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### Regulating E-Cigarettes: Why Policies Diverge

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## “Regulating E-Cigarettes: Why Policies Diverge”<sup>1</sup>

Eric A. Feldman, University of Pennsylvania Law School

Conference celebrating the work of Malcolm Feeley, October 2015

### **INTRODUCTION**

From their origins in the laboratory of a Chinese pharmacist in 2003 to their place in the portfolios of the world’s largest tobacco companies, electronic cigarettes have emerged as one of the most popular and controversial products of the 21<sup>st</sup> century. Some current smokers see e-cigarettes as offering an opportunity to reduce their dependence on conventional combustible tobacco products and instead make use of a potentially less dangerous substitute. Others, particularly young non-smokers, embrace e-cigarettes because they offer a taste of the unknown, a chance to assert independence by using a new product that they see as edgy and experimental. Public health professionals are divided about the health consequences of e-cigarettes, with some arguing that they will perpetuate or even exacerbate the public health harms caused by conventional

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<sup>1</sup> I am grateful for the exemplary research assistance of Brian Ruocco and abundant bibliographical help from Timothy Von Dulm. Support for this paper was generously provided by a University of Pennsylvania Law School Summer Research Grant.

cigarettes and others claiming that they will reduce tobacco-related morbidity and mortality. For many, e-cigarettes represent an attractive business opportunity; from single-proprietor vaping shops in suburban malls to multinational companies with global tobacco holdings, e-cigarettes have taken root as an important new consumer product.

Faced with such diverse perspectives, what are regulators doing to control the manufacture, sale, and use of e-cigarettes? The answer, perhaps surprising in this age of supposed globalization, depends in large part upon where those regulators are located. Public Health England (PHE), for example, has embraced the e-cigarette, recently stating that “vaping is at least 95% less harmful than smoking” and highlighting “the large difference in relative risk” between smoking and vaping “so that more smokers are encouraged to make the switch”(McNeill et al. 2018). PHE’s enthusiasm for e-cigarettes is reflected in the widespread use of e-cigarettes in England, where 6% of the adult population are vapers, almost all of whom are smokers or ex-smokers (McNeill et al. 2018, 14). In contrast, regulators in 25 countries as diverse as the UAE, Brazil, Panama, and Singapore have banned the sale and/or use of e-cigarettes (Kennedy et al. 2017) Where e-cigarettes are not banned they are regulated in widely different ways, ranging from the

stringent imposition of pharmaceutical regulations to lax consumer product controls (Ibid).

Although the texture of e-cigarette regulations is highly variable, it would be an exaggeration to suggest that the forces of globalization are entirely absent. The most significant example of transnational e-cigarette regulation is found in the European Community, where the European Parliament approved a revision of the Tobacco Products Directive (TPD) in 2014 (Directive (2014/40/EU)). The revised TPD, which came into force in May 2016, applies many pre-existing tobacco control policies to e-cigarettes, such as banning advertising, requiring child-proof packaging, and including packet health warnings. In addition, it includes regulations specific to e-cigarettes, such as setting the maximum size of e-cigarette refill containers (10ml), the maximum concentration of nicotine in e-liquid (20 mg/ml), the maximum size of liquid tanks (2ml), and requirements that e-cigarettes use liquids “that do not pose a risk to human health in heated or unheated form,” that “electronic cigarettes deliver the nicotine doses at consistent levels,” and that the packaging include a detailed list of ingredients.

Even within the EU, however, policy differences remain, and beyond the EU the regulation of e-cigarettes varies dramatically across borders. What explains the divergence of e-cigarette policies globally? Why haven't we seen the

opposite—general convergence of laws and regulations governing the sale and use of e-cigarettes?

This paper explores the landscape of e-cigarette policy globally by looking at three jurisdictions that have taken starkly different approaches to regulating e-cigarettes—the US, Japan, and China. Each of those countries has a robust tobacco industry, government agencies entrusted with protecting public health, an active and sophisticated scientific and medical community, and a regulatory structure for managing new pharmaceutical, tobacco, and consumer products. All three are signatories of the World Health Organization’s (WHO) Framework Convention on Tobacco Control (United Nations 2003),<sup>2</sup> all are signatories of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (World Intellectual Property Organization n.d.), and all are members of the World Trade Organization (World Trade Organization, Understanding n.d.). Which legal, economic, social and political differences between the three countries explain their diverse approaches to regulating e-cigarettes? Why have they embraced such dramatically different postures toward e-cigarettes?

Although Malcolm has not (yet!) studied e-cigarettes, this paper builds on his legacy in several ways. First, a great deal of Malcolm’s work is explicitly or

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<sup>2</sup> In addition, both China and Japan have ratified the FCTC, but not the US.

implicitly comparative. He is always thinking about the full spectrum of possible answers to the questions he poses; considering cross-border similarities and differences between legal institutions; questioning assumptions about how politics, economics, law, and society interact; and probing to see how different institutional configurations might lead to different legal outcomes. E-cigarette regulation invites exactly that type of analysis. What differentiates policy approaches to e-cigarettes has little to do with science or with the nature of e-cigarette devices. Instead, the differences are institutional, political, economic, sociological, legal. In that way, e-cigarette regulation provides a window through which to examine the foundation, and the operation, of different legal systems – Malcolm’s stock and trade.

This paper also owes a debt to Malcolm’s work on complex policy choices, in which he undertakes an almost surgical dismantling of policy options. He would surely relish the opportunity to put the full set of e-cigarette regulatory options on the operating table and use his analytical scalpel to demonstrate their costs and benefits. Third, Malcolm is a brilliant theorist, but I have always been even more impressed by his commitment to the law in action, and particularly by his focus on the impact of legal rules and practices on those who are less fortunate. E-cigarettes invite exactly that set of concerns; at root, the issues raised by e-

cigarettes implicate basic questions of values and social justice, and the degree to which e-cigarettes might exacerbate or alleviate the disproportionate harm combustible tobacco imposes on those with less education and income.

### **E-CIGARETTE POLICY: CONVERGENCE AND DIVERGENCE**

Over the past several decades the idea of policy convergence has garnered increasing attention among legal scholars, political scientists, scholars of international relations, and others, who have identified specific regulated activities in which policies converge and theorized the how(s) and why(s) of convergence (Linos 2013; Simmons, Dobbin, and Garrett 2006).<sup>3</sup> This paper takes a different approach. It highlights a concrete policy question—whether and how to regulate electronic cigarettes—and asks why the regulatory paths followed in three countries have led one to treat e-cigarettes as tobacco products (the US), another as pharmaceutical products (Japan), and a third as ordinary consumer products (China). Scientific and epidemiological data about e-cigarettes travels easily across borders; public health officials in those countries have multiple

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<sup>3</sup> See generally KATERINA LINOS, THE DEMOCRATIC FOUNDATIONS OF POLICY DIFFUSION: HOW HEALTH, FAMILY AND EMPLOYMENT LAWS SPREAD ACROSS COUNTRIES (2013) (arguing that policy convergence occurs because of the backing of a technocratic elite and because of the support of ordinary voters); Beth A. Simmons et al., *Introduction: The International Diffusion of Liberalism* 60 INT'L ORG. 781 (2006) (positing that the worldwide spread of political and economic liberalism is produced interdependently – i.e., that governments adopt new policies not in isolation, but in response to coercion, cross-border learning, and emulation).

points of connection; political leaders have a shared interest in limiting unnecessary health risks and avoiding unnecessary expenditures; for those and other reasons, convergence rather than divergence would appear to be the most likely policy outcome. Why, then, have the United States, Japan, and China –each of which is home to one of the world’s most successful tobacco companies, has a large segment of the population that suffers from tobacco-related diseases, and spends billions of dollars caring for people whose deaths are preventable-- followed such different paths?

There is, of course, a short and simple answer. Policies in the US, Japan, and China frequently diverge, be it trade policy, tax policy, health care policy, and more (KPMG 2015).<sup>4</sup> The three nations are differently situated economically, diplomatically, politically, and culturally, and those differences generate different policy preferences. Indeed, one might argue that policy convergence in the area

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<sup>4</sup> Japan, China, and the United States have very different tax structures. See, e.g., KPMG, *2015 Global Tax Trade Survey*, <https://www.kpmg.com/CN/en/IssuesAndInsights/ArticlesPublications/Documents/global-tax-rate-survey-2015-O-201510.pdf> (recording, for instance that social security taxes on employers is 35% in China, 14.7% in Japan, and 7.65% in the United States, and the corporate tax rates are 25% in China, 33.06% in Japan, and 40% in the United States). These countries have had divergent experiences with healthcare policy. See *The Shifting Landscape of Healthcare in Asia-Pacific: A Look at Australia, China, India, Japan, and South Korea*, THE ECONOMIST (2015), [http://www.eiuperspectives.economist.com/sites/default/files/The%20shifting%20landscape%20of%20healthcare%20in%20Asia-Pacific\\_Oct%2015\\_0.pdf](http://www.eiuperspectives.economist.com/sites/default/files/The%20shifting%20landscape%20of%20healthcare%20in%20Asia-Pacific_Oct%2015_0.pdf); Naoki Ikegami & Gerard F. Anderson, *In Japan, All-Payer Rate Setting Under Tight Government Control Has Proved to Be An Effective Approach to Containing Costs*, 31 HEALTH AFF. 1049 (comparing the healthcare paying systems for Japan and the United States). The trading policies and outcomes for these countries differ as well. See *Trade Profiles*, WORLD TRADE ORGANIZATION, <http://stat.wto.org/CountryProfile/WSDBCountryPFReporter.aspx?Language=E> (select China, Japan, and United States, then select “continue”).

of e-cigarettes, not policy divergence, would be the greater surprise. But to do so would ignore the burgeoning literature on globalization and policy convergence, which makes a compelling argument for why there should be at least some degree of e-cigarette policy convergence in the US, Japan, and China (Linos 2013; Simmons, Dobbin, and Garrett 2006; Fullerton and Alvarez 2012; Scherer 1997).<sup>5</sup>

Recent scholarship on cross-border cooperation and global networks in the area of finance, for example, like Terry Halliday and Greg Shaffer's *Transnational Legal Orders*, highlights the growth of powerful transnational financial institutions. Halliday and Shaffer argue that the influence of cross-border financial institutions has muted the differences between national regulatory approaches and increased the degree to which they overlap. Countries across the globe, in their view, when confronted by similar policy questions, deploy common regulatory strategies and construct similar regulatory institutions (Halliday and Shaffer 2016).

Anne-Marie Slaughter's *A New World Order* offers a related set of arguments about the increasing amount of policy commonality among the world's

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<sup>5</sup> See generally KATERINA LINOS, THE DEMOCRATIC FOUNDATIONS OF POLICY DIFFUSION: HOW HEALTH, FAMILY AND EMPLOYMENT LAWS SPREAD ACROSS COUNTRIES (2013); Beth A. Simmons et al., *Introduction: The International Diffusion of Liberalism* 60 INT'L ORG. 781 (2006); see, e.g., Larry Fullerton & Megan Alvarez, *Convergence in International Merger Control*, 26 ANTITRUST 20 (2012) (discussing policy convergence regarding merger control regulations); F.M. Scherer, *Competition Policy Convergence: Where Next?*, 24 INT'L BUS. LAW 485 (1996) (describing the convergence in national competition policies as a result of the intensification of globalized trade).

nations. She highlights the importance of global networks—judges, legislators, the police, bankers, ministers, trade officials, and others—and argues that they have become critically important actors in the shaping of both national and global policy.<sup>6</sup> Hers is a vision of governance that has its locus not in unitary state action but in the simultaneous interaction of multiple networks, which negotiate and influence each other as they address common problems (Slaughter 2005, 5). Viewed through this lens, one should expect e-cigarette policy to be shaped not by isolated nation-states but through the cross-border interaction of public health experts, tobacco and pharmaceutical company executives; government officials specializing in finance, health, and drugs; legislators; and more. Such interaction would presumably lead to a set of policy outcomes that share at least some key features, not outcomes that are fundamentally at odds.

One network of actors with a strong interest in e-cigarette regulation is made up of scientists, epidemiologists, and other public health experts and policymakers whose work involves the collection and interpretation of data about the health impact of e-cigarettes. The network is relatively small and tightly knit; many members train at the same schools, attend the same conferences, read and

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<sup>6</sup> One might see Slaughter's approach as a similar but somewhat thicker web of actors as that described by Feeley et al in Terence C. Halliday, Lucien Karpik, and Malcolm M. Feeley, eds, *Fighting for Political Freedom: Comparative Studies of the Legal Complex and Political Liberalism*, Portland, OR: Hart Publishing, 2007.

publish in the same journals, and are invited to the same international meetings at the WHO and elsewhere. Network members also share a common goal, reflective of the public health field more generally—to limit preventable illness and death. Given those circumstances, one might expect similar, if not identical, epidemiological findings and policy prescriptions for managing e-cigarettes to emerge from such a group.

Despite the various reasons for expecting some degree of e-cigarette policy convergence, it is difficult, at least so far, to find any evidence of such convergence. Instead, e-cigarette regulations in the US, Japan, and China have taken dramatically different forms. Three factors help to explain why.

First, some degree of scientific consensus, which is often a necessary (though rarely a sufficient) condition for policy convergence, is missing. Although scientists around the world are studying the health consequences of e-cigarettes on users and bystanders, even basic scientific and epidemiological agreement is lacking. To what extent do e-cigarettes imperil the health of those who use them? How risky is the secondhand vapor of e-cigarettes to children and other bystanders? Does the use of e-cigarettes among youth make it more likely that they will become smokers of combustible tobacco? As will be discussed in more detail below, the honest response to all of these questions is “we don’t know.”

Consequently, policy makers are relatively unconstrained by the data; they can advocate a wide variety of policy approaches, all of which are defensible in light of current scientific uncertainty.

Second, economic and political interests are rarely divorced from policy outcomes, and in the area of e-cigarettes those interests are particularly pronounced. In the US, for example, the growth, manufacture, and sale of tobacco products has been left to the corporate sector, which evaded substantial regulation by the federal government until 2009. In contrast, the Japanese government created a monopoly in the early 20<sup>th</sup> century that controlled all aspects of the tobacco business. The monopoly was turned into a publicly traded company, Japan Tobacco, Inc., in 1985, but even today the Ministry of Finance continues to hold one third of its stock. The Chinese central government also has a tobacco monopoly (the China National Tobacco Corporation, or CNTC), but unlike Japan there has not been a move toward privatization. It is the world's largest manufacturer of cigarettes in a country that consumes approximately 30% of the world's tobacco products, and is a critical source of revenue for the central government. In each of the three countries, the distinctive institutional configuration and financial interests of the tobacco sector have powerfully influenced e-cigarette policy, and help to explain their divergent approaches.

Third, although the role and prominence of courts as policymaking bodies clearly differs across borders, courts are not often highlighted as an explanation for policy divergence. When it comes to e-cigarettes, however, litigation and judicial decisions have been active components of policymaking in the US, whereas in both Japan and China the courts have been silent. Indeed, were it not for litigation over e-cigarette regulation in the US, the government's approach to e-cigarettes would look much more like Japan's. This is not to suggest that courts in the US are engaged in inappropriate judicial activism, but simply to point out that interested parties in the US quickly turned to the courts to adjudicate different perspectives on how e-cigarettes should be regulated, and the courts obliged by issuing judgments that have fundamentally shaped government regulation. Each of these three factors will be discussed in greater detail below.

## **E-CIGARETTES: TECHNOLOGY, USE, AND IMPACT ON HEALTH**

### **A. What is an Electronic Cigarette?**

Before regulating any product, regulators must describe and define what it is they are regulating. For e-cigarettes, that turns out to be extremely difficult

(Lempert, Grana, and Glantz 2014).<sup>7</sup> The first e-cigarettes to reach the market, and the ones that are most visually similar to combustible cigarettes, are known as cig-a-likes because they have the shape, look, and feel of a conventional cigarette. Manufacturers quickly realized that cig-a-likes had an important downside—by mimicking the aesthetic of cigarettes, consumers sensibly associated them with cigarettes. For many consumers that was a negative association, given the well-known health risks of smoking and the pejorative moral undertones of doing so. Indeed, many e-cigarette users are keen to distinguish themselves from smokers and disassociate their devices from conventional cigarettes.<sup>8</sup>

As a result, a plethora of other products now use a similar technology to cig-a-likes but take a different form. Those products, collectively known as vaporizers and sometimes called vaping pens, e-hookahs, and more, can take a variety of forms (Mistic E Cigs 2015).<sup>9</sup> Some are rectangular, others look like skulls, a particularly popular device (Juul) is shaped like a USB drive, and a few

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<sup>7</sup> Although there is a generic term for e-cigarettes—electronic nicotine delivery systems (ENDS)—it covers a wide variety of products. For simplicity, this paper uses the term e-cigarette to refer to the complete range of available devices. See Lauren K. Lempert, *The Importance of Product Definitions in US E-Cigarette Laws and Regulations*, BMJ: TOBACCO CONTROL (2014), <http://tobaccocontrol.bmj.com/content/early/2014/12/14/tobaccocontrol-2014-051913.full.pdf>.

<sup>8</sup> Those who use vaporizers, and e-cigarettes more generally, call themselves vapers, not smokers.

<sup>9</sup> These devices are sometimes lumped into a category called vapor-tanks-mods, or VTMs. See [http://www.vaporworldexpo.com/PDFs/Vapor\\_World\\_Expo\\_Key\\_Takeaways.pdf](http://www.vaporworldexpo.com/PDFs/Vapor_World_Expo_Key_Takeaways.pdf).

appear to have come out of Apple's creative department, with slick and appealing contours and colors. The market for vaporizers has expanded rapidly and the devices have changed apace, with some of the newest products featuring options like adjustable wattage, which allows consumers to change the amount of vapor inhaled from each puff.

Despite their aesthetic differences, all e-cigarettes are based on a common technology. They include a rechargeable battery, a liquid (or in a few cases a chamber that can be filled with leaf) that generally contains nicotine, an atomizer that converts liquid into vapor, an LED light to simulate a burning cigarette, and a computer chip that senses inhalation and triggers the atomizer. Some e-cigarettes come prepackaged with a liquid-filled container and are discarded when all of the liquid is vaporized. Others operate on the same principle as Nescafe coffee machines; a reusable device that is recharged with disposable pods. Still others contain liquid chambers that can be refilled by consumers with whatever e-liquid they prefer, or vaporize leaf tobacco rather than liquid.

One factor that makes it difficult to regulate e-cigarettes, therefore, is the rapidity with which the technology has, and continues to, evolve. The question 'what is an e-cigarette' does not have a simple or clear answer, and without a crisp definition of an e-cigarette regulators have struggled to develop a regulatory

strategy. Japanese officials in the Ministry of Health, Labor and Welfare, for example, have stated that they are not able to specify the meaning of ‘e-cigarette,’ and as a result they worry about the coherence of e-cigarette regulation (MHLW officials, personal communication with author, December 2014.).

### **B. How Popular are E-Cigarettes?**

While the US e-cigarette market is still modest in comparison to the \$94 billion in annual sales of combustible cigarettes, some analysts, like Bonnie Herzog at Wells Fargo, have predicted that over the next two decades the market for e-cigarettes may surpass that for combustible cigarettes (Euromonitor International 2017; NACS 2013). Overall, electronic cigarette sales in the US have been increasing rapidly, from just \$20 million in 2008 to an estimated \$5.5 billion in 2018. The global market for e-cigarettes has also exploded, and is projected to grow at least 20% annually, reaching an estimated \$48 billion by 2023 (Business Wire, 2018). Retail outlets for e-cigarettes have also proliferated. Just a few years ago there were no specialty vaping stores. Today, every major city in the US has dozens, often hundreds, of such shops, which in total numbered over 15,000 in 2015 (Mincer 2015). Those shops are frequented by the ever-increasing number of vapers.. Although estimates vary, the Centers for Disease Control and

Prevention (CDC) in 2016 reported that 15.4% of adults aged 18 years of age or older had tried e-cigarettes, and 11.3% of high school students had used e-cigarettes in the past 30 days (CDC 2017; CDC 2018). In Japan, because of strict regulation (see below), vaping is almost nonexistent. Data on e-cigarette use in China is spotty, but since 2013 China's domestic e-cigarette market has grown quickly, with knowledgeable insiders claiming that over the next 5 to 10 years the market will increase by more than 30% annually, and in the coming decades will overtake conventional combustible cigarettes (Feldman and Yue 2016; People 2014).

### **C. Are E-Cigarettes Harmful?**

Not only is it difficult to identify the key qualities and market size of e-cigarettes; it is also challenging to determine whether e-cigarettes will ultimately harm or enhance public health. A growing number of researchers globally are studying the health consequences of vaping, particularly: What is the impact of vaping on the health of vapers? Does vaping harm the health of bystanders? Will e-cigarettes substitute for, or be used in addition to, combustible cigarettes? How popular will e-cigarettes be among people below the age of 18? Are the chemicals used to flavor e-liquid harmful? Will e-cigarettes be an effective harm reduction device for those who want to quit smoking? Might e-cigarettes create an

atmosphere of public tolerance toward vaping that risks 're-normalizing' the use of combustible cigarettes?

Because data collection and analysis will take many years, at this point it is impossible to accurately answer any of the key questions involving e-cigarettes and health. Surely there are reasons for both optimism and concern. If e-cigarettes are capturing the interest of youth, for example, who first vape and then turn to combustible cigarettes, long-running declines in tobacco consumption could level off or be reversed. If current smokers turn to e-cigarettes to supplement but not substitute for cigarette consumption, then e-cigarettes might be reducing the number of people who quit smoking. If certain components of e-cigarettes, perhaps contained in e-liquid base ingredients or flavorings, turn out to be harmful, then e-cigarettes could be ushering in a new era of cancers and other diseases. On the other hand, e-cigarettes might be helping current smokers quit, keeping youth from initiating smoking, and playing a key role in reducing tobacco-related morbidity and mortality.

Scientific uncertainty appears to have heightened the tenor of the debate between those who see little but danger in e-cigarettes and those who embrace

them as the centerpiece of a harm reduction strategy. <sup>11</sup> Stanton Glantz, for example, who runs the Center for Tobacco Control Research and Education at the University of California, San Francisco, argues that his research demonstrates that “among youth who had experimented with cigarettes but had not progressed to established smoking, additional use of e-cigarettes was positively associated with future onset of current established smoking (Chaffee, Watkins, and Glantz 2018).” Thomas Glynn of the American Cancer Society offers a different interpretation, arguing that “[t]he data in [Glantz’s] study do not allow many of the broad conclusions that it draws.” Glynn, in a review of e-cigarettes, expanded upon his view.

“If, at some point in the very near future, the preponderance of objective data show e-cigarettes to be demonstrably unsafe and/or ineffective, we will want to move on to other approaches that can lower the appalling toll from cigarette smoking. Or, in a similarly abbreviated time span, if objective data demonstrate their safety compared with combusted cigarettes and their effectiveness compared with current treatment approaches for

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<sup>11</sup> Combustible tobacco has approximately eighty carcinogens and the scientific evidence of their negative impact on health is overwhelming. Most (but not all) e-cigarettes vaporize a nicotine-containing liquid, which makes them potentially addictive. But nicotine is not what kills smokers and is not likely to be the key vector of whatever harm may be caused by e-cigarettes. Although it is possible that e-cigarettes contain certain carcinogens in concentrations that will affect vapers, such harms are, at least at this point, hypothetical.

tobacco dependence, then smokers can add e-cigarettes to the menu of options they can use to end their combusted cigarette habit and extend their lives (Glynn 2014).”

If Glantz represents the critical end of the spectrum of views about the health impact of e-cigarettes, and Glynn is positioned in the middle, other respected scientists have a decidedly positive view of e-cigarettes. David Abrams, the Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies at the Legacy Foundation, is perhaps the most prominent example. Abrams is enthusiastic about the potential of e-cigarettes to greatly reduce tobacco-related morbidity and mortality, arguing that “if most current American smokers switched to vaping e-cigarettes over the next 10 years, there could be as many as 6.6 million fewer premature deaths and 86.7 million fewer life years would be lost (New York University 2018).”

For now, the weight of objective, professional opinion favors the middle ground. As the US Food and Drug Administration (FDA) has stated, “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 (U.S. Food and Drug Administration 2017).” Similarly, an August 2015 report of the US National Institutes of Health notes that e-cigarettes “have not been thoroughly evaluated in scientific studies. This may change in the near future, but for now, very little data exists on the safety of e-cigarettes, and consumers have no way of knowing whether there are any therapeutic benefits or how the health effects compare to conventional cigarettes (National Institute on Drug Abuse 2017).” That finding was echoed in an authoritative review conducted by the National Academies, which concluded that “e-cigarettes cannot be simply categorized as either beneficial or harmful to health. The net public health outcome depends on the balance between adverse outcomes (increased youth initiation of combustible tobacco cigarettes, low or even decreased cessation rates in adults, and a high-risk profile) and positive outcomes (very low youth initiation, high cessation rates in adults, and a low-risk profile) (National Academies 2018)”.

In contrast to the uncertainty about e-cigarettes expressed by government officials in the US, policymakers in England have been far more enthusiastic. . . Public Health England, for example, has vigorously embraced e-cigarettes,

declaring that “vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking (McNeill et al. 2018).” In contrast, although China manufactures over 90% of the world’s electronic cigarettes, there have been no Chinese studies on the health consequences of vaping, and the government has devoted scant energy to studying the impact of e-cigarettes on youth, on current smokers (of which China has more than any other country in the world), or on bystanders (Feldman and Yue 2016). In Japan, one finds a similar cleavage between public health researchers as in the US. Some experts, like those working at the National Cancer Center in Tokyo, express strong reservations about the safety of e-cigarettes, whereas others, particularly those based in Osaka, have endorsed e-cigarettes as an effective harm reduction technology ( Personal communication with author).

Public health policy rarely rests on a bed of scientific certainty. But the wide range of views among experts about the safety of e-cigarettes goes well beyond the usual lack of consensus. Some researchers consider e-cigarettes themselves to be harmful, or believe that e-cigarettes will encourage the use of combustible tobacco and insist that they be banned or aggressively regulated. Others conclude that e-cigarettes are an effective harm reduction tool, and should be made

available to the many people for whom they could provide a benefit. These opposing policy options, both lacking strong empirical support, help to explain the lack of policy convergence in the regulation of e-cigarettes. Faced with an array of policy options and little scientific support for any particular policy outcome, policymakers have instead based their policy choices on other factors—political pressure, financial opportunities and constraints, their perception of the public good, and more. One can see the result of the lack of scientific consensus in the current e-cigarette policies of the US, Japan, and China. In the US, the FDA has moved haltingly toward e-cigarette regulation; after an initial effort to regulate e-cigarettes as pharmaceutical products was challenged in court, the agency decided to treat them as tobacco products, but has so far failed to issue specific regulations. Various municipalities, cities, and states have developed their own e-cigarette policies, most of which fold e-cigarettes into existing tobacco control law.

Compared to the absence of national policy in the US, Japan has followed a much more aggressive path. Policy makers in the Ministry of Health, Labor, and Welfare have concluded that the nicotine in e-cigarettes is a drug, meaning that e-cigarettes fall under the umbrella of pharmaceutical regulation.<sup>12</sup> To market

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<sup>12</sup> E-cigarettes that do not contain nicotine are not affected by the regulations.

their products, manufacturers of e-cigarettes are therefore required to submit data to the Ministry demonstrating that their products are both safe and effective. Since they currently have no such data, nicotine-containing e-cigarettes cannot be marketed. Japan's de facto e-cigarette ban stands in stark contrast to the Chinese government's approach. There, health officials, finance officials, pharmaceutical regulators, and others have seemingly ignored the debate over e-cigarettes in the US, Europe, Japan, and elsewhere, and have allowed e-cigarettes to be manufactured, sold, and consumed in a regulatory vacuum.

In an era when scholars so often see policy convergence as the norm, the inconsistency one finds in e-cigarette policy is notable.<sup>13</sup> The absence of robust scientific data about the health impact of e-cigarettes is critical to explaining that inconsistency. Freed from the constraints of robust epidemiological and scientific findings, policymakers in the US, Japan, and China have adopted three dramatically different approaches to e-cigarette regulation, ranging from the de facto prohibition of e-cigarettes to a highly permissive, unregulated posture. But science is not the only factor that explains regulatory divergence. The political and economic forces that have shaped tobacco policy in different nations are also a crucial part of the explanation.

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<sup>13</sup> See supra N.3 for a small sample of the literature on policy convergence.

## **LAW, POLITICS, AND MARKETS: THE IMPACT OF TOBACCO POLICY ON E-**

### **CIGARETTE REGULATION**

When e-cigarettes entered the global marketplace in 2003, they did so against a background that was etched by over a century of conflict over tobacco regulation. In the US, industrialists in the early 20<sup>th</sup> century worked hard to ensure that tobacco products escaped government control (Kluger 1997; Brandt 2009). They used their growing wealth—soon, they would be among the largest companies in the US, and the world—to influence local politicians, hire prominent law firms, and recruit top advertising agencies, and for over a century succeeded in minimizing the regulation of combustible tobacco products. The FDA, created in 1927 as the Food, Drug and Insecticide Administration and renamed in 1930, had no jurisdiction over tobacco, so federal regulation came primarily from the Federal Trade Commission (FTC), which in 1966 imposed limits on tobacco advertising and required warnings on cigarette packets (U.S. Food and Drug Administration 2018; Federal Cigarette Labeling and Advertising Act of 1966). Over time, states and municipalities picked up some of the regulatory slack, and by the late 20<sup>th</sup> century had developed a web of clean air and workplace restrictions.

Calls for more government regulation of tobacco started early in the 20<sup>th</sup> century, but it was not until the publication of the Surgeon General's 1964 Report "Smoking and Health," which clearly identified smoking as a cause of lung cancer, that tobacco control advocates had a firm scientific footing (U.S. Department of Health, Education, and Welfare 1964). The report catalyzed the emergence of a powerful tobacco control movement, triggered a long, steady decline in tobacco consumption, and ushered in a half century of tort litigation brought by smokers who accused the industry of acting negligently and defective products. Most of their claims failed, but they spawned additional lawsuits against the industry by state and federal government (Rabin 1991-1992; Rabin 2001). In 2009, Congress granted the FDA authority to regulate tobacco products, and some optimistic tobacco control advocates declared that 'the end of tobacco' was at hand (Tobacco Control 2013; Family Smoking Prevention and Tobacco Control Act 2009).<sup>14</sup>

At least initially, e-cigarette companies have little in common with their 20<sup>th</sup> century predecessors. The industry, if one can call it that, was made up of individual entrepreneurs who imported small quantities of merchandise from e-

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<sup>14</sup> Tobacco control, special issue on tobacco endgame; *Family Smoking Prevention and Tobacco Control Act*, H.R.1256, Public Law 111-31, June 22, 2009. It is the 2009 law that the FDA is using to assert regulatory authority over e-cigarettes.

cigarette manufacturers in China, and sold it either online or in small shops. As the popularity of e-cigarettes increased, however, the nature of the e-cigarette business quickly changed, and what was originally a niche product is now a multibillion-dollar global industry controlled by some of the world's richest companies. Lorillard, for example, purchased the US market-leading e-cigarette, Blu, for \$135 million in 2012 and sold it in 2014 (along with several of its tobacco brands) to Imperial Tobacco in a \$7.1 billion deal (Solomon 2014).<sup>15</sup> Altria Group, the parent company of Philip Morris, joined with its international spinoff, Philip Morris International, to develop and market MarkTen, Green Smoke, and iQOS, and in 2014 purchased UK e-cigarette company Nicocigs. R.J. Reynold's popular e-cigarette, Vuse, was released in 2014, and for a while controlled almost 1/3 of the US market (Craver 2015). British American Tobacco developed and markets Vype. Japan Tobacco Inc. first acquired UK-based E-Lites and later purchased Logic, a major US e-cigarette brand (JTI 2014; JTI 2015).<sup>16</sup> A notable exception to the dominance of global tobacco brands is Pax Labs, originally founded in 2007 as Ploom, which developed a novel e-cigarette product called Juul in 2015 and

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<sup>15</sup> The sale to Imperial was part of deal in which Reynolds American bought Lorillard for \$27.4 billion. <http://www.forbes.com/sites/briansolomon/2014/07/15/reynolds-lorillard-dump-blu-e-cigarettes-in-27-billion-merger/#4849ab5bd1c6>.

<sup>16</sup> Japan Tobacco also owns a minority interest in Ploom, a California-based leaf vaporizer.

founded a new company, Juul Labs, in 2017. Sales of Juul increased more than 600% in 2017, and by mid-2018 Juul accounted for over 60% of all e-cigarette sales in the US (Campaign for Tobacco Free Kids 2018).

Collectively, these companies bring to e-cigarettes an extraordinary amount of wealth, market savvy, and regulatory experience. They have pumped significant resources into marketing and advertising, carefully avoiding claims about the intended use of their products (claiming that e-cigarettes are intended to help smokers quit, for example, invites regulation as a smoking cessation device, which brings them under the ambit of pharmaceutical regulators). They hire top law firms that provide expert corporate advice and litigation defense. And they have teams of lobbyists who know how to work the corridors of power and influence regulators. Globally, e-cigarette regulators must contend with companies that successfully evaded government regulation for most of the 20<sup>th</sup> century.

The key forces at play in US tobacco regulation have greatly influenced the regulation of e-cigarettes. First, the tobacco industry consists of a number of private companies, some of which have grown into the world's most robust multinational corporations. Those corporations now control the US e-cigarette industry. Second, tobacco companies have worked hard and spent aggressively to

protect themselves from regulation, and are doing the same to fend off and/or shape e-cigarette regulation. Third, for over a century the government has taken a relatively hands-off approach to tobacco regulation, which has changed only since the enactment of the *Family Smoking Prevention and Tobacco Control Act* in 2009. But that Act only allows the FDA to regulate certain enumerated tobacco products, not including e-cigarettes. So the FDA is engaged in a lengthy effort to ‘deem’ e-cigarettes as tobacco products under the Act (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 (Proposed Rule) 2015; FDA 2011).<sup>17</sup> Fourth, a combination of municipal, state, and federal regulations now restrict the sale and use of tobacco in a variety of ways: only adults can purchase tobacco products, such products can only be used in certain places, advertising tobacco products is restricted, tobacco is subject to various types of taxation, and more. As a matter of convenience if not coherence, e-cigarettes have in some places been folded into those laws. Fifth, the tobacco control community consistently presses for further regulation of tobacco that will

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<sup>17</sup> 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 (Proposed Rule), FDA (Aug. 8, 2015) <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm394922.htm> (detailing efforts by the FDA to promulgate regulations that would give the FDA authority to regulate e-cigarettes); Stakeholder Letter: Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> (describing the FDA’s intent to extend its authority to regulate e-cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009).

improve public health. But it is divided as to how best to manage e-cigarettes, because there is broad disagreement as to whether e-cigarettes are more or a threat or an asset to public health. In short, the spectrum of economic and political interests that shaped US tobacco policy are now defining US e-cigarette policy.

The key institutions and interests at play in the US are dramatically different from those that characterize the economic and political framework of tobacco regulation in Japan. In the late 19<sup>th</sup> century the Japanese government took control of tobacco leaf cultivation through the Leaf Tobacco Monopoly Law, and the 1904 Tobacco Monopoly Law completed the state's monopolization of the cultivation, manufacture, and sale of tobacco products (Executory Order and Reasons for a Tobacco Manufacturing Monopoly 1991).<sup>18</sup> Creating a tobacco monopoly brought a number of benefits to the government. One was that it facilitated the collection of tobacco-related taxes, which initially helped to fund the Russo-Japanese War and ultimately constituted a significant portion of the country's total tax revenue (Rothacher 1989; Honjo and Kawachi 2000)<sup>19</sup> In

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<sup>18</sup> For a detailed official history of the tobacco monopoly, see *Tabako Senbaishi*, [A History of the Tobacco Monopoly], Nihon Tabako Sangyō K.K. Shashi Hensan-shitsu, 6th ed., 1991, volumes 1-6.

<sup>19</sup> At one point tobacco constituted 18% of total government tax-related revenue, a figure that had declined to 1-2% today. Albrecht Rothacher, *Japan's Agro-Food Sector: The Politics and Economics of Excess Protection*, London: MacMillan, 1989, 87. See also, Kaori Honjo and Ichiro Kawachi, "Effects of Market Liberalization on Smoking in Japan," *Tobacco Control*, vol. 9, 193-200, 2000, 193.

addition, and in what foreshadowed tobacco-related trade conflict between the US and Japan in the 1980s, the government worried about the increasing prominence of the US tobacco industry and its impact on the health of its domestic tobacco market (Levin 1997; Executory Order and Reasons for a Tobacco Manufacturing Monopoly 1991, 7).<sup>20</sup> A tobacco monopoly, in the government's view, was the best way to protect its domestic interests.

There was a third benefit of the tobacco monopoly; it created a set of institutional relationships that continue to serve the needs of key tobacco policy players—the state, tobacco growers, and Japan's dominant political party (the Liberal Democratic Party, or LDP). In the context of tobacco policy, the most significant government actor is the Ministry of Finance (MoF), which oversaw the monopoly until 1985 and continues to be the locus of the government's tobacco strategy. MoF told tobacco farmers how much land they could cultivate and how many plants they could grow. It owned and operated cigarette factories throughout the country. It licensed tobacco retailers, and set the price of tobacco products. After 1985, when the tobacco monopoly was eliminated, MoF

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<sup>20</sup> See, for example, Executory Order and Reasons for a Tobacco Manufacturing Monopoly (*Tabako seizō sembai seido riyū oyobi shikō junjo*), quoted in *Tabako Sembai-shi* [A History of the Tobacco Monopoly], Nihon Tabako Sangyō K.K. Shashi Hensan-shitsu, 6th ed., 1991, volume 1, p.7, translated and discussed in Mark Levin's detailed article about Japanese tobacco regulation, "Smoke Around the Rising Sun: An American Look at Tobacco Regulation in Japan," *Stanford Journal of Law and Policy* 8(1), 99-123, 1997.

continued to be the controlling shareholder in Japan's only tobacco company, Japan Tobacco (JT), and it (not the Ministry of Health, Labor, and Welfare) makes all important tobacco policy decisions.

Tobacco growers appear to have flourished under this scheme. They were guaranteed a buyer for all of their tobacco leaf, and received a generous price for their crops. In exchange, they were loyal to their patrons by showing up at the voting booth and supporting the LDP. The disproportionate weight accorded to rural votes in Japan made the support of tobacco farmers (and agriculture more generally) particularly valuable. Japan Tobacco, Japan's sole tobacco company, was also a beneficiary of the system. For many years JT was the sole purveyor of tobacco products in Japan, and it continues to be protected from undue foreign competition. The high post-war rate of tobacco consumption in Japan brought significant revenue to MoF and JT, and JT's international division, Japan Tobacco International (JTI), is now a major global tobacco player.

When e-cigarettes appeared in Japan in the early 2000s, everyone could easily evaluate their preferred policy outcomes. JT had not yet invested in the e-cigarette business, so keeping the domestic market free of competition was a priority. From MoF's perspective, the decline in tobacco consumption in Japan since the 1970s had resulted in decreasing tobacco-related government revenue,

and a further decline caused by Japanese cigarette smokers switching to foreign e-cigarettes was undesirable (Funatogawa, Funatogawa, and Tano 2013). For health regulators at the MHLW, long excluded from tobacco regulation by MoF, e-cigarettes were an opportunity to extend their regulatory turf. Tobacco growers, retailers, and others in the industry could not have welcomed competition from e-cigarettes, and members of the LDP had little to gain from a policy that opened the Japanese market to e-cigarettes. In short, the political and economic interests of the key players leaned clearly against a liberal regulatory posture for e-cigarettes. By deciding that e-cigarettes were not tobacco products and would instead be regulated under the Pharmaceutical Affairs Law, MHLW and MoF effectively kept nicotine-containing e-cigarettes out of Japan.<sup>21</sup>

Like Japan, China also has a long history of tobacco cultivation and consumption. The commercialized growth of tobacco started in the 16th century, and by the 1750s tobacco had become an important source of revenue for both central and local government (Benedict 2011, 2). In 1981 China created a state tobacco monopoly controlled by an agency with two parts; the State Tobacco Monopoly Administration (STMA), charged with regulating and monitoring the

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<sup>21</sup> In contrast, the Japanese government permits the sale of so-called heat-not-burn products, which use a vaporizing technology similar to e-cigarettes but contain processed leaf tobacco rather than liquid. Such products fit the government's definition of 'tobacco products,' and therefore have been folded into the preexisting regulatory framework for combustible cigarettes.

tobacco industry, and China National Tobacco Company (CNTC), tasked with the production, procurement, processing, and pricing of tobacco leaf and the marketing of cigarettes (Li 2012, 82).

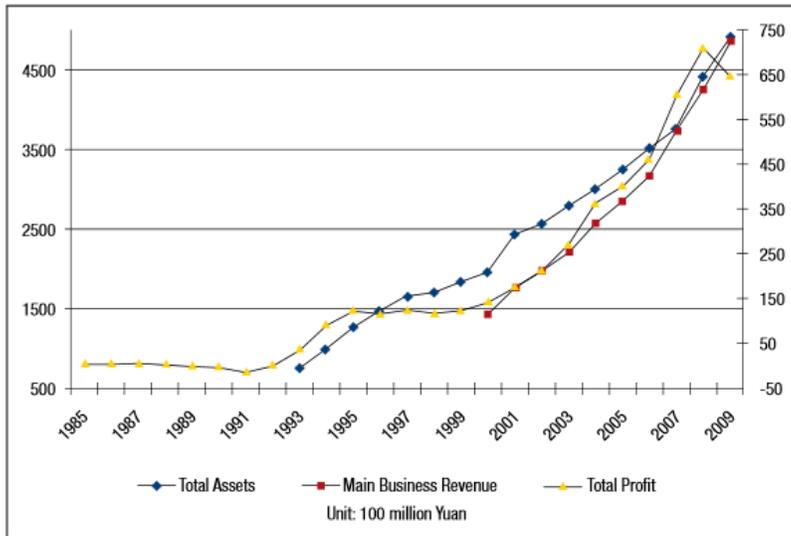
With 300 million smokers (25% of all smokers globally) who consume 40% of the world's cigarettes, the political, economic, and health impacts of tobacco in China are enormous (Li 2012, ix).<sup>22</sup> The most significant issue is revenue; as Chart 1 demonstrates, the tobacco industry is a cash cow, even in China's rapidly expanding economy, and tobacco-related taxes are critical to the state's coffers (Baojiang 2010; Li 2012, x; USDA and FAS 2000).<sup>23</sup> The tobacco sector is also a major employer, providing jobs for more than 500,000 people, with an additional 20 million deriving some income from tobacco, including 1.3 million farming households and 5 million retail workers (Martin 2014).

### Chart 1: Assets, Revenue and Profit of China's Tobacco Processing and Manufacturing Industries (1985-2009)

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<sup>22</sup> Ibid, p.ix. China's total cigarette production is approximately four times greater than the United States, the world's second largest tobacco-producing country.

<sup>23</sup>Li Baojiang, "Effects of increasing tobacco taxes on government revenue and consumption in China," *Acta Tabacaria Sinica*, October 2010, Vol. 16 No. 5. The central government collects a tobacco excise tax, a value-added tax and a certain amount of net profit from the China National Tobacco Corporation. Tobacco taxes combined with profit constituted over 6% of total government income in 2014, and considerably more in previous years. ("Over the past decade, the tobacco industry has consistently contributed 7-10 percent of total annual central government revenues, similar to a number of lucrative and fast-growing sectors such as real estate and petroleum." Cheng Li, *The Political Mapping of China's Tobacco Industry and Anti-Smoking Campaign*, Brookings, 2012, x.) See also Global Agriculture Information Network, United States Department of Agriculture, "Peoples Republic of China, Tobacco and Products, Tobacco Update 2000," GAIN Report #CH0044, 1, which states that China derives 10% of its total tax revenue from tobacco.



Source: Li 2012, 89.

The economic importance of tobacco is underscored by the regulatory power of the State Tobacco Monopoly Administration (STMA), which through the China National Tobacco Corporation (CNTC) controls the Chinese cigarette industry. The CNTC oversees tobacco growth, production, sales, human resources, finance, marketing, and trade, and includes 33 provincial subsidiaries (Tobacco Monopoly Administrations) and a multitude of industrial and commercial enterprises. At the regional level, a tobacco leaf tax (20%) flows directly to local government, together with 25% of the national value-added tax. In provinces like Yunnan and Guizhou, the epicenters of China’s tobacco production, tobacco is the “pillar of the economy (Li 2012).”

Superficially, the Chinese government has made tobacco control a policy priority. It signed and ratified the WHO's Framework Convention on Tobacco Control, and in 2007 the State Council established the "FCTC Implementation Inter-Ministerial Coordination Leading Group," with members from a spectrum of relevant ministries (World Health Organization n.d.). That group has discussed the possibility of prohibiting tobacco advertising in the mass media, banning tobacco use in indoor public places, and forbidding sales to minors.<sup>24</sup> More recently, the China Tobacco Control Plan proposed measures like prohibiting smoking in public places, strengthening warnings on cigarette packets, and banning tobacco promotion and sponsorship (Feldman and Yue 2016).

Nonetheless, the political and economic importance of tobacco in China ensures that tobacco control policy will remain weak and ineffective (Hong 2014; Lv, Su, Hong 2011; Li 2012, x). Per capita smoking rates are high, second-hand smoke exposure is ubiquitous, youth access is widespread, and public education is poor. Rather than limit per capita tobacco consumption, CNTC's goal is to improve tobacco sales and profits. As a distinguished scholar of Chinese politics puts it,

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<sup>24</sup>The Smoking Control Ordinance of Shenzhen Special Economic Zone focused on strengthening the enforcement of smoking-bans in public places. It created six municipal agencies; Public Security Bureau, Urban Management Bureau, Transportation Commission, Health Supervision Bureau, Sports and Tourism Bureau and Market Supervision Bureau, responsible for enforcing the Ordinance in their own domains. From March 1 to December 31 2014, 100,253 public places were inspected and 8,675 people were administratively fined a total of ¥420,100. Shenzhen, where the most aggressive smoking regulations were implemented in 2014, is seen as a model tobacco control city in China.

Despite growing public concern over the smoking epidemic's severe health consequences, as well as the massive long-term economic burden it presents, Chinese authorities have been slow to acknowledge this increasingly devastating public health crisis. Their hesitance to effectively curtail tobacco production and consumption is driven primarily by the fact that the tobacco industry is one of the largest sources of tax revenue for the Chinese government (Li 2012, x)

Likewise, an historian of the Chinese tobacco industry argues that "a major barrier to effective tobacco control in China remains the significant economic clout wielded by China's highly profitable tobacco industry (Benedict 2011, 253).

With these political and economic factors in mind, how should one expect the government to regulate e-cigarettes? One option might be to reign in the proliferation of private e-cigarette manufacturers by including them in the state e-cigarette monopoly, enabling the government to capture revenue generated by the e-cigarette business. Another approach might be to protect the combustible tobacco industry by prohibiting e-cigarettes. A third option could involve regulating e-cigarettes as tobacco products, but allowing private e-cigarette enterprises to operate. Faced with these and perhaps other regulatory options, the government has so far taken no action; it does not regulate e-cigarettes as

medical devices, dangerous chemicals, pharmaceutical products, or tobacco products. No government agency has been tasked with the regulation of e-cigarettes, and those agencies that could plausibly take the reins—the Ministry of Health, the CNTC, the State Administration of Work Safety, the State Administration for Industry and Commerce, the State Food and Drug Administration—have each disclaimed responsibility (Feldman and Yue 2016). What one finds in China, therefore, is an e-cigarette market unburdened by regulation, at least until the government determines that some form of regulation is politically and economically advantageous.<sup>25</sup>

It is no surprise that political pressures, financial interests, and institutional arrangements play an important role in determining how policies are shaped, which policies are adopted, and how vigorously policies are enforced. When the stakes are high, the influence of such factors can be particularly acute. Tobacco policy is one such area: the financial interests of parties as diverse as multinational corporations and individual farmers are strong; the political stakes are considerable; and a wide array of institutional actors have skin in the game. What is true for tobacco turns out to be true for e-cigarettes, with many of the

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<sup>25</sup> At this point, the most likely scenario was presented in an article by Li Baojiang, deputy director of the STMA, who told China Daily: "Regulating e-cigarettes, like traditional tobacco products under the State monopoly, is highly feasible. And that helps with consumer safety and rights, product quality control and the government coffers."

same players involved in tobacco regulation staking out positions regarding e-cigarette regulation. The different goals and interests of those players help to explain the divergent approaches to e-cigarette regulation the US, Japan, and China.

### **E-CIGARETTES AND THE COURTS**

In addition to the absence of scientific consensus and the influence of political and economic interests, the role of courts in the policymaking process also helps to explain divergent e-cigarette policies in the US, Japan, and China. Perhaps not surprisingly, there is only one jurisdiction in which the courts have powerfully influenced e-cigarette policy—the United States. In neither Japan nor China have the courts played even a minor role in determining if, or how, the government should regulate e-cigarettes. In the US, however, courts have been a central actor, arguably *the* central actor, in the evolving debate over e-cigarette regulation.

Between late 2008 and early 2009, as the e-cigarette business was taking off in the US, the FDA detained a series of e-cigarette shipments at Los Angeles International Airport and ordered the importers to destroy or export their wares (Feldman 2014). The FDA claimed that the importers were violating the Food,

Drug, and Cosmetic Act; in the agency's view, e-cigarettes were combination drugs/drug delivery devices that required FDA evaluation for safety and efficacy (21 U.S.C. § 360d (1938)). Not surprisingly, the merchants held a different view. Their products should not be regulated as drugs, they argued, because they had not made any representations about their impact on health, a fundamental aspect of the legal definition of a drug. Seeking legal relief, the importers filed a claim in the United States District Court for the District of Columbia, in what is now known as *Smoking Everywhere vs. FDA* (*Smoking Everywhere, Inc. v. Food & Drug Admin.* 2010)).

The FDA's position was complicated by two factors. One was that after a century without the legal authority to regulate combustible tobacco products, Representative Henry Waxman in 2009 introduced the *Family Smoking Prevention and Tobacco Control Act*, which provided the FDA with the legal authority to regulate certain combustible tobacco products (FDA 2018).<sup>26</sup> Although regulating tobacco had long been a goal of the FDA, the timing was inauspicious. Without regulatory authority over tobacco, the FDA could potentially justify treating e-cigarettes as pharmaceuticals. Once Congress gave it jurisdiction, regulating e-

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<sup>26</sup> 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 manufacture, distribution, and marketing of tobacco products).

cigarettes as drugs/drug delivery devices became more difficult. Filing their complaint to coincide with the passage of the Tobacco Control Act, plaintiff e-cigarette corporations insisted that their products be regulated as tobacco, not pharmaceuticals, since under the latter e-cigarettes would be subject to a lengthy, costly, and potentially unsuccessful approval process.<sup>27</sup>

The second factor that complicated the FDA's position was presiding judge Richard Leon, who earlier in his career served as Republican chief counsel investigating Whitewater (Smoking Everywhere, Inc. v. Food & Drug Admin. 2010)). Described as "a conservative...who does not shrink from criticizing the federal government on matters as varied as pornography, death penalty, drugs, and terrorism suspects at Guantánamo Bay, Cuba," Judge Leon's general antipathy toward government has also surfaced in a series of decisions involving the FDA (Stolberg 2013). In three cases brought against the agency—e-cigarettes, graphic warning labels on cigarette packets, and mentholated cigarettes—the judge handed the FDA stinging defeats.

Judge Leon's ruling in the *Smoking Everywhere*, affirmed on appeal, made a relatively straightforward argument. If the FDA wants to regulate e-cigarettes, the

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<sup>27</sup> The FDA requires data on safety and efficacy before drugs can be sold, and e-cigarette manufactures have no such data.

judge argued, it can do so. In the absence of claims that the products are being sold as smoking cessation devices, however, it can only regulate them under the Tobacco Control Act, not as pharmaceuticals. Judge Leon did not simply reject the FDA's regulatory approach; he also called into question the FDA's motives.

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 (*Smoking Everywhere, Inc. v. Food & Drug Admin.* 2010, 72, 78).

Reflecting on *Sottera* and other tobacco-related cases, Matthew L. Myers, President of the Campaign for Tobacco Free Kids, argues that Judge Leon "has fundamentally altered FDA's authority and ability to carry out its congressional mandate (Levin 2014)."<sup>28</sup> Indeed, in the absence of *Sottera*, the US would have

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<sup>28</sup> Cases are randomly assigned, which meant that Judge Leon's chance of being assigned all three was one in 1,859 <http://www.fairwarning.org/2014/09/fda-batting-o-3-federal-judge/>.

been on the same regulatory path as Japan, with e-cigarettes effectively banned until manufacturers could present evidence that they were safe and effective nicotine replacement therapies. Instead, because of Judge Leon's decision in *Smoking Everywhere*, the FDA can only regulate e-cigarettes as tobacco products, a long and arduous task that is still underway (FDA 2014).<sup>29</sup>

The *Sottera* case has exerted tremendous influence on US e-cigarette policy. It denied the FDA's efforts to apply drug regulation to e-cigarettes, and instead made the new Tobacco Control Act the only plausible regulatory option. Yet the fact that a complex policy choice was fundamentally shaped by the courts is of little surprise in the US, where scholars have long acknowledged the role of courts in the policymaking process (Kagan 2003.) The difference between the influence of the courts on e-cigarette policy in the US and in Japan/China could not be more vivid. In neither Japan nor China has there been any litigation over e-cigarette policy; it is difficult even to imagine a legal challenge to the regulatory authority of, for example, Japan's Ministry of Finance over e-cigarettes, or of China's CNTC. Judicial policymaking is not the only explanation for the divergence

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<sup>29</sup> To do so requires a number of time-consuming and difficult administrative maneuvers, which the FDA has been pursuing since April 2014. 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, April 25, 2014.

of e-cigarette regulations in the US, Japan, and China, but it is one important part of the puzzle.

## **CONCLUSION**

A paper on comparative e-cigarette regulation may not be the obvious way to pay homage to Malcolm Feeley. The topic does not speak to fundamental tensions in criminal law and procedure for which Malcolm is so justly celebrated, nor does it directly engage his interest in Federalism. Nonetheless, several aspects of Malcolm's work are critically important to how the paper is structured. First, like so much of Malcolm's work, the paper is explicitly comparative. Rather than focus on e-cigarette regulation in a single jurisdiction, it looks across three different nations so as to better analyze the range of factors that influence policy in each of them. Second, Malcolm's work often engages complex policy choices, and analyzes the range of policy approaches available to state actors. This study follows his example by exploring a thorny policy question—the regulation of e-cigarettes—and examining a spectrum of policy approaches. Third, Malcolm's work is almost always concerned with the law in action, and demonstrates a deep engagement with how legal rules and practices affect the populace, particularly marginalized populations. This paper indirectly reflects that concern; the use of

combustible tobacco has been increasingly relegated to those with lower incomes and less education, and e-cigarette policy will undoubtedly have an impact on the social gradient of smoking, though the details of that impact are not yet clear.

Those central aspects of Malcolm's work motivate this paper. A comparative analysis of e-cigarette policy reveals that three important jurisdictions—the US, Japan, and China—have taken starkly different approaches to the regulation of e-cigarettes. Divergence, not convergence, describes the landscape of e-cigarette regulation, for three reasons; the unclear scientific and epidemiological impact of e-cigarettes, the economic and political interests of key actors, and the role of the courts. Although this paper underscores the particular importance of those reasons, one can easily identify other possible explanations that the paper leaves unexplored. Malcolm gets the final word: "I would hope that the evidence and observations I present here will be tested against additional information...Only if such collective work takes place can social science proceed successfully (Feeley 1992, xxxiv.)."

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