

Fall 2014

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Online ISSN: 2643-7759

Recommended Citation

Eric A. Feldman, *Layers of Law: The Case of E-Cigarettes*, 10 FIU L. Rev. 111 (2014).

DOI: <https://dx.doi.org/10.25148/lawrev.10.1.10>

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Layers of Law: The Case of E-Cigarettes

Eric A. Feldman*

I. INTRODUCTION

Just a few years ago, it was impossible to imagine that e-cigarettes (more technically, electronic nicotine delivery systems, or “ENDS”) would become a popular consumer product. They seemed so gimmicky, so obviously unsatisfying, so fake, so un-cool; who could conceivably be attracted to the idea of sucking on a piece of plastic, inhaling an addictive substance, and exhaling an ephemeral vapor? Even worse, e-cigarettes lacked certain qualities that made conventional cigarettes so popular, like the ritual of lighting up, the smell of smoke, and the aesthetic of a smoke-filled room, but had the drawback of containing addictive quantities of nicotine. From almost every perspective, e-cigarettes seemed unlikely to gain traction in the marketplace.

The expectation—for some a hope—that e-cigarettes had little market potential was also propelled by the tobacco control community’s sense that it was finally winning what had come to be called the “tobacco wars.”¹ *Tobacco Control*, for example, a journal published by the prestigious *British Medical Journal*, titled its May 2013 issue “The Tobacco Endgame.”² Authors in that issue announced that the final days of smoking had arrived, noting that cigarette consumption was declining throughout the developed world and that multinational tobacco companies were on the defensive.³ Similarly, the fiftieth anniversary of the U.S. Surgeon General’s 1964 *Report on Tobacco and Health* represented a milestone in the tobacco control effort and made the second decade of the new millennium an opportune time to celebrate the triumph of public health over the

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¹ See, e.g., Stanton A. Glantz & Edith D. Balbach, *Tobacco War: Inside the California Battles* (2000) (detailing the complex history of tobacco politics in California, and dubbing such political battles “the tobacco war”). The Research and writing of this article was supported by a University of Pennsylvania Law School Faculty Summer Research Grant.

² British Medical Journal Publishing Group Ltd., *The Tobacco Endgame*, 22 TOBACCO CONTROL (Supp. May 2013).

³ Elizabeth A. Smith, *Questions for a Tobacco-Free Future*, 22 TOBACCO CONTROL (Supp. May 2013).

preventable harms caused by smoking.⁴

The celebration, however, was premature. With rapidity and stealth, the appearance of e-cigarettes threatened the idea that smoking was a dying habit. Borrowing the shape and size of cigarettes but utilizing twenty-first-century vaporizing technology, the new e-cigarette devices raised the possibility that the decline of tobacco-related morbidity and mortality would be stalled by a product that was evocative of conventional cigarettes and might entice a new generation of smokers. Moreover, in the eyes of many in the tobacco control community, the acceptance of e-cigarettes challenged one of the central strategic priorities of tobacco control—the “denormalization” of smoking. Successfully doing so had the potential to lead to a resurgence of smoking.⁵

This paper connects the current debate over the regulation of e-cigarettes with socio-legal scholarship on law, norms, and social control. It accepts, indeed it assumes, that almost every aspect of modern life that is subject to regulation has a variety of legal interfaces, and is thus shaped by multiple “layers of law.” What makes e-cigarettes distinctive is the rapid emergence of an unusually dense legal and regulatory web. In part, the dense fabric of e-cigarette law and regulation results from the lack of robust scientific and epidemiological data on the behavioral and health consequences of e-cigarettes, without which regulators can justify a wide range of legal interventions. In the absence of compelling science that supports particular types of policies, regulators in different jurisdictions can, with equal justification, pursue either permissive or prohibitory regulations. The result is a broad spectrum of policy interventions.

Moreover, the absence of shared social norms about the product (e-cigarettes) and behavior (vaping, i.e., using e-cigarettes) further invites a multiplicity of e-cigarette regulations. If there were data demonstrating that e-cigarettes caused health harms to users or bystanders, it would surely influence the informal rules of conduct that developed to govern their use. In the absence of such widely-accepted data, however, the health impact of vaping does not serve as a constraint on the types of vaping norms that are seen as appropriate. In short, the lack of widespread scientific agreement about the health impact of vaping, along with the absence of shared social norms about vaping, are at least in part responsible for the divergent types of e-cigarette regulations promoted by international bodies, local and national government, industry, and small private enterprises.

Despite the diversity of e-cigarette regulation, however, the policies

⁴ U.S. DEP’T OF HEALTH & HUM. SERVICES, THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS, A REPORT OF THE SURGEON GENERAL (2014).

⁵ Amy L. Fairchild, Ronald Bayer, & James Colgrove, *The Renormalization of Smoking? E-Cigarettes and the Tobacco Endgame*, 370 N. ENG. J. MED. 293 (Jan. 23, 2014).

that have emerged follow a certain pattern. In the jurisdictions discussed below, e-cigarette regulation clearly reflects a set of well-established institutional opportunities and constraints. In most cases, the architects of e-cigarette policy, and the policy tools they have deployed, will be familiar to anyone conversant with the key legal, political, and economic interests that shaped tobacco control policy in previous decades. In the US, for example, e-cigarette policy reflects long-standing conflicts over the United States Food and Drug Administration's ("FDA") legal authority to regulate combustible tobacco, whereas in Japan the regulatory approach to e-cigarettes has been crafted by the Ministry of Finance. In both jurisdictions, and many others, key players and institutions in the legal and regulatory conflict over tobacco policy have engaged with and exerted a powerful influence on the shape and content of e-cigarette law and policy. Although the web of e-cigarette regulations is dense and the policies themselves are often poorly justified, there is a logic to the types of policies that have emerged in particular places.

II. CHALLENGES TO THE REGULATION OF E-CIGARETTES

At least initially, the rise of e-cigarettes occurred in a legal vacuum. Even as it became clear that at least some sort of legal response was necessary—there was near-consensus, for example, that sales to children should be prohibited—the nature of the response remained uncertain.⁶ There was little agreement about whether e-cigarette regulation should be local, national or transnational; punitive or permissive; or whether it should utilize the framework of tobacco regulation, pharmaceutical regulation, or consumer protection.

One initial challenge was that regulators had to be able to describe the product they were regulating. Automobile safety regulations, for example, depend upon a definition of an automobile that distinguishes it from a truck, a motorcycle, and a bicycle. But there is no set definition of an “e-cigarette.” The technical terms for e-cigarettes, “non-combustible tobacco products” and “electronic nicotine delivery systems,” do not do an adequate job of describing the wide array of products that have entered (and continue to enter) the market as e-hookahs, hookah pens, hookah sticks, vape pens, vape pipes, and more.⁷ Those who use these devices sometimes (but rarely)

⁶ Both the FDA and the WHO have called for restrictions on e-cigarette sales to minors. Nina Larson, *WHO Calls for Ban on E-Cigarette Sales to Minors*, YAHOO! NEWS (Aug. 26, 2014, 12:52 PM), <http://news.yahoo.com/recommends-banning-e-cigarette-sales-minors-091728046.html>; *FDA: Ban Sales of Electronic Cigarettes to Minors*, CBS NEWS (Apr. 24, 2014, 4:28 AM), <http://www.cbsnews.com/news/fda-ban-sales-of-electronic-cigarettes-to-minors/>.

⁷ These products do share certain features. They do not involve combustion and generally include a microchip, battery, heating element/atomizer, and a cartridge/tank that holds a liquid solution.

call themselves smokers, instead preferring the term “vaper,” as in “those who use products that produce vapor rather than smoke.” The products come in a dizzying array of shapes, colors, and styles, make use of different technologies, and are rapidly evolving. As a result, it is difficult to define the class of products subject to regulation, and consequently to issue regulations with the desired scope.

Uncertainty about the health impact of e-cigarettes was (and continues to be) a significant impediment to regulation. Evidence that e-cigarettes are harmful to the health of vapers, or that vaping imposes harms on bystanders, may invite certain types of regulation, such as age restrictions, bans on use in certain settings, taxation, and perhaps more. Similarly, evidence that the use of e-cigarettes serves as a gateway to smoking suggests a different regulatory posture than evidence that the use of e-cigarettes facilitates smoking cessation. Unfortunately, not enough is yet known about the health impact of e-cigarettes or their effect on smoking-related behavior.⁸ The FDA has this to say:

E-cigarettes have not been fully studied, so consumers currently don't know the potential risks of e-cigarettes when used as intended, how much nicotine or other potentially harmful chemicals are being inhaled during use, or whether there are any benefits associated with using these products. Additionally, it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.⁹

The FDA's outlook is supported by scientists like Belinda Borrelli, Professor of Psychiatry and Director of the Program in Nicotine and Tobacco at the Miriam Hospital, who states, “[t]he jury is still out in terms of the long-term effects.”¹⁰ Similarly, David Abrams, Executive Director of

In most cases, the liquid contains nicotine (at a range of concentrations) that is dissolved in propylene glycol or glycerin, and flavorings that can include gummy bear, coffee, cotton candy, fruit loops, cherry, and many more. When users inhale, the solution is heated, and vapor is created and inhaled. The exhaled vapor disappears quickly and is generally odorless.

⁸ For an example of the contested nature of the science, see R. Paul Jensen et al., *Hidden Formaldehyde in E-Cigarette Aerosols*, 374 N. ENG. J. MED. 392 (Jan. 22, 2015). The article reports high levels of a carcinogen, formaldehyde, in certain types of vapor, and which ignited an immediate debate between those who saw its results as justifying a conclusion that e-cigs are more dangerous than combustible tobacco and those who did not see the results as relevant to the health impact of vaping. For a discussion of the debate, see Joe Nocera, *Is Vaping Worse Than Smoking?*, N.Y. TIMES (Jan. 27, 2015), <http://www.nytimes.com/2015/01/27/opinion/joe-nocera-is-vaping-worse-than-smoking.html?rref=collection%2Fcolumn%2Fjoe-nocera>.

⁹ U.S. FOOD AND DRUG ADMINISTRATION, *Electronic Cigarettes (e-Cigarettes)*, (Aug. 11, 2014), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>.

¹⁰ Kian Ivey, *As E-Cigarette Use Increases, Experts Investigate Health Risks*, THE BROWN DAILY HERALD (Dec. 6, 2013), available at <http://www.browndailyherald.com/2013/12/06/e-cigarette->

the Schroeder Institute for Tobacco Research and Policy Studies at Johns Hopkins Bloomberg School of Public Health, argues, “[w]hile we don’t really know the long-term impact of inhalation, logic would suggest and some preliminary studies would suggest that it’s going to be less harmful than combusted tobacco in any form, mainly cigarettes or hookah.”¹¹ Indeed, an expert panel convened by the National Institute of Health to assess the scientific and epidemiological literature on e-cigarettes recently concluded:

There is extensive public discussion on whether e-cigarettes could substantially reduce conventional cigarette smoking, be an effective aid for nicotine cessation, or both. However, there is limited data available that directly addresses these issues. Concerns have also been raised about the potential for e-cigarettes to facilitate nicotine addiction, especially among youths and young adults, and to promote relapse among former smokers. The short-term and long-term effects of e-cigarettes on human physiology and behavior have yet to be fully explored. Independent, peer-reviewed research is the appropriate mechanism to evaluate e-cigarettes to assess both the potential risks and potential opportunities they represent.¹²

Underlying such scientific assessments is the fact that e-cigarettes, like combustible tobacco products, contain nicotine. The oft-repeated statement that “smokers smoke for the nicotine but die from the tar” is a useful reminder that nicotine is not what makes conventional cigarettes so harmful. Instead, the carcinogens contained in tobacco leaf, which are not found in e-cigarettes, are what lead to tobacco-related disease. Abrams’ view that e-cigarettes are likely to be significantly less harmful than tobacco cigarettes is therefore plausible, though it does not account for the possibility that using e-cigarettes could potentially serve as a gateway to smoking, that dual use (of combustible and electronic cigarettes) may become common, and that much remains unknown about chemical-containing vapor.

The sparseness of data on the public health impact of e-cigarettes has invited a volatile conflict between those in the U.S. public health community pressing for a precautionary approach to e-cigarettes and others insisting on a harm reduction strategy. From the precautionary perspective, uncertainty about the potential public health harms of e-cigarettes demands regulatory action. As Thomas Frieden, Director of the Centers for Disease

use-increases-experts-investigate-health-risks/.

¹¹ *Id.*

¹² Kevin Walton et al, “NIH Electronic Cigarette Workshop: Developing a Research Agenda,” *Nicotine & Tobacco Research*, 2014.

Control and Prevention (“CDC”) puts it, “I think the precautionary principle—better safe than sorry—rules here.”¹³ In contrast, prioritizing harm reduction suggests a less aggressive regulatory posture that underscores the likelihood that e-cigarettes are less hazardous than combustible cigarettes and have the potential to improve public health by reducing per capita cigarette consumption. Those who subscribe to a harm reduction perspective believe that embracing the precautionary principle could mute the potential of e-cigarettes to reduce tobacco-related morbidity and mortality.

Despite their differences, most public health experts agree that e-cigarettes need at least some regulation. Their popularity has exploded in the past five years, as evidenced by the opening of over 16,000 vape shops in the U.S., a dramatic increase in the sale of e-cigarette products, and a rapid rise in the number of people trying e-cigarettes.¹⁴ The fastest growing segment of the market is vaporizers, often called e-hookahs or vape pens, which lack the shape and color of traditional tobacco cigarettes, have larger batteries than most e-cigarettes, and contain large refillable chambers that hold e-juice, the nicotine-containing liquid that is vaporized by e-cigarettes. Users of such products can purchase e-juice in bulk both at specialty stores and online, with different flavorings and a range of nicotine concentrations. Because e-juice is unregulated, there is the potential for significant and potentially dangerous variation in how much nicotine particular products contains, and in the safety of other ingredients contained in those products. One relatively uncontroversial step in regulating e-cigarettes, therefore, would be to set standards for the safety and quality of the increasingly popular refillable liquids used by vapers.

In addition to product standards, some public health experts and regulators see the need for a significantly more robust set of regulations to combat the rapid changes that have occurred in the e-cigarette industry. In the early days of e-cigarettes, 2007-11, hundreds of companies in the U.S. imported e-cigarette products from China, competing in a small but rapidly evolving market. As e-cigarettes grew in popularity, those companies were pushed aside by multinational tobacco companies, which are now the key players in the e-cigarette market. Lorillard, for example, purchased the market-leading e-cigarette in the U.S., Blu, for \$135 million in 2012 and

¹³ Sabrina Tavernise, *A Hot Debate Over E-Cigarettes as a Path to Tobacco, or From It*, N.Y. TIMES (Feb. 22, 2014), <http://www.nytimes.com/2014/02/23/health/a-hot-debate-over-e-cigarettes-as-a-path-to-tobacco-or-from-it.html>.

¹⁴ See Mike Esterl, *'Vaporizers' Are the New Draw in E-Cigarettes*, N.Y. TIMES (May 29, 2014, 5:23 PM), <http://www.wsj.com/articles/vaporizers-are-the-new-draw-in-e-cigarettes-1401378596> (estimating that there are 16,000 vape shops in the U.S. as of May 2014, and claiming that e-cigarette product sales rose 71% between May 2013 and May 2014).

sold it in 2014 (along with several of its tobacco brands) to Imperial Tobacco in a multi-billion dollar deal.¹⁵ Altria introduced MarkTen during the summer of 2014, Philip Morris International (PMI), began test marketing IQOS (the result of ten years and two billion dollars in R&D) in Italy and Japan in late 2014, and in that same year purchased a UK e-cigarette company, Nicocigs. PMI officials are enthusiastic about the future of e-cigarettes, pronouncing such products “our greatest growth opportunity in the years to come, which we believe has the very real potential to transform the industry.”¹⁶ Other major tobacco companies have not been left behind: R.J. Reynolds released Vuse in 2014; Japan Tobacco International (JTI) owns a minority interest in Ploom; and British American Tobacco owns Vype. Indeed all of the major tobacco industry players have rapidly embraced the e-cigarette business.

For those who have long labored to improve public health by reducing tobacco-related morbidity and mortality, the reappearance of their traditional foe—“big tobacco”—is an unwelcome surprise. Douglas Bettcher, Director of the World Health Organization’s Department for the Prevention of Noncommunicable Diseases, makes the case in blunt terms: “[t]he tobacco industry has a history of deception when using harm-reduction marketing ploys to promote tobacco products with the pretense of being less harmful.”¹⁷ Similarly, three prominent tobacco control researchers have noted how the traditional tobacco companies are “using the same political and public relations strategies” that were deployed to market combustible tobacco.¹⁸ In their view, the tobacco companies are likely to hide the potential dangers of e-cigarettes while aggressively and effectively marketing them. Indeed, their marketing prowess is already evident. Because the legal prohibitions on most tobacco advertising and sponsorship do not apply to e-cigarettes, one can already see a steady

¹⁵ See Mike Esterl, *Got a Light—er Charger? Big Tobacco’s Latest Buzz*, WALL ST. J. (April 25, 2012, 7:14 PM), <http://www.wsj.com/articles/SB10001424052702304723304577365723851497152> (detailing Lorillard’s purchase of Blu); see also Brian Solomon, *Reynolds, Lorillard Dump Blu E-Cigarettes in \$27 Billion Merger*, FORBES (Jul. 15, 2014, 2:53 PM), <http://www.forbes.com/sites/briansolomon/2014/07/15/reynolds-lorillard-dump-blu-e-cigarettes-in-27-billion-merger/> (detailing the sale of Blue to Imperial Tobacco Group).

¹⁶ Tom Gara, *Introducing the New USB-Powered Pack of Marlboros*, WALL ST. J. (Jun. 27, 2014, 11:13 AM), <http://blogs.wsj.com/corporate-intelligence/2014/06/27/introducing-the-new-usb-powered-pack-of-marlboros/>.

¹⁷ Mike Esterl & Peter Evans, *World Health Organization Calls for Tougher Rules on E-Cigarettes*, WALL ST. J. (Aug. 26, 2014), <http://www.wsj.com/articles/world-health-organization-calls-for-tougher-rules-on-e-cigarettes-1409074077>.

¹⁸ Rachel Grana, Neal Benowitz, & Stanton Glantz, *Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems)*, WORLD HEALTH ORGANIZATION TOBACCO FREE INITIATIVE (December 2013), available at <https://escholarship.org/uc/item/13p2b72n>.

increase in spending on e-cigarette advertising.¹⁹ Ads promoting e-cigarettes are found in a wide range of magazines; racing cars are covered in e-cigarette designs; cartoon characters are used for product promotion; ads have even found their way into that most hallowed of television advertising slots, the Super Bowl. Like their tobacco predecessors, e-cigarette ads feature rugged men and attractive women, often famous actors and actresses, stress freedom and independence, promote the “sexiness” of vaping, and underscore the contrast between the negative association of smoking tobacco cigarettes and the positives of using e-cigarettes. The rapid increase in the use of e-cigarettes may in significant part be a result of those advertising dollars.

E-cigarette companies, in addition to conventional marketing efforts, have also engaged in a battle over the social acceptance and meaning of vaping. Public health advocates had for years worked to counter the tobacco industry’s valorization of smoking by promoting the view that smoking was an unappealing, anti-social, smelly habit and that smokers were deviant and foolish. The marketers of e-cigarettes picked up on that argument and promoted e-cigarettes as a route to the “renormalization” of cigarette-like products.²⁰ They have highlighted the difference between combustible and non-combustible products, insisting that the demonization of smokers and smoking should not be carried over to vapers and vaping. The industry’s explicit engagement of the denormalization of smoking is well illustrated by Lorillard’s “take back your freedom” advertising campaign for Blu e-cigarettes, which promotes vaping as an opportunity for smokers to regain the moral high-ground by using a product that warrants social acceptance.

So far, those efforts have met with only limited success. Although e-cigarettes are not yet tarnished by the powerfully negative view of combustible tobacco products, social norms about vaping are still evolving. Neither those who use e-cigarettes, nor the population more generally, have yet determined the content of the informal social rules governing vaping, such as whether it is acceptable to use e-cigarettes in restaurants, in public parks, or around kids. Unwritten rules of social conduct are also lacking when it comes to e-cigarette use in homes, workplaces, social settings,

¹⁹ See *State Health Officer Issues Health Advisory and New E-Cigarette Report*, IMPERIAL VALLEY NEWS (Jan. 29, 2015), <http://www.imperialvalleynews.com/index.php/news/health-news/1287-state-health-officer-issues-health-advisory-and-new-e-cigarette-report.html> (citing a report that found a 1,200 percent increase in e-cigarette advertising spending nationwide between 2011 and 2013).

²⁰ See Amy Fairchild, Ronald Bayer, & James Colgrove, *The Renormalization of Smoking? E-Cigarettes and the Tobacco “Endgame”*, NEW ENG. J. MED. (Jan. 23, 2014), <http://www.nejm.org/doi/full/10.1056/NEJMp1313940> (detailing how the chief advertising officer of a major e-cigarette manufacturer said that vaping may renormalize smoking traditional tobacco products) [hereinafter *Renormalization*].

cinemas, stadiums, beaches, or at sporting events, and the jury is out when it comes to the question of whether vaping is cool or ridiculous, sexy or silly, macho or emasculating.

There is nothing subtle about the battle for social acceptability. Soon after a former smoker who turned to vaping published an article in *Business Insider* titled “The 9 Laws of E-Cigarette Etiquette: A Handy Guide for Smokers,” various e-cigarette companies reprinted his “laws” and invited a discussion among vapers about what constitutes appropriate vaping conduct.²¹ Among the “laws” of “e-cigarette etiquette” proposed in the article are:

- Puffing on your e-cigarette at the movies is not allowed;
- Do not vape at the dinner table;
- Don’t vape in the bathroom;
- Cigarette smokers are not your inferiors, don’t act like it;
- Don’t leave a trail of e-cig wrappers and cartridges lying around.²²

Although the specific issues are trivial the general point is not. Public health researchers appreciate that the battle over the social acceptability of vaping is at the heart of the e-cigarette debate, and cite the battle over “renormalization” as the central issue in the regulation of e-cigarettes.²³

The financial muscle of the e-cigarette industry, the lack of data on the public health consequences of e-cigarettes, the uncertainty surrounding the social norms of vaping, and the divide between public health policy experts pressing for a precautionary approach and those advocating harm reduction have all contributed to the current regulatory framework of e-cigarettes. That framework consists of a multi-layered patchwork of formal, informal, local, and global legal and social norms: pronouncements by international organizations, multinational regulations, single-nation policies, and sub-national regulations promulgated by states, localities, and private organizations. It is that web of e-cigarette regulations, dense in some places and thin in others, with overlaps and gaps, areas of strength and areas of incoherence, to which this article now turns.

²¹ Chris Anderson, *The 9 Laws of E-Cigarette Etiquette: A Handy Guide for E-Cigarette Smokers*, BUS. INSIDER (Sep. 4, 2013, 11:49 AM), <http://www.businessinsider.com/the-9-laws-of-e-cigarette-etiquette-infographic-2013-9>.

²² *Id.*

²³ See Fairchild, *supra* note 20.

III. THE WEB OF E-CIGARETTE REGULATIONS

A. International Organizations

On the global level, the World Health Organization (“WHO”) remained on the sidelines of the e-cigarette debate until July 2014, when based on a commissioned analysis of the evidence about the health impact of ENDS it announced a set of policy recommendations. They included a prohibition on the use of e-cigarettes in enclosed spaces; the regulation and possible prohibition of advertising, promotion, and sponsorship; a ban on sales to minors; and a mandatory packet warning.²⁴ Formally, WHO’s recommendations have no legal force and are merely suggestions that nations are free to embrace or ignore. WHO’s key role in global tobacco policy and its influential Framework Convention on Tobacco Control, however, give the agency an unusual degree of moral force when it comes to tobacco-related regulation. This may help to explain the controversy ignited by its foray into the e-cigarette area, including harsh criticism from a group of UK scientists who published an article in the journal *Addiction* accusing WHO of significantly overplaying the health risks of e-cigarettes.²⁵

WHO is not the only cross-border agency to enter the debate over e-cigarettes. With more direct regulatory authority than the WHO, the European Union has gotten involved through its revised Tobacco Products Directive, approved by the European Parliament in February 2014.²⁶ Under that Directive, beginning in 2016 all e-cigarette products must include a health warning that covers sixty-five percent of both the front and back of the packaging. Products marketed as smoking cessation tools are required to be licensed as medicines, whereas those marketed as tobacco products are subject to restrictions, including: maximum quantities of nicotine (twenty mg per ml); the same advertising bans the EU imposes on tobacco cigarettes; restrictions on the sizes of cartridges, refillable tanks, and e-liquid bottles; and quality and safety standards. Untouched by the EU regulations are e-cigarette flavorings, sales to minors, and advertising that

²⁴ *Electronic Nicotine Delivery Systems: Report by WHO*, CONF. OF THE PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (Jul. 21, 2014), http://apps.who.int/gb/ftc/PDF/cop6/FTC_COP6_10-en.pdf?ua=1.

²⁵ Ann McNeill, Jean-Francois Etter, Konstantinos Farsalinos, Peter Hajek, Jacques le Houezec, & Hayden McRobbie, *A Critique of a World Health Organization-Commissioned Report and Associated Paper on Electronic Cigarettes*, 109 *ADDICTION* J. CLUB 2128, 2134 (December 2014), available at <http://onlinelibrary.wiley.com/doi/10.1111/add.12730/epdf>.

²⁶ *Directives on the Approximation of the Laws, Regulation, and Administrative Provisions of the Member States Concerning the Manufacture, Presentation, and Sale of Tobacco and Related Products*, Council Directive 2014/40 (EU), (Apr. 3, 2014), available at http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf.

does not reach outside a nation's borders.

B. National Regulations

In almost all cases, national policy makers have had to determine whether e-cigarettes should be regulated as pharmaceutical products, tobacco products, or general consumer products. A number of countries, like Singapore, have avoided the need to make fine-grained regulatory decisions by simply banning all e-cigarettes.²⁷ Singapore's ban is rooted in its Tobacco Act, which "prohibits the import, distribution, sale or offer for sale of any article that is designed to resemble a tobacco product; this includes vaporizers such as e-cigarettes, e-pipes, e-cigars and the likes."²⁸

Other countries have imposed de facto bans on e-cigarettes by treating them as smoking cessation aids that are controlled by pharmaceutical laws, which requires manufacturers to submit evidence of product safety and efficacy. In Norway, for example, only nicotine-free e-cigarettes are permitted.²⁹ Consumers who prefer nicotine-containing products—the great majority of vapers—can import their own products in limited quantities, or wait until manufacturers have enough evidence to obtain regulatory approval, which could take years (or may never occur). Some countries, notably China, where over ninety percent of the world's e-cigarettes are manufactured, have not yet developed any e-cigarette regulations. The regulatory conflicts in Japan and the United States have been particularly pointed, and provide good examples of how differently national governments are approaching e-cigarette policy.

1. Japan

Japan's approach to e-cigarettes is shaped by the history of the government's tobacco monopoly, particularly the fact that the Ministry of Finance has the legal authority to regulate tobacco products and continues to be a controlling shareholder in Japan's only domestic tobacco company, Japan Tobacco.³⁰ Tax revenues from tobacco sales have long defined the

²⁷ *Prohibition on Imitation Tobacco Products*, HSA.GOV, http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Tobacco_Control/Overview/Tobacco_Legislation/Prohibition_on_Certain_Products.html (last visited May 7, 2014).

²⁸ *HSA Prosecutes Three Persons for Selling Electronic Cigarettes*, HEALTH SCIENCES AUTH. (Apr. 21, 2014), http://www.hsa.gov.sg/content/hsa/en/News_Events/Press_Releases/2014/HSA_Prosecutes_Three_Persons.html.

²⁹ *See Electronic Cigarette Norway—E-Cigarette Legal Status in Norway*, AIR SMOKE (Jan. 28, 2014), <http://www.airsmokecig.com/blog/electronic-cigarette-norway/> ("E-cigarettes and nicotine-free cartridges may be sold, but nicotine-containing refills are prohibited. All marketing is prohibited. Sale to under-18s is prohibited.")

³⁰ Eric A. Feldman, *The Landscape of Japanese Tobacco Policy: Law, Smoking and Social Change*, 44 AM. J. COMP. L. 679 (Autumn 2001).

government's regulatory objective in the tobacco area, and political support by the agricultural sector (within which tobacco farmers have been influential) has further muted the state's interest in regulations that might decrease domestic tobacco consumption. The interesting regulatory question raised by e-cigarettes in Japan is whether they are tobacco products subject to control by the Ministry of Finance ("MoF"), or if they fall under the Ministry of Health, Labor, and Welfare's ("MHLW") authority over pharmaceutical products.

To make that determination, Japanese bureaucrats turned to the 1984 Tobacco Business Act.³¹ They concluded that because the law defines tobacco products as containing tobacco leaf, e-cigarettes with the nicotine-containing liquids (but no leaf) could not be defined as tobacco products. Instead, since nicotine is classified as a drug and several nicotine-containing products (like nicotine gum) are regulated by the MHLW, e-cigarettes that use a liquid solution with nicotine are considered pharmaceutical products subject to regulation by the MHLW. Like in Norway, nicotine-containing e-cigarettes will only be approved (by the Pharmaceutical Affairs Bureau of the MHLW) if data indicates that they are safe and effective. No e-cigarette company has yet sought MHLW approval in Japan.

There is, however, a regulatory quirk; certain vaporizers operate by vaporizing tobacco leaf rather than liquid. Most notably, Japan Tobacco holds a minority interest in a San Francisco-based company, Ploom, and government regulators decided that it was not subject to MHLW control because its leaf vaporizer fit the definition of a tobacco product and is thus more appropriately regulated by MoF.³² Philip Morris International also recently started test marketing a leaf vaporizer, IQOS, in Nagoya, Japan, and it too escapes MHLW regulation because it contains tobacco leaf.³³ Both leaf vaporizers are now available to Japanese consumers. From a public health perspective there is no justification for such a regulatory divide. Leaf vaporizers have not been shown to pose fewer health concerns than liquid-vaporizing e-cigarettes, and the fact that tobacco leaf contains far more known carcinogens than e-liquids and leaf vaporizers operate at higher heat than liquid vaporizers raises the possibility that they are more harmful than liquid-based products. Nonetheless, in a move that preserved Japan Tobacco's dominant market position and underscores the Ministry of Finance's regulatory control of tobacco policy, leaf vaporizers have now entered the Japanese market, whereas liquid vaporizers are effectively

³¹ Tobacco Business Act, Law No. 68 of 1984 (Japan).

³² Verbal discussions with officials at the Japanese Ministry of Finance and the Ministry of Health, Labour and Welfare (Dec. 2014).

³³ *Phillip Morris Launches New Type of Smokeless Cigarette*, VAPE RANKS (Nov. 25, 2014), <http://vaperanks.com/phillip-morris-launches-new-type-of-smokeless-cigarette/>.

banned.

2. United States

The situation in the U.S. has certain similarities to that in Japan. In both countries, e-cigarette companies would prefer to be regulated under the relatively lenient standards that govern tobacco products, rather than under the laws governing pharmaceutical products, which involve time consuming and expensive data collection with no guarantee of product approval. Whereas Japanese regulators concluded that e-cigarettes containing nicotine were pharmaceutical products subject to MHLW control, however, the U.S. Food and Drug Administration's (FDA) effort to assert regulatory authority over e-cigarettes as combination drugs/delivery devices met with less success.

In October 2008, the FDA detained a number of shipments of electronic cigarettes at the Los Angeles International Airport.³⁴ The e-cigarettes were being imported from China by two e-cigarette companies, NJOY and Smoking Everywhere, but the FDA claimed that importing these nicotine-containing products violated the Food, Drug, and Cosmetic Act (FDCA) because they had not yet been evaluated by the FDA for safety and efficacy, as required for all drugs marketed in the U.S.³⁵ The FDA therefore ordered the companies to either export or destroy the e-cigarettes within ninety days. During the ensuing fourteen months the FDA refused entry to dozens of additional shipments of e-cigarettes. According to FDA Commissioner Margaret Hamburg, “[t]he FDA is concerned about the safety of these products and how they are marketed to the public.”³⁶

E-cigarette importers, not surprisingly, had a different view. By carefully avoiding claims about the therapeutic effects of e-cigarettes—as a treatment for nicotine withdrawal, for example—they argued that their products did not fall within the FDA's jurisdiction over drugs and drug delivery devices. Instead, if the FDA was going to regulate e-cigarettes, importers argued that it could only do so under its recently acquired power to regulate tobacco products.³⁷ They demanded that the FDA put a halt to

³⁴ See *FDA Fighting for Authority to Regulate Electronic Cigarettes*, AAFP (Mar. 2, 2010), <http://www.aafp.org/news/health-of-the-public/20100302e-cig-fda.html> (detailing the October 2008 detainment); *Electronic Cigarettes and the FDA*, ELECTRONIC CIGARETTE SPOT, <http://electroniccigarettespot.com/book/export/html/9> (last visited Feb. 20, 2015) (same).

³⁵ 21 U.S.C. § 360d (1938).

³⁶ Press Release, Food and Drug Administration, FDA and Public Health Experts Warn About Electronic Cigarettes (July 22, 2009), available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm173222.htm>.

³⁷ See *Tobacco Control Act*, FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm> (last visited Feb. 23, 2015) (describing how the Tobacco Control Act of 2009 gives the FDA broad authority to regulate the

the detention of their products, and brought their claim to the D.C. Circuit Court.

In a stinging rebuke to the FDA's position, later affirmed on appeal, U.S. District Court Judge Richard Leon ruled that the FDA could not regulate e-cigarettes as drugs or drug delivery devices unless the products were marketed with claims about their therapeutic effects.³⁸ Judge Leon did not simply disagree with the FDA; he scolded the agency in the harshest of tones:

This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices under the Food, Drug, and Cosmetic Act (FDCA). Ironically, notwithstanding that Congress has now taken the unprecedented step of granting FDA jurisdiction over those products, FDA remains undeterred. Unfortunately, its tenacious drive to maximize its regulatory power has resulted in its advocacy of an interpretation of the relevant law that I find, at first blush, to be unreasonable and unacceptable.³⁹

In April 2014, more than four years later, the FDA announced its intention to extend its regulatory authority over tobacco to e-cigarettes and a variety of other "tobacco products" like cigars and hookah.⁴⁰ Under the FDA's proposed regulations, e-cigarette manufacturers will have to comply with a number of requirements, including: providing the FDA with a list of product ingredients; submitting all "new" products for FDA review; refraining from claims about the reduced risk posed by their products; and not distributing free samples.⁴¹ In addition, the FDA applied several regulations central to its tobacco control agenda to e-cigarettes, including age restrictions on sales, health warnings on packs, and limitations on vending machine.⁴²

The FDA's proposed regulatory scheme represents a significant effort to control the quality of e-cigarettes, limit their distribution, and ensure that the public has at least some information about their potential to be addictive. Nonetheless, some members of the public health community have been critical of the FDA's approach, particularly what they consider

manufacture, distribution, and marketing of tobacco products).

³⁸ *Smoking Everywhere, Inc. v. Food & Drug Admin.*, 680 F. Supp. 2d 62, 72 (D.D.C. 2010).

³⁹ *Id.* at 78.

⁴⁰ Food and Drug Administration, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 79 FR 23141, Apr. 25, 2014.

⁴¹ *Id.*

⁴² *Id.*

the FDA's failure to adequately guard against the potential of e-cigarettes to appeal to kids.⁴³ E-cigarette flavorings, for example, available in everything from Gummi Bear to Cotton Candy, were left unregulated, as were the use of cartoon characters to promote e-cigarettes and the sponsorship of a wide range of events by e-cigarette companies and brands. The FDA's repeated legal defeats by industry in the area of tobacco regulation also kept it from proposing limits or prohibitions on e-cigarette advertising, since doing so would invite First Amendment challenges.⁴⁴

The publication of the FDA's proposed e-cigarette regulations in the Federal Register triggered over 135,000 public comments. Until the FDA reviews the comments and finalizes its regulations, e-cigarettes will remain largely unregulated by the Federal Government. Even assuming that the FDA regulations are finalized in close to their current form, they will contain significant gaps, as described above. As a result, a patchwork of state and local regulations have started to emerge, some of which fill the gaps left by federal inaction.

The fastest and least politically controversial move by the states has been to fold e-cigarettes into existing regulations aimed at combustible cigarettes. Since there are laws in every state limiting tobacco sales to minors, forty-one states have extended those regulations to e-cigarette sales.⁴⁵ Nine states classify e-cigarettes as tobacco products and apply all state tobacco regulations to e-cigarettes, and twenty-eight states ban the use of e-cigarettes at work.⁴⁶ Although one can appreciate the political ease of extending tobacco regulations to e-cigarettes, it is a somewhat vexing move conceptually. It took decades for regulators to legislate smoke-free laws that limited or prohibited smoking in public places, and those laws were almost always justified by pointing to data about the health harms to third

⁴³ See *E-Cig-Related Poison Control Calls Jump*, BCTV.org (Feb. 20, 2015, 6:30 AM), http://www.bctv.org/special_reports/health/e-cig-related-poison-control-calls-jump/article_bf82f824-b6db-11e4-92cc-03476ac41965.html (detailing the Campaign for Tobacco-Free Kids's criticism of the FDA for failing to expedite the process of finalizing its proposed rule to regulate e-cigarettes amidst a report that the number of e-cigarette-related poisoning incidents more than doubled in 2014).

⁴⁴ See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (holding that FDA regulations prohibiting outdoor advertising of smokeless tobacco or cigars within 1,000 feet of schools or playgrounds violated the First Amendment); *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012) (ruling that the FDA did not provide substantial evidence that graphic warnings on cigarette advertising would sufficiently advance its interest in reducing smoking to a material degree).

⁴⁵ See *Alternative Nicotine Products; Electronic Cigarettes*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Feb. 18, 2015), <http://www.ncsl.org/research/health/alternative-nicotine-products-e-cigarettes.aspx> (listing every state that has taken legislative action against the sale of electronic cigarettes to children, and providing each state's rationale).

⁴⁶ Katie Johnston, *E-cigarettes Put Corporate Smoking Policies to the Test*, THE BOSTON GLOBE (June 22, 2014), <http://www.bostonglobe.com/business/2014/06/21/vape-debate/CZgoq271D88Svpejr2qzVN/story.html>.

parties exposed to secondhand smoke.⁴⁷ The lack of data on third-party harms caused by e-cigarettes, however, makes it disingenuous to ban their use in public settings to protect the health of non-vapers. State legislators do not appear troubled by the lack of evidence-based policy, and have instead simply widened their tobacco laws without providing an explicit justification for doing so.

In other policy areas, e-cigarette policy is far from uniform. Taxation, used effectively to increase the cost of combustible cigarettes and decrease their use, has so far been embraced only by Minnesota and North Carolina, which impose a dedicated sales tax on e-cigarettes.⁴⁸ A few states, notably New Jersey, Utah, and North Dakota, ban the use of e-cigarettes in restaurants, bars, and the workplace. No states have thus far attempted to limit e-cigarette advertising or impose controls on flavorings. In statehouses around the country, however, politicians and regulators are discussing what their next steps should be, if any, to control the use of e-cigarettes and captures revenue from their sales.

With regulatory gaps at both the state and federal level, some U.S. cities have entered the regulatory mix. Most of them have, like states, folded e-cigarettes into existing tobacco regulations. Chicago, for example, banned e-cigarette use (like tobacco use) in bars, restaurants, and in most other indoor environments, which Alderman Will Burns justifies by saying that “they make it seem OK to smoke.”⁴⁹ New York City prohibits the sale of e-cigarettes to anyone under the age of twenty-one, and bans their use wherever tobacco use is prohibited.⁵⁰ Likewise, Los Angeles extends its broad ban on the use of cigarettes—prohibited on beaches and in public parks—to e-cigarettes, and requires that retailers have a tobacco sales license.⁵¹ Boston bans the use of e-cigarettes in the workplace.

⁴⁷ Ronald Bayer and James Colgrove, “Children and Bystanders First: The Ethics and Politics of Tobacco Control in the United States,” in Eric A. Feldman and Ronald Bayer, eds, *Unfiltered: Conflicts over Tobacco Policy and Public Health*, Cambridge, MA: Harvard University Press, 2004.

⁴⁸ Delaware, Hawaii, Indiana, Kentucky, New Jersey, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Vermont, and Washington are considering or have considered similar action. Elaine S. Povich, *States Look to Tax E-Cigarettes*, THE PEW CHARITABLE TRUSTS (Jan. 23, 2015), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/1/23/states-look-to-tax-e-cigarettes>.

⁴⁹ Jacob Sullum, *Chicago on the Verge of Banning E-Cigarettes in Public Places Because They ‘Normalize Smoking’*, HIT & RUN (Jan. 14, 2014, 5:00 PM), <http://reason.com/blog/2014/01/14/chicago-on-the-verge-of-banning-e-cigare>.

⁵⁰ Dan Goldberg, *Ban on E-Cigarettes Takes Effect Today*, CAPITAL NEW YORK (Apr. 29, 2014, 5:00 AM), <http://www.capitalnewyork.com/article/city-hall/2014/04/8544438/ban-e-cigarettes-takes-effect-today>.

⁵¹ See, e.g., *Los Angeles E-Cig Ban Takes Effect*, CITY NEWS SERVICE (Apr. 19, 2014, 6:31 PM), <http://www.10news.com/news/los-angeles-e-cig-ban-takes-effect> (describing the potential economic impact of the ban on local vapor lounges).

Philadelphia, which regulates e-cigarettes like tobacco products, in late 2014 became the first city to consider imposing a dedicated tax on e-cigarettes, which it hopes will generate revenue for its failing public school system.⁵² Many cities, of course, have been silent, and in such places legal controls on e-cigarettes depend upon whether the state has taken any action.

With such significant unevenness in the legal control of e-cigarettes on the federal, state, and city levels, e-cigarette regulation has been taken up by a broad range of additional entities. At least 225 towns, for example, have passed laws restricting e-cigarette use in venues that are tobacco-free, and well over 100 have restricted the use of e-cigarettes in other venues.⁵³ Individual counties in sixteen states have banned the use of e-cigarettes, as have a large number of small localities. All U.S. airlines, both domestic and international, have prohibited the use of e-cigarettes on board (many non-U.S. carriers have not yet formulated a policy), but airports are more mixed, with some prohibiting e-cigarette usage and others allowing it in designated areas.⁵⁴

Restaurants in jurisdictions with e-cigarette regulations must abide by them, but those located in areas that lack regulation have had to make their own rules, with some printing their e-cigarette policies at the bottom of their menus. Closer to home, some homeowner's associations have adopted rules prohibiting the use of e-cigarettes in common areas. Prince Georges County in Maryland considered, but ultimately shelved, a law that would have banned the use of e-cigarettes in public housing, and the Town Council of Corte Madera, California, located in upscale Marin County, will soon implement a ban on using e-cigarettes in new and existing multifamily dwellings.⁵⁵

In the workplace, a number of large employers have adopted explicit bans on e-cigarettes. Starbucks, for example, states that it:

⁵² Kay Lazar, *E-Cigarettes Banned in Workplaces in Boston, and City Prohibits Sales to Minors*, BOSTON.COM (Dec. 1, 2011, 5:27 PM), <http://www.boston.com/2011/12/01/ecigs/el6HXuVTwWDRgDAEZMB5yM/story.html>; Claudia Vargas, *Phila. Councilwoman Wants to Tax E-Cigarettes*, PHILLY.COM (Oct. 17, 2014), http://articles.philly.com/2014-10-17/news/55112664_1_e-cigarettes-e-cigarette-users-liquid-nicotine.

⁵³ See *U.S. State and Local Laws Regulating Use of Electronic Cigarettes*, American Nonsmokers' Rights Foundation (Jan. 1, 2015), <http://www.no-smoke.org/pdf/ecigslaws.pdf> (providing a table of every city or county in the United States that has enacted regulations regarding electronic cigarettes).

⁵⁴ Jolie Lee, *Some Airports Give Green Light to E-Cigarettes*, USA TODAY (Dec. 4, 2013), <http://www.usatoday.com/story/travel/flights/2013/12/04/airports-e-cigarettes-rules/3783347/>.

⁵⁵ Tracee Wilkins, *Maryland County Holds Off on E-Cigarette Ban*, NBC WASHINGTON (Nov. 5, 2013, 6:32 PM), <http://www.nbcwashington.com/news/local/Md-County-Holds-Off-on-E-Cigarette-Ban-230732221.html>; Megan Hansen, *Corte Madera Votes to Ban Smoking, E-Cigarette use in Multifamily Housing Units*, MARINIJ (Apr. 15, 2014, 12:01 AM), <http://www.marinij.com/general-news/20140415/corte-madera-votes-to-ban-smoking-e-cigarette-use-in-multifamily-housing-units>.

[D]oes not allow the use or smoking of cigarettes regardless of their form (including electronic and vapor producing ones) in any of our stores. This has always been our policy to ensure we preserve the quality of our coffee and consistently offer a comfortable environment for all our customers where they can relax and enjoy their favorite beverage.

Similarly, AT&T, Wal-Mart, GE, CVS, UPS, Home Depot, Kroger, and Target ban e-cigarettes from the workplace, as do all company-owned McDonalds (otherwise, it is left up to the franchise).⁵⁶ Walgreen's and Kraft allow local managers to set e-cigarette policies, and Exxon Mobile and General Motors allow vaping in designated smoking areas.⁵⁷ Small companies have similarly moved in the general direction of vaping bans, with eighty-two percent of respondent employers in one survey reporting that they do not permit the use of e-cigarettes at work.⁵⁸ Ebsco, a seventy-person company in Tulsa, Oklahoma that manufactures industrial springs has gone in a different direction. The CEO of Ebsco found e-cigarettes to be a helpful smoking cessation tool, and spent \$100 on vaping kits for every smoking employee with the hope that it would help them quit using combustible cigarettes.

It is not yet clear how insurance companies will factor the use of e-cigarettes into health insurance premiums, but a survey of underwriters revealed that eighty-nine percent of them consider e-cigarette users to be smokers.⁵⁹ Some large employers appear to believe that employees who vape will drive up corporate health care costs; Wal-Mart imposes a \$2000 health insurance premium surcharge on those who use e-cigarettes, which is waived if the employee provides a doctor's statement that not vaping would be medically inadvisable or impossible, and UPS charges non-union vapers the same \$150 extra monthly insurance premium as non-union tobacco users.⁶⁰ Some large hotel chains, like Starwood, prohibit e-cigarette use by

⁵⁶ Ben Popken, *Vaping Electronic Cigarettes Gets Green Light in Some Offices*, NBC NEWS (May 7, 2014), <http://www.nbcnews.com/business/consumer/vaping-electronic-cigarettes-gets-green-light-some-offices-n94746>.

⁵⁷ Chris Burritt, *E-Cigs Wafting Into Workplace 25 Years After Smoking Ban*, BLOOMBERG (Nov. 6, 2013), <http://www.bloomberg.com/news/2013-11-06/e-cigs-wafting-into-workplace-25-years-after-smoking-ban.html>; Lauren Weber and Mike Esterl, *E-Cigarette Rise Poses Quandary for Employers*, WALL ST. J. (Jan. 16, 2014).

⁵⁸ Tyrel Linkhorn, *Policies on Puffing Ecigarettes at Work or in Public Are Cloudy*, THE BLADE (Mar. 2, 2014), <http://www.toledoblade.com/Retail/2014/03/02/Policies-on-puffing-ecigarettes-at-work-or-in-public-are-cloudy.html>.

⁵⁹ John Tozzi, *Life Insurers Treat E-Cigs Just Like Other Cigarettes*, BUSINESSWEEK (May 14, 2014), http://www.businessweek.com/articles/2014-05-14/life-insurers-treat-e-cigs-just-like-other-cigarettes?campaign_id=ebsco.

⁶⁰ Susan Adams, *Should E-cigarettes Be Allowed in the Workplace?*, FORBES (Apr. 29, 2014), <http://www.forbes.com/sites/susanadams/2014/04/29/should-e-cigarettes-be-allowed-in-the-workplace/>.

treating it just like smoking. And finally, vaping is prohibited in all NFL stadiums.⁶¹

Both health care and educational institutions have also gotten involved in the regulation of e-cigarettes. Some hospitals and medical centers, like the prestigious Cleveland Clinic, have bans both against the use of e-cigarettes in their facilities and also against hiring smokers and vapers, which can be enforced by testing the urine of prospective employees for nicotine.⁶² Many institutions of higher education have also started to ban the use of e-cigarettes on campus. The American Nonsmokers' Rights Foundation reports that as of January 1, 2015, there were 1,514 smoke-free college and university campuses in the U.S., 587 of which prohibited the use of e-cigarettes.⁶³ The movement to ban e-cigarettes on campuses appears to be growing quickly, with an ever-larger number of schools imposing bans.

In addition to the complex web of regulations being spun by global, national, state, local, and private actors, e-cigarette companies themselves have also entered the regulatory arena. Although the federal government does not currently mandate a package warning for e-cigarettes, the FDA's proposed 2014 regulations include a warning that states, "Warning: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."⁶⁴ Interestingly, some companies, most notably Altria, have taken that warning several steps further. The warning on the side of its MarkTen e-cigarette box is the most comprehensive:

⁶¹ Richard Mullins, *Gray Area About Where E-Cigs Can Be Used*, TAMPA BAY ONLINE (Mar. 18, 2014), <http://tbo.com/news/business/gray-area-about-where-e-cigs-can-be-used-20140318/>. See American Nonsmokers' Rights Foundation, *Smoking Policies at NFL Stadiums* (Aug. 3, 2015), <http://www.no-smoke.org/pdf/smokingpoliciesNFLstadiums.pdf>.

⁶² A number of other medical centers, including Summit Healthcare Regional Medical Center in Arizona, Anne Arundel Medical Center in Maryland, Geisinger Health System in Pennsylvania, Texas-based Baylor Scott & White HealthCare System, and Bon Secours Virginia Health System, have similar policies. Judy Packer-Tursman, *How One Hospital Is Enforcing—and Improving—Employee Health*, ANNE ARUNDEL MEDICAL CENTER (Jun. 25, 2014), www.aahs.org/news/wp-content/uploads/Healthdive-online-6.25.14-How-one-hospital-is-enforcing-and-improving-employee-health.pdf; *Bon Secours Virginia Health System Adopts Nicotine Free Hiring Policy*, BON SECOURS VA. HEALTH SYSTEM (Nov. 15, 2011 4:06 PM), <http://www.bonsecoursgoodsharing.org/posts-for-patients/pr/bon-secours-virginia-health-system-adopts-nicotine-free-hiring-policy/>; *Tobacco/Nicotine-Free Hiring Policy*, SUMMIT HEALTHCARE, <http://www.summithealthcare.net/index.php/employment-volunteer-opportunities/tobacco-nicotine-free-hiring-policy> (last visited Mar. 7, 2015); *More Hospitals Won't Hire Smokers. Is it Discrimination?*, DAILY BRIEFING, (Jan. 9, 2012), <http://www.advisory.com/daily-briefing/2012/01/09/hiring-smokers>.

⁶³ *Colleges and Universities*, AMERICANS FOR NONSMOKERS' RIGHTS, <http://no-smoke.org/goingsmokefree.php?id=447> (last visited Feb. 23, 2015).

⁶⁴ Food and Drug Administration, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 79 FR 23141, Apr. 25, 2014.

This product is not a smoking cessation product and has not been tested as such. This product is intended for use by persons of legal age or older, and not by children, women who are pregnant or breast-feeding, or persons with or at risk of heart disease, high blood pressure, diabetes, or taking medicine for depression or asthma. Nicotine is addictive and habit forming, and it is very toxic by inhalation, in contact with the skin, or if swallowed. Nicotine can increase your heart rate and blood pressure and cause dizziness, nausea, and stomach pain. Inhalation of this product may aggravate existing respiratory conditions. Ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous.⁶⁵

Altria is surely aware that their warning is unlikely to lose them any customers, and may well help them to defend future product liability suits. Nonetheless, it represents yet another thread in the messy regulatory web surrounding the use of e-cigarettes.

IV. CONCLUSION

Law and society scholars have long appreciated that law exists in “many rooms.”⁶⁶ Rare is the situation in which a simple legal text is all that it takes to create or control behavior. If it were, speed limits would have put an end to speeding, and copyright laws would have ended illegal music downloads. Instead, social control—the effort to create and maintain social order by the state and private parties—depends upon a complex brew of coercion and persuasion, hard laws and soft nudges, far-reaching pronouncements and narrowly tailored rules.

E-cigarettes provide an opportunity to examine the early stages of a wide-ranging effort to impose a set of legal controls on a new product that is enjoying a rapid increase in popularity. In some ways, it is a simple and predictable story. Uncertainty about a new product results in uncertainty about whether and how it should be regulated, which regulatory body is responsible for creating whatever regulations are deemed necessary, and how to ensure that the regulations have the desired effect. Although uncertainty is almost always a feature of policymaking, especially in the area of public health, the rapid innovation of e-cigarette technology, along with the fast uptick in the popularity of vaping, have created a greater degree of uncertainty than usual. The result has been the emergence of a complex web of e-cigarette-related legal rules and social norms.

The layers of e-cigarette law that have arisen, however, follow a

⁶⁵ MARKTEN, https://www.markten.com/gconnect/login_input.action (last visited Feb. 23, 2015).

⁶⁶ Marc Galanter, *Justice in Many Rooms*, in *ACCESS TO JUSTICE AND THE WELFARE STATE* 147, 162 (Mauro Cappelletti ed., 1981).

certain logic. In most cases, the response of regulators to uncertainty about the health consequences of e-cigarettes has been to rely on pre-existing institutional structures to shape their legal strategies. Officials at the FDA, for example, turned to the FDCA to justify regulating e-cigarettes as pharmaceuticals, were taken to court by e-cigarette importers, and were then left to rely on Congress's recently-passed Tobacco Control Act. States and cities turned to preexisting policies aimed at controlling combustible tobacco and decided to extend them to e-cigarettes. Similarly, companies invoked their tobacco control strategies and applied them to e-cigarettes. The institutional mix that has dominated the first stages of e-cigarette policy in the US are thus deeply familiar—the FDA seeking to extend its regulatory reach; regulated industry using the courts to push back on government regulation; state and local government stepping in to fill a void left by federal inaction; companies deploying privatized regulation. At every level, thinking about the approach to the regulation of e-cigarettes has been shaped by the concepts and conflicts that gave rise to tobacco control. The Japanese e-cigarette experience is similarly reflective of domestic institutional configurations, particularly the long-standing dominance of the Ministry of Finance as the key driver of tobacco policy and the priority it places on financial rather than health considerations.

In short, uncertainty about e-cigarettes—the nature of the product, its impact on the health of users and nonusers, its social acceptability—has resulted in an unusually complex regulatory mix. At every level of possible regulatory activity, including global organizations like the WHO, national governments, municipalities, corporations, and small local actors, one finds debate over and the emergence of some type of e-cigarette regulation. In many cases, the regulations are starkly contradictory, with some treating e-cigarettes as tobacco products, others as pharmaceutical products, and yet others as ordinary consumer products. Where one finds some degree of convergence in regulatory strategy, like the laws enacted by a number of large cities in the U.S. that fold e-cigarettes into existing tobacco laws, the regulations lack a clear justification, and instead reflect the fact that it has been easier to expand existing laws to include e-cigarettes than to create more tailored (and more appropriate) regulations. E-cigarette regulation is therefore best described not simply as “layers of law” but as a web of social controls encompassing formal legal pronouncements of government, less formal regulatory positions of private sector actors, and evolving social norms. As the technology of e-cigarettes evolves, and the powerful corporate actors who have increasingly come to dominate the e-cigarette business further assert their commercial interests, the tangled web of e-cigarette regulation is likely to become ever more complex.