release

a product with a nicotine concentration of 20 mg/ml (the limit set by the EU). Deputy Health Minister Yaakov Litzman explicitly mentioned EU regulations in his statement endorsing a ban: “The ministry’s stance is that a product that contains a concentration of nicotine that is almost three times the level permitted in the European Union constitutes a danger to public health” (Linder-Ganz, 2018). Policymakers clearly react to and consider the policies of other countries, particularly when it comes to newly-established areas of regulation.

Interest groups, advocacy coalitions, and political meta-narratives also play a key role in shaping regulatory outcomes. The views of medical organizations differ between countries yet align with regulatory action – suggesting that policymakers have adopted these positions (or independently reached the same conclusion, which still implies that competing interests have not diluted the messages that health organizations have been pushing). Policymakers and interest groups successfully utilize dominant political meta-narratives in each country to push regulation. E-cigarette companies and FDA commissioner Scott Gottlieb invoke capitalist libertarianism, and diffuse libertarian culture generally guides the US’s relative lack of regulation, particularly with regards to the lack of product specifications that other countries have preemptively adopted. British e-cigarette narratives align with their dominant traditional conservative political ideology that supports free-market and supply-side economics. Finally, in Canada, the precautionary principle is evident in the approach to e-cigarette regulation and in line with the liberal acceptance of government intervention when necessary, such as in matters of public health. In alignment with political ideologies, Canada (as well as the EU) is more precautionary in the face of scientific uncertainty than the UK or the US in this particular context.

The fact that medical organizations wield surprising influence in a way they did not during the fight over tobacco regulation is facilitated by the division of the business lobby. While pharmaceutical companies advocate for greater regulation, tobacco companies prefer selective regulation because they are, increasingly, e-cigarette companies as well. In addition, the legacy and lingering shame of tobacco companies' protracted efforts to deceive the public about the hazards of smoking likely dissuades them from trying to shape scientific consensus (and perhaps to drastically alter regulatory decision-making as well) regarding e-cigarettes. One could further explore this hypothesis through investigation of internal company documents and interviews with corporate leaders.

Finally, these case studies reveal how policymakers treat risk-risk trade-offs in the face of scientific uncertainty. Governments have focused on the most salient trade-offs – risk substitutions (that e-cigarette vapor can also cause harm) and risk transformations (the tension between adult smoking cessation and youth initiation). Regulations reveal that policymakers' views on e-cigarette risk substitution vary based on societal perceptions of risk transformations. For example, the youth vaping crisis in the US forces regulators and medical organizations to hedge their endorsement of e-cigarettes as smoking cessation aids. In contrast, the low rate of youth vaping allows the UK to promote that view. This difference also suggests that many key policymakers focus on empirical evidence, which in this context does seem to spur and shape regulatory decision-making. That this focus seems aided by the division of business interests perhaps indicates that consideration of complex evidence will be greater in the absence of a strong, unified opposition (that is also potentially wary of further tarnishing their reputations). Social scientists should investigate this hypothesis in other regulatory contexts involving significant scientific uncertainty.

Priorities for E-Cigarette Health Research

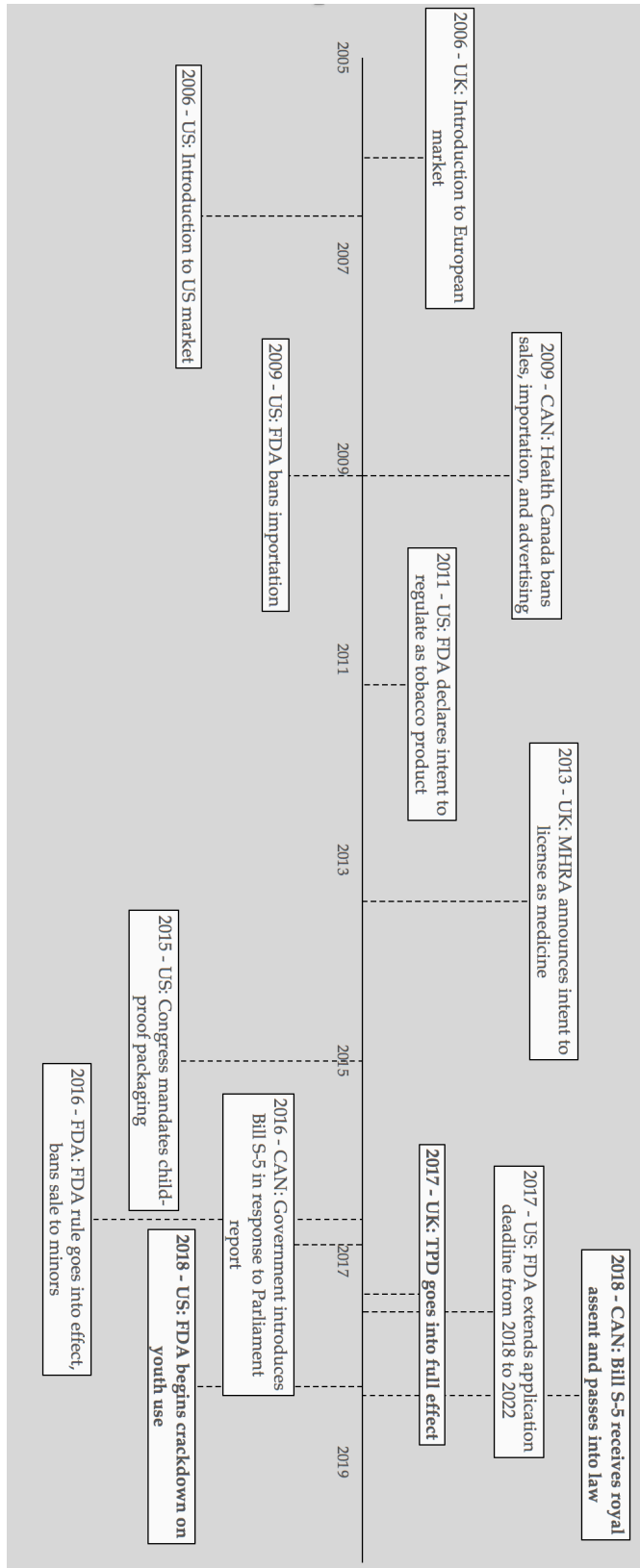
As e-cigarettes are still relatively new, we need more longitudinal studies to ascertain the longer-term effects of vaping on both smokers who switch to vaping and non-smokers and adolescents who have only ever vaped. In addition, new research should investigate the extent to which e-cigarettes act as “gateway drugs” to e-cigarettes. Given the popularity and longevity of this view with little to no evidence to back it up or dispel it, this question is an important one to answer. Finally, and perhaps most importantly, we need to understand the role of advertising and flavors in persuading smokers to switch and adolescents and non-users to start vaping. These two issues directly feed into risk-risk trade-offs and impact the magnitude of e-cigarette risk transformations.

Avenues for Further Social Science Research

As for further social science research, this paper demonstrates the need to understand what would better inform cost-benefit analyses of risk-risk trade-offs. Key issues include the accuracy of statistics regarding e-cigarette usage, potential health benefits from switching from cigarette to e-cigarettes, the likelihood that smokers will use e-cigarettes as a supplement and/or long-term alternative to traditional cigarettes, and the benefits of fully switching to e-cigarettes. Another question that deserves to be explored is the extent to which “policy entrepreneurship” influences (e-cigarette) regulation and what that says about the regulatory process. Particularly in Canada, where it seems that one individual or group within Health Canada is organizing some of the key medical organizations, this question is particularly salient and interesting. Finally, this thesis highlights that groups utilize political meta-narratives, but has less to say about the mechanisms behind successful deployment of such meta-narratives to shape policy debates. Thus, more research is needed to understand what differentiates successful meta-narrative usage by interest groups to push policy. An

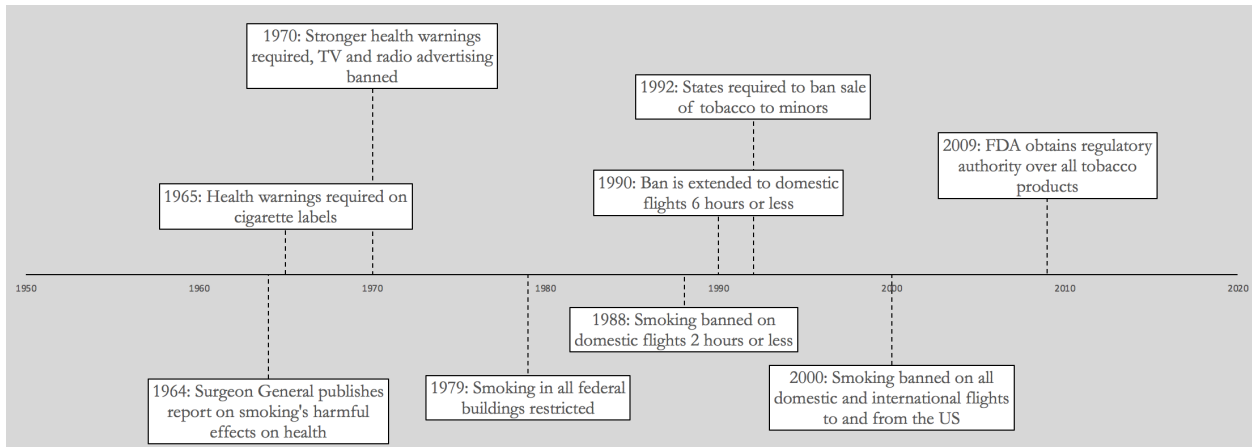
analysis of this question could use surveys or interviews to understand the degree to which groups consciously and actively utilize political meta-narratives, as well as case studies to identify and highlight outside factors that promote or inhibit successful deployment.

Appendix A: Evolution of E-Cigarette Regulation

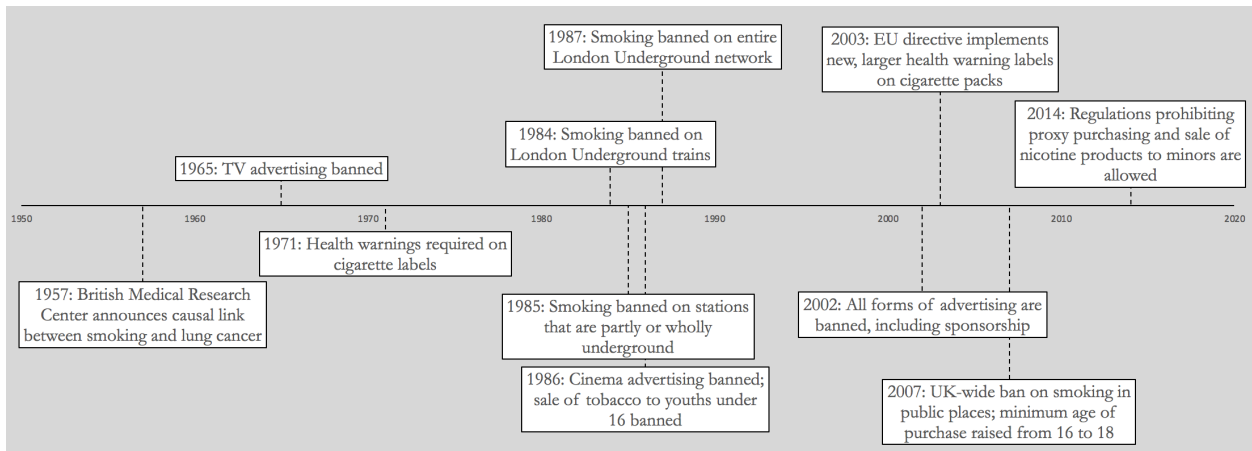


Appendix B: Histories of Tobacco Regulation

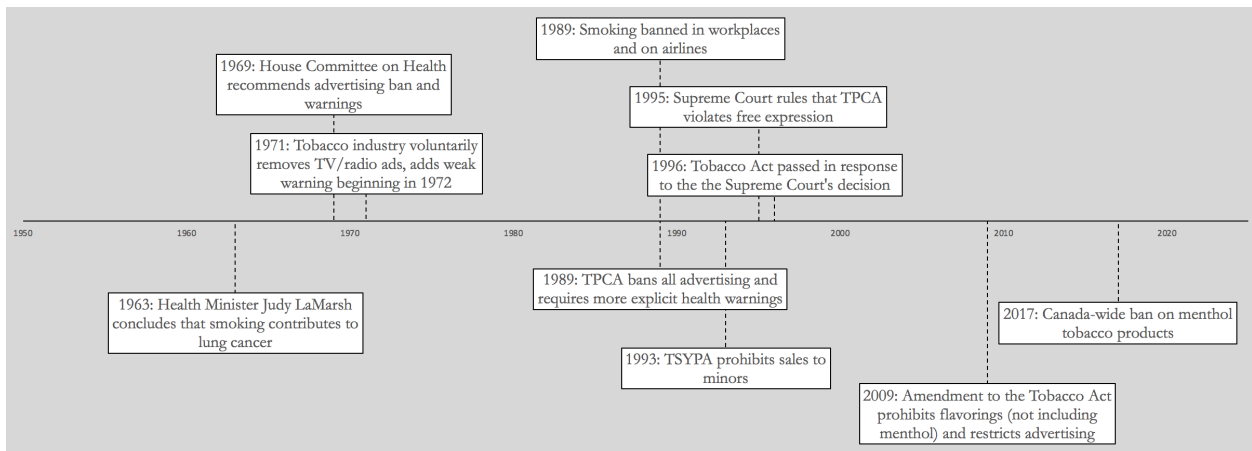
US



UK



Canada



Appendix C: Current Usage Trends

Country	Rate of current teen use	Rate of current adult use	Rate of current never-smoking adult vapers
United States	11.7% (2017)	4.5% (2016)	15% (2016)
United Kingdom	2% (2018)	6.2% (2018)	4.2% (2018)
Canada	6.8% (2017)	3% (2017)	1.4% (2015)

These numbers cannot be directly compared because the data is from different years and researchers from different countries asked different questions. For example, the US teen rate only includes high school students, whereas the UK data includes 11-18 year-olds and the Canadian data includes 7th-12th grade students. As e-cigarette use tends to increase with age, the UK data underestimates compared to the US data. As mentioned before however, the rate of e-cigarette use among middle schoolers in the US is 3.3%, so the teen rate would still be higher than in the UK. In the UK and Canada, current teen use is defined as at least weekly use. For adult use, the Canadian data includes adolescents 15 and older, therefore probably inflating the true rate of adult use since e-cigarette use peaks around young adulthood and declines as age increases. The proportion of never-smoking adults in Canada is based on past 30-day use, while it is based on current vapers in the UK and the US. Canada’s 2017 proportion of current never-smoking adult vapers is “not reportable due to small sample size” (Health Canada, 2018).

However, this table reveals the general trends of e-cigarette use; it is immediately evident that teen use is staggeringly high in the US, but extremely low in the UK. In addition, the proportion of teen use nearly triples that of adult use in the US – a trend that is reversed in the UK.

Appendix D: Interest Groups and Policy Positions

Stakeholders	Talking Points	Policy Priorities
Lung Associations	<ul style="list-style-type: none"> ○ US: worries about secondhand emissions, lack of evidence about smoking cessation; gateway to cigs ○ UK: smoking cessation aid ○ Canada: last resort for hopeful quitters 	US: ban flavors
Cancer Societies	<ul style="list-style-type: none"> ○ US & Canada: safer alternative to cigs ○ UK: smoking cessation aid 	Prevent youth use UK: minimal regulation
Pediatric Groups	<ul style="list-style-type: none"> ○ US & Canada: gateway to smoking ○ UK: little engagement on issue 	US & Canada: ban access & advertising to youth
Mental Health Facilities	<ul style="list-style-type: none"> ○ UK: mental health facilities see high smoking rates 	Allow vaping in all facilities
Pharmaceutical Companies	Unproven smoking cessation aid	GSK: regulate e-cigarettes like cigs
Tobacco Companies	E-cigarettes present reduced harm alternative to tobacco	No retroactive approval; regulate “appropriately”
Libertarian Think Tanks	<ul style="list-style-type: none"> ○ Safer than cigarettes ○ Regulation stifles innovation & choice 	Liberalize regulation
Vaping Trade Associations	<ul style="list-style-type: none"> ○ US: regulation is burdensome ○ UK: Brexit = opportunity to lift restrictions ○ Canada: new policies harms public health 	UK & Canada: do not ban flavors
Convenience Store Associations	<ul style="list-style-type: none"> ○ US & Canada: uniform regulation promotes competition across platforms 	Allow point-of-sale advertising

Appendix E: E-Cigarette Trade Associations

A devoted and active community of vape shops and avid consumers buttresses the small but rapidly growing e-cigarette industry. Below is a table of the vaping trade associations in each country:

US	UK	Canada
American E-Liquid Manufacturing Standards Association	Independent British Vape Trade Association	Canadian Vaping Association
American Vaping Association	UK Vaping Industry Association	Electronic Cigarette Trade Association of Canada
Consumer Advocates for Smoke-Free Alternatives Association		L'Association Québécoise des Vapoteries
National Vape Association		Tobacco Harm Reduction Association of Canada
Not Blowing Smoke: Vapor Advocacy and Harm Reduction		Vapor Advocates of Ontario
Right to be Smoke-Free Coalition		
Smoke Free Alternatives Trade Association		
Tobacco Vapor Electronic Cigarette Association		
Vapor Technology Associations		

Although the number of vaping trade associations greatly varies by country, only one or two seem to have real clout.

Works Cited

- 111th Congress. (2009, June 22). *H.R.1256 - Family Smoking Prevention and Tobacco Control Act*. Retrieved from Congress.gov: <https://www.congress.gov/bill/111th-congress/house-bill/1256>
- 114th Congress. (2016, January 28). *S.142 - Child Nicotine Poisoning Prevention Act of 2015*. Retrieved from Congress.gov: <https://www.congress.gov/bill/114th-congress/senate-bill/142>
- Action on Smoking and Health. (2016). *UK Tobacco Control Policy and Expenditure*. London: Action on Smoking and Health.
- Action on Smoking and Health. (2016). *Use of electronic cigarettes among children in Great Britain*. London: Action on Smoking and Health.
- Action on Smoking and Health. (2017, May 8). *Large national survey finds 2.9 million people now vape in Britain: For the first time over half don't smoke*. Retrieved from Action on Smoking and Health: <http://ash.org.uk/media-and-news/press-releases-media-and-news/large-national-survey-finds-2-9-million-people-now-vape-in-britain-for-the-first-time-over-half-no-longer-smoke/>
- Action on Smoking and Health. (2018, March 27). *ASH presents new data on e-cigarettes to Science and Technology Select Committee*. Retrieved from Action on Smoking and Health: <http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-to-present-new-data-on-e-cigarettes-to-science-and-technology-select-committee/>
- Action on Smoking and Health. (2018, September). *Use of e-cigarettes among adults in Great Britain, 2018*. Retrieved from Action on Smoking and Health: <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/>
- Altria. (2018, October 8). *Supporting Appropriate Regulatory & Legislative Policies*. Retrieved from Altria: <http://www.altria.com/harm-reduction/supporting-appropriate-regulatory-and-legislative-policies/Pages/default.aspx?src=topnav>
- American Academy of Pediatrics. (2015). Electronic Nicotine Delivery Systems. *Pediatrics*, 1018-1026.
- American Cancer Society. (2018, February 15). *American Cancer Society Position Statement on Electronic Cigarettes*. Retrieved from American Cancer Society: <https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>
- American Lung Association. (2015, March). *Statement on E-cigarettes*. Retrieved from American Lung Association: <https://www.lung.org/our-initiatives/tobacco/oversight-and-regulation/statement-on-e-cigarettes.html>
- American Lung Association. (2018, September 18). *American Lung Association Applauds FDA for Adding E-Cigarettes to Its The Real Cost Campaign*. Retrieved from American Lung Association: <https://www.lung.org/about-us/media/press-releases/FDA-The-Real-Cost.html>

- American Lung Association. (2018, September 12). *FDA Considers Meaningful Action Against E-Cigarette Manufacturers But Will It Act?* Retrieved from American Lung Association: <https://www.lung.org/about-us/media/press-releases/FDA-Considers-Ecig-Action.html>
- American Nonsmokers' Rights Foundation. (2018, October 1). *Overview List – How many Smokefree Laws?* Retrieved from American Nonsmokers' Rights Foundation: <https://no-smoke.org/wp-content/uploads/pdf/mediaordlist.pdf>
- Bakst, D. (2016, April 19). *Congress Needs to Stop FDA Attack on E-Cigarettes*. Retrieved from The Heritage Foundation: <https://www.heritage.org/government-regulation/commentary/congress-needs-stop-fda-attack-e-cigarettes>
- Bakst, D., & Stier, J. (2017, February 24). *Rethinking Tobacco Policy: The Federal Government Should Stop Blocking Alternatives to Smoking*. Retrieved from The Heritage Foundation: <https://www.heritage.org/government-regulation/report/rethinking-tobacco-policy-the-federal-government-should-stop-blocking>
- Barshad, A. (2018, April 7). *The Juul Is Too Cool*. Retrieved from The New York Times: <https://www.nytimes.com/2018/04/07/style/the-juul-is-too-cool.html>
- BBC News. (2010, May 13). *Q&A: The Conservative-Lib Dem coalition*. Retrieved from BBC News: http://news.bbc.co.uk/2/hi/uk_news/politics/election_2010/8675848.stm
- Becker, R. (2018, July 24). *Juul is being investigated by Massachusetts for booking kids on vaping*. Retrieved from The Verge: <https://www.theverge.com/2018/7/24/17608136/juul-investigation-electronic-cigarettes-massachusetts-attorney-general-subpoena>
- Behavioural Insights Team. (2011). *Annual Update 2010-2011*. London, UK: Cabinet Office.
- Bellafante, G. (2018, February 16). *Cool-Looking and Sweet, Juul Is a Vice Teens Can't Resist*. Retrieved from The New York Times: <https://www.nytimes.com/2018/02/16/nyregion/juul-teenagers-vaping-ecigarettes-dangers.html?module=Uisil>
- Bhattacharya, S. (2018, September 22). *Why teenagers are addicted to their Juuls – the iPhone of e-cigarettes*. Retrieved from The Times: <https://www.thetimes.co.uk/article/why-teenagers-are-addicted-to-their-juuls-the-iphone-of-e-cigarettes-dtswdsswg>
- British American Tobacco. (2018, October 8). *Regulation: We want to be part of the debate*. Retrieved from British American Tobacco: http://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DO9DFFYA
- British Lung Foundation. (2016, February). *Stop smoking treatments*. Retrieved from British Lung Foundation: <https://www.blf.org.uk/support-for-you/smoking/stop-smoking-treatments>
- British Lung Foundation. (2018, August 17). *The latest on e-cigarettes*. Retrieved from British Lung Foundation: <https://www.blf.org.uk/your-stories/the-latest-on-e-cigarettes>

- Britton, J., & Bogdanovica, I. (2014). *Electronic Cigarettes*. Nottingham, UK: UK Centre for Tobacco and Alcohol Studies.
- Bunnell, R., Agaku, I., Arrazola, R., Apelberg, B., Caraballo, R., Corey, C., . . . King, B. (2014). Intentions to Smoke Cigarettes Among Never-Smoking US Middle and High School Electronic Cigarette Users: National Youth Tobacco Survey, 2011–2013. *Nicotine & Tobacco Research, 17*(2), 228-235.
- Burrus, T. (2016, May 5). *Why Big Tobacco Loves the New FDA E-Cig Regulations*. Retrieved from Cato Institute: <https://www.cato.org/blog/why-big-tobacco-loves-new-fda-e-cig-regulations>
- Calder, V. B. (2018, September 27). *E-Cig Regulation Likely to Burn Low-Income Americans*. Retrieved from Cato Institute: <https://www.cato.org/publications/commentary/e-cig-regulation-likely-burn-low-income-americans>
- Campaign for Tobacco-Free Kids. (2014, September 3). *Comment from Campaign for Tobacco-Free Kids (CTFK)*. Retrieved from Regulations.gov: <https://www.regulations.gov/document?D=FDA-2014-N-0189-80087>
- Campaign for Tobacco-Free Kids. (2018, March 15). *FDA Authority Over Tobacco*. Retrieved from Campaign for Tobacco-Free Kids: <https://www.tobaccofreekids.org/what-we-do/us/fda>
- Canadian Cancer Society. (2018, May 24). *Our perspective on e-cigarettes*. Retrieved from Canadian Cancer Society: <http://www.cancer.ca/en/about-us/news/national/2018/may/our-perspective-on-e-cigarettes/?region=on>
- Canadian Convenience Stores Association. (2014, February 14). *Submission House of Commons Standing Committee on Health Bill S-5: An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts*. Retrieved from Parliament of Canada: <https://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR9684795/br-external/CanadianConvenienceStoresAssociation-e.pdf>
- Canadian Legal Information Institute. (1997, April 25). *Tobacco and Vaping Products Act, SC 1997, c 13*. Retrieved August 6, 2018, from CanLII: <https://www.canlii.org/en/ca/laws/stat/sc-1997-c-13/36684/sc-1997-c-13.html>
- Canadian Lung Association. (2018, June 7). *E-cigarettes*. Retrieved from Canadian Lung Association: <https://www.lung.ca/news/expert-opinions/e-cigarettes>
- Canadian Paediatric Society. (2018, February 28). *E-cigarettes: Are we renormalizing public smoking? Reversing five decades of tobacco control and revitalizing nicotine dependency in children and youth in Canada*. Retrieved from Canadian Paediatric Society: <https://www.cps.ca/en/documents/position/e-cigarettes>
- Canadian Public Health Association. (2018, March 31). *A Public Health Approach to Nicotine-containing Vaping Devices*. Retrieved from Canadian Public Health Association: <https://www.cpha.ca/public-health-approach-nicotine-containing-vaping-devices>

- Cancer Research UK. (2016, November). *Cancer Research UK Briefing: Electronic Cigarettes*. Retrieved from Cancer Research UK: https://www.cancerresearchuk.org/sites/default/files/cruk_e-cigarette_briefing.pdf
- Cancer Research UK. (2018, July). *Cancer Research UK Briefing: Electronic Cigarettes*. Retrieved from Cancer Research UK: https://www.cancerresearchuk.org/sites/default/files/e-cigarette_briefing_july_2018_final.pdf
- Center for Responsive Politics. (2018, October 8). *Altria Group - Bills*. Retrieved from Open Secrets: <https://www.opensecrets.org/lobby/clientbills.php?id=D000000067&year=2018>
- Centers for Disease Control and Prevention. (2017, February 9). *Smoking & Tobacco Use: Fast Facts and Fact Sheets*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm
- Centers for Disease Control and Prevention. (2018, February 20). *Smoking & Tobacco Use: Fast Facts*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm
- Clarkson, S. (2014). *The Big Red Machine: How the Liberal Party Dominates Canadian Politics*. Vancouver: UBC Press.
- CNBC. (2013, June 11). *Marlboro Maker Altria Is Jumping Into E-Cigarettes*. Retrieved from CNBC: <https://www.cnbc.com/id/100806458>
- Consumers' Association of Canada. (2018, February 14). *Consumers' Association of Canada Brief*. Retrieved from Parliament of Canada: <https://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR9682355/br-external/ConsumersAssociationOfCanada-e.pdf>
- Dickson, J. (2018, June 16). *Health Canada seeking social media influencers to warn teens about vaping*. Retrieved from The Star: <https://www.thestar.com/news/canada/2018/06/16/health-canada-seeking-social-media-influencers-to-warn-teens-about-vaping.html>
- Dockrell, M. (2018, February 20). *Clearing up some myths around e-cigarettes*. Retrieved from Public Health England: <https://publichealthmatters.blog.gov.uk/2018/02/20/clearing-up-some-myths-around-e-cigarettes/>
- Doward, J. (2018, September 9). *Council's vaping project with British American Tobacco labelled 'a disgrace'*. Retrieved from The Guardian: <https://www.theguardian.com/uk-news/2018/sep/09/birmingham-city-council-project-british-american-tobacco-a-disgrace>
- EUR-Lex. (2014, January 13). *Manufacture, presentation and sale of tobacco products*. Retrieved from EUR-Lex: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Ac11567>
- EUR-Lex. (2016, November 30). *The precautionary principle*. Retrieved from EUR-Lex: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3A132042>

- Farsalinos, K., & Polosa, R. (2014). Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety*, 5(2), 67-86.
- Geller, M. (2017, January 5). *BAT quits nicotine inhaler to focus on vaping*. Retrieved from Reuters: <https://www.reuters.com/article/us-brit-am-tobacco-voke-kind/bat-quits-nicotine-inhaler-to-focus-on-vaping-idUSKBN14P12V>
- Gilmore, A., & Hartwell, G. (2014). E-cigarettes: threat or opportunity? *European Journal of Public Health*, 24(4), 532-533.
- Giovacchini, C., Pacek, L., McClernon, F. J., & Que, L. (2017). Use and Perceived Risk of Electronic Cigarettes Among North Carolina Middle and High School Students. *North Carolina Medical Journal*, 78(1), 7-13.
- Glasser, A. M., Collins, L., Pearson, J. L., Abudayyeh, H., Niaura, R. S., Abrams, D. B., & Villanti, A. C. (2017). Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *American Journal of Preventative Medicine*, e33-e66.
- GlaxoSmithKline. (2014). *Statement from GlaxoSmithKline Consumer Healthcare on FDA's Proposed Regulation of Electronic Cigarettes and Other Nicotine-Delivering Products*. Parsippany, NJ: GlaxoSmithKline.
- GlaxoSmithKline Consumer Healthcare. (2014, August 8). *Comment from Erin Oliver, MS, MBA, RAC*. Retrieved from Regulations.gov: <https://www.regulations.gov/document?D=FDA-2014-N-0189-62796>
- Graham, J., & Wiener, J. (1995). *Risk vs. Risk*. Cambridge, MA: Harvard University Press.
- Guénette, J. (2017, August 31). *Feds Don't Want You To Know About Safer Tobacco Products*. Retrieved from Montreal Economic Institute: <https://www.iedm.org/73832-feds-dont-want-you-know-about-safer-tobacco-products>
- Hajek, P., Etter, J.-F., Benowitz, N., Eissenberg, T., & McRobbie, H. (2014). Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*, 109(11), 1801-1810.
- Health Canada. (2018, November 7). *Canadian Tobacco, Alcohol and Drugs Survey (CTADS): summary of results for 2017*. Retrieved from Health Canada: <https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.html>
- Health Canada. (2018, June 12). *Detailed tables for the Canadian Student Tobacco, Alcohol and Drugs Survey 2016-17*. Retrieved from Government of Canada: <https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2016-2017-supplementary-tables.html#t6>

- Hilts, P. J. (1994, April 15). *Tobacco Chiefs Say Cigarettes Aren't Addictive*. Retrieved from New York Times: <https://www.nytimes.com/1994/04/15/us/tobacco-chiefs-say-cigarettes-aren-t-addictive.html>
- HM Government. (2012, February). *How government works*. Retrieved from Gov.uk: <https://www.gov.uk/government/how-government-works>
- Hoffman, J. (2018, October 2). *F.D.A. Seizes Documents From Juul Headquarters*. Retrieved from The New York Times: <https://www.nytimes.com/2018/10/02/health/juul-cigarettes-fda-raid.html>
- Hornung, P. (1962). *Marlboro Ad*. Retrieved from Vintage Cigarette Posters: <http://vintage-cigarette-posters.tumblr.com/post/97284969360/paul-hornung-for-marlboro-cigarettes-ads-1962>
- Imperial Tobacco Canada. (2018, October 8). *Next Generation Products*. Retrieved from Imperial Tobacco Canada: http://www.imperialtobaccocanada.com/group/sites/BAT_AXYKCM.nsf/vwPagesWebLive/DO9T5KJU?opendocument
- Independent British Vape Trade Association. (2018, August 17). *IBVTA response to Science and Technology Committee Report*. Retrieved from Independent British Vape Trade Association: <https://www.ibvta.org.uk/ibvta-response-to-science-and-technology-committee-report>
- Irvine, I. (2015, July 21). *'Vaping' is not similar to smoking*. Retrieved from Montreal Economic Institute: <https://www.iedm.org/54466-vaping-is-not-similar-to-smoking>
- Jamal, A., Gentzke, A., Hu, S. S., Cullen, K., Apelberg, B., Homa, D., & King, B. (2017). Tobacco Use Among Middle and High School Students — United States, 2011–2016. *Morbidity and Mortality Weekly Report*, 66(23), 597-603.
- Jennings, K. (2018, August 17). *British MPs push e-cigarettes as health benefit*. Retrieved from Politico : <https://www.politico.eu/article/e-cigarettes-forget-big-tobacco-back-vaping-for-health-benefits-say-mps/>
- Kelland, K. (2015, January 16). *GSK's nicotine patches and gum feel the heat from e-cigarettes*. Retrieved from Reuters: <https://uk.reuters.com/article/uk-gsk-ceo-ecigarettes/gsk-nicotine-patches-and-gum-feel-the-heat-from-e-cigarettes-idUKKBN0KP0X020150116>
- Kennedy, R., Awopegba, A., De Léon, E., & Cohen, J. (2017). Global approaches to regulating electronic cigarettes . *Tobacco Control*, 26(4), 440-445.
- Kosmider, L., Sobczak, A., Fik, M., Knysak, J., Zaciera, M., Kurek, J., & Goniewicz, M. (2014). Carbonyl Compounds in Electronic Cigarette Vapors: Effects of Nicotine Solvent and Battery Output Voltage. *Nicotine & Tobacco Research*, 1319-1326.

- Krashinsky Robertson, S. (2017, July 9). *Selling vaping: E-cigarette industry grapples with cloudy rules*. Retrieved from The Globe and Mail: <https://www.theglobeandmail.com/report-on-business/industry-news/marketing/selling-vaping-e-cigarette-industry-grapples-with-cloudy-rules/article35625105/>
- LaVito, A. (2018, August 4). *Juul built an e-cigarette empire. Its popularity with teens threatens its future*. Retrieved from CNBC: <https://www.cnbc.com/2018/08/03/juul-e-cigarettes-popularity-among-teens-concerns-schools-fda.html>
- Linder-Ganz, R. (2018, June 3). *Juul Warns It Will Fight Israel Over Potential Ban on Its E-cigarettes*. Retrieved from Haaretz: <https://www.haaretz.com/israel-news/business/juul-warns-it-will-fight-israel-over-potential-ban-on-its-e-cigarettes-1.6140058>
- Lipton, E. (2016, September 2). *A Lobbyist Wrote the Bill. Will the Tobacco Industry Win Its E-Cigarette Fight?* Retrieved from The New York Times: <https://www.nytimes.com/2016/09/03/us/politics/e-cigarettes-vaping-cigars-fda-altria.html>
- Lofstedt, R., & Schlag, A. (2016). Risk-risk tradeoffs: what should we do in Europe? *Journal of Risk Research*.
- Marlow, M. L. (2014, Fall). Regulating a Less Unhealthy Cigarette. *Regulation*, pp. 28-32.
- Mashable. (2014, June 18). *E-Cigarette Brands Battle to Keep Marketing Rights*. Retrieved from Mashable: <https://mashable.com/2014/06/18/e-cigarette-brands-marketing/#kZb85CSMBiq4>
- Mayer, F. W. (2014). *Narrative Politics: Stories and Collective Action*. Oxford, UK: Oxford University Press.
- Mirbolouk, M., Charkhchi, P., Kianoush, S., Uddin, S. I., Orimoloye, O. A., Jaber, R., & Bhatnagar, A. (2016). Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016. *Annals of Internal Medicine*, 428-438.
- National Association of Convenience Stores. (2014, September 2). *Comment from National Association of Convenience Stores*. Retrieved from Regulations.gov: <https://www.regulations.gov/document?D=FDA-2014-N-0189-79667>
- Non-Smokers' Rights Association. (2018, February 27). *A Submission on Bill S-5: An Act to Amend the Tobacco Act Standing Committee on Health*. Retrieved from Parliament of Canada: <https://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR9709265/br-external/SweanorDavidT-e.pdf>
- Office of Information & Regulatory Affairs. (2017, April). *FAQs*. Retrieved from Office of Information & Regulatory Affairs: <https://www.reginfo.gov/public/jsp/Utilities/faq.jsp#oira>

- Office of the Federal Register. (2011, January). *A Guide to the Rulemaking Process*. Retrieved from Office of the Federal Register: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf
- Office of the Surgeon General. (2016). *E-Cigarette Use Among Youth and Young Adults*. Rockville: U.S. Department of Health and Human Services.
- Orlando Sentinel. (2017, April 12). *Tobacco companies ordered to pay \$35M in Florida case*. Retrieved from Orlando Sentinel: <https://www.orlandosentinel.com/business/os-bz-nsf-florida-tobacco-ruling-20170412-story.html>
- Parliament. (2002, November 7). *Tobacco Advertising and Promotion Act 2002*. Retrieved from legislation.gov.uk: <https://www.legislation.gov.uk/ukpga/2002/36/contents>
- Parliament. (2018, April 27). *Bill S-5 An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts*. Retrieved from Open Parliament: <https://openparliament.ca/bills/42-1/S-5/>
- Parliament. (2018, August 17). *Government missing opportunity with e-cigarettes*. Retrieved from Parliament.UK: <https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2017/e-cigarettes-report-publication-17-19/>
- Parliament of Canada. (n.d.). *Our Country, Our Parliament*. Retrieved July 26, 2018, from Parliament of Canada.
- Pear, R. (2009, January 13). *Anti-Smoking Advocate Is Named to Health Post*. Retrieved from The New York Times: <https://www.nytimes.com/2009/01/14/us/politics/14appoint.html>
- Pfizer. (2014, September 2). *Comment from Pfizer Inc*. Retrieved from Regulations.gov: <https://www.regulations.gov/document?D=FDA-2014-N-0189-79938>
- Pfizer. (2016). *Value of Medicines: Smoking Cessation*. New York: Pfizer.
- Pfizer Canada. (2015, April 15). *Smokers Who Also Use E-Cigarettes Still Smoke On Average 13 Cigarettes Per Day*. Retrieved from Pfizer Canada: <https://www.pfizer.ca/node/1846>
- Philip Morris International. (2018, October 8). *A Common-Sense Approach*. Retrieved from Philip Morris International: <https://www.pmi.com/markets/canada/en/about-us/regulation>
- Phillips, C. V. (2014, June 19). *CASAA's Comment to OMB/OIRA regarding Paperwork Reduction Act and FDA Deeming Regulation*. Retrieved from Regulations.gov: <https://www.regulations.gov/document?D=FDA-2014-N-0189-9634>
- Pisinger, C., & Døssing, M. (2014). A systematic review of health effects of electronic cigarettes. *Preventative Medicine*, 248-260.

- Pryor, D. (2018). *1 Million Years of Life: How harm reduction in tobacco policy can save lives*. London: Adam Smith Institute.
- Public Health England. (2015, September 15). *E-cigarettes: an emerging public health consensus*. Retrieved from Gov.uk: <https://www.gov.uk/government/news/e-cigarettes-an-emerging-public-health-consensus>
- Public Health England. (2015). *E-cigarettes: an evidence update*. London, UK: Public Health England.
- Public Health England. (2018, February 6). *PHE publishes independent expert e-cigarettes evidence review*. Retrieved from Gov.uk: <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>
- Reuters. (2018, August 21). *Israel bans Juul e-cigarettes citing 'grave' public health risk*. Retrieved from Reuters: <https://www.reuters.com/article/us-usa-fda-ecigarettes/fda-seizes-documents-from-juul-in-latest-e-cigarette-crackdown-idUSKCN1MC26P>
- Richtel, M., & Kaplan, S. (2018, August 27). *Did Juul Lure Teenagers and Get 'Customers for Life'?* Retrieved from The New York Times: <https://www.nytimes.com/2018/08/27/science/juul-vaping-teen-marketing.html>
- Royal College of Paediatrics and Child Health. (2018, September 11). *A policy response for England to the State of Child Health report*. Retrieved from Royal College of Paediatrics and Child Health: <https://www.rcpch.ac.uk/resources/policy-response-england-state-child-health-report>
- Royal College of Paediatrics and Child Health. (2018, April 16). *Subject archives guide - Smoking*. Retrieved from Royal College of Paediatrics and Child Health: <https://www.rcpch.ac.uk/resources/subject-archives-guide-smoking#children-and-smoking>
- Schleicher, E. (2016, July 16). *Gilla Global Expansion Leading to Increased Share of Growing Vapor Market*. Retrieved from OTC Markets: <https://www.otcmarkets.com/stock/GLLA/news?id=135716>
- Schoenborn, C. A., & Gindi, R. M. (2015). *Electronic Cigarette Use Among Adults: United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics.
- Science & Environmental Health Network. (1998, January 26). *Wingspread Conference on the Precautionary Principle*. Retrieved from Science & Environmental Health Network: <http://sehn.org/wingspread-conference-on-the-precautionary-principle/>
- Science and Technology Committee. (2018). *E-cigarettes*. London: House of Commons.
- Sharkey, J. (2018, May 23). *E-cigarette and vaping ads coming soon to a TV, radio or newspaper near you*. Retrieved from CBC News: <https://www.cbc.ca/news/canada/kitchener-waterloo/tobacco-vaping-products-act-advertising-1.4673365>
- Snowdon, C. (2017). *Vaping Solution: An easy Brexit win*. London: Institute for Economic Affairs.

- Standing Committee on Health. (2015). *Vaping: Towards a Regulatory Framework for E-cigarettes*. Ottawa: House of Commons. Retrieved from http://www.ourcommons.ca/DocumentViewer/en/41-2/HESA/report-9/page-39#_ftn31
- Surgeon General. (2016). *E-Cigarette Use Among Youth and Young Adults*. Atlanta, GA: Centers for Disease Control and Prevention.
- The Canadian Vaping Association. (2017, April 6). *Notes for Remarks Presentation to the Standing Committee Social Affairs, Science & Technology*. Retrieved from The Canadian Vaping Association: <https://chambermaster.blob.core.windows.net/userfiles/UserFiles/chambers/9417/CMS/S5/FINAL-Notes-for-Remarks-Senate-Presentation.pdf>
- The Canadian Vaping Association. (2018, October 18). *CVA's Position on Electronic Cigarette Regulations*. Retrieved from The Canadian Vaping Association: <http://canadianvapingassociation.org/home>
- The National Academies of Sciences, Engineering, and Medicine. (2018). *Public Health Consequences of E-Cigarettes*. Washington, D.C.: The National Academy of Science.
- The Times of Israel. (2018, August 23). *Manufacturers of Juul e-cigarette to sue over Israel ban*. Retrieved from The Times of Israel: <https://www.timesofisrael.com/manufacturers-of-juul-e-cigarette-to-sue-over-israel-ban/>
- The Washington Post. (2015, November 12). *Who still smokes in the United States — in seven simple charts*. Retrieved from The Washington Post: https://www.washingtonpost.com/news/to-your-health/wp/2015/11/12/smoking-among-u-s-adults-has-fallen-to-historic-lows-these-7-charts-show-who-still-lights-up-the-most/?utm_term=.79f51df926b0
- Trilling, D. (2017, March 20). *E-Cigarettes Exploding in Popularity: New Data*. Retrieved from Journalist's Resource: <https://journalistsresource.org/studies/society/public-health/ecigarettes-sales-increase-tobacco-cdc-research>
- U.S. Food and Drug Administration. (2017, July 28). *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death*. Retrieved from U.S. Food and Drug Administration: <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm>
- U.S. Food and Drug Administration. (2018, January 8). *Cigarette Graphic Health Warnings*. Retrieved August 13, 2018, from U.S. Food and Drug Administration: <https://www.fda.gov/tobaccoproducts/labeling/labeling/ucm257774.htm>
- U.S. Food and Drug Administration. (2018, September 18). *FDA launches new, comprehensive campaign to warn kids about the dangers of e-cigarette use as part of agency's Youth Tobacco Prevention Plan, amid evidence of sharply rising use among kids*. Retrieved from U.S. Food and Drug Administration: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm>

- U.S. Food and Drug Administration. (2018, September 12). *FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access*. Retrieved from U.S. Food and Drug Administration: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>
- U.S. Food and Drug Administration. (2018, June 18). *FDA's Nicotine and Tobacco Regulation and the Key Role of Regulatory Science*. Retrieved from U.S. Food and Drug Administration: <https://www.fda.gov/NewsEvents/Speeches/UCM611033>
- U.S. Food and Drug Administration. (2018, September 12). *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*. Retrieved from U.S. Food and Drug Administration: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>
- Ubelacker, S. (2018, May 31). *Imperial Tobacco gets into vaping business, but still leading cigarette seller*. Retrieved from The Telegram: <https://www.thetelegram.com/news/regional/imperial-tobacco-gets-into-vaping-business-but-still-leading-cigarette-seller-214693/>
- UK Parliament. (2007). *Delegated Legislation*. Retrieved from UK Parliament: <https://publications.parliament.uk/pa/ld/ldcomp/ldctso37.htm>
- UK Vaping Industry Association. (2018, October 18). *Members*. Retrieved from UK Vaping Industry Association: <http://www.ukvia.co.uk/members/>
- UK Vaping Industry Association. (2018, October 18). *Policy positions*. Retrieved from UK Vaping Industry Association: <http://www.ukvia.co.uk/politics-of-vaping/>
- Viscusi, W. K. (1994). Risk-Risk Analysis. *Journal of Risk and Uncertainty*, 5-17.
- Warner Bros. (2018, December 1). *Rebel Without a Cause*. Retrieved from Warner Bros.: <https://www.warnerbros.com/rebel-without-cause>
- Wills, T., Sargent, J., Knight, R., Pagano, I., & Gibbons, F. (2016). E-cigarette use and willingness to smoke: a sample of adolescent non-smokers. *Tobacco Control*.
- Zernike, K. (2018, April 2). *I Can't Stop': Schools Struggle With Vaping Explosion*. Retrieved from The New York Times: <https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html>
- Zhu, S.-H., Zhang, Y.-L., Wong, S., Cummins, S. E., & Tedeschi, G. J. (2017). E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ*, 358-362.
- Zhuang, Y.-L., Cummins, S. E., Sun, J. Y., & Zhu, S.-H. (2016). Long-term e-cigarette use and smoking cessation: a longitudinal study with US population. *Tobacco Control*, 90-95.