

Baptists, Bootleggers & Electronic Cigarettes

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Electronic cigarettes pose a competitive threat to the makers of cigarettes and other tobacco products, as well as to nicotine replacement therapies such as nicotine gum and patches. A common response to such a threat is support for government regulation to suppress competition. Predictably, cigarette manufacturers and other threatened producers, as well as the governments that earn revenue from tobacco taxes, are supporting greater regulation of electronic cigarettes that would replicate the cartel-supporting rules of the Master Settlement Agreement. These efforts are aided by anti-smoking organizations that would like to prevent the growth of demand for electronic cigarettes. This episode allows application of the Bootlegger and Baptist theory of regulation. Groups with divergent interests have aligned in support of cartelizing regulation of electronic cigarettes. As with other episodes of Bootlegger and Baptist coalitions, it is unclear whether the resulting policies will serve the public interest. There is evidence that electronic cigarettes pose substantially lower health risks than traditional cigarettes and may help smokers quit or reduce their tobacco consumption. Therefore, insofar as regulation restricts electronic cigarettes, it may undermine public health.

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Introduction

In May 2016, the United States Food & Drug Administration (FDA) finalized regulations subjecting electronic cigarettes (also known as “e-cigarettes”) to federal regulation.¹ Utilizing authority provided by federal tobacco legislation enacted in 2009, the FDA “deemed” e-cigarettes and other vaping products (collectively known as “electronic nicotine delivery systems” or ENDS) as “tobacco products” subject to federal regulation. This rule subjects e-cigarettes to a wide range of federal regulatory requirements, including restrictions on advertising and promotion, as well as various reporting and disclosure requirements. Perhaps most significantly, deeming e-cigarettes to be regulated as tobacco products subjects all such products to a mandatory approval process that could hamstring all but the largest e-cigarette producers.²

1. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974 (May 10, 2016) [hereinafter *Deeming Tobacco Products to Be Subject to FDCA*]. E-cigarettes are devices that heat and vaporize a propylene-glycol solution that typically contains nicotine and some sort of flavoring. See Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL’Y 16, 17 (2011); see also *infra* Section III.A (discussing development of e-cigarettes and growth in e-cigarette market).

2. See Sabrina Tavernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, N.Y. TIMES (May 5, 2016), <http://nyti.ms/23rXQXX> (noting potential of new regulations to benefit “large tobacco companies” at the expense of smaller firms); Shari Rudavsky, *Indiana Vape Shop Owners Say New FDA Rule Will Crush Industry*, IND. STAR (May 9, 2016), <http://www.indystar.com/story/news/2016/05/08/indiana-vape-shop-owners-say-new-fda-rule-crush-industry/84036264/> (noting fears that FDA rules will force smaller firms and stores to close).

The FDA initially proposed the deeming rule in April 2014, *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act*, 79 Fed. Reg. 23141 (April 25, 2014), and was expected to make a final decision on whether to deem e-cigarettes as “tobacco products” in 2015, but the decision was delayed, reportedly due to pressure from various interest groups. See Lydia Wheeler, *Business and Health Groups Jockey to Shape E-Cigarette Rule*, THE HILL (Dec. 3, 2015), <http://thehill.com/regulation/261897-business-health-groups-jockey-to-shape-e-cig-rule>.

Some health groups, particularly traditional anti-smoking groups, praised the FDA's action.³ Such groups would like to see federal regulation of all tobacco and tobacco-related products. Interestingly enough, major cigarette manufacturers lined up in support of the FDA regulation as well, as have some drug manufacturers.⁴ Major cigarette producers and some of the industry's most persistent critics have aligned in support of greater regulation of e-cigarettes.

It may seem strange that "Big Tobacco" and public health advocates are on the same page when it comes to e-cigarettes. After all, smoking has long been recognized as one of the greatest avoidable risks to public health, and tobacco companies are despised by health organizations for the industry's history of deceptive marketing practices.⁵ Yet as odd as it may sound, the economic interests of incumbent tobacco firms are often aligned with the pro-regulatory agenda of at least some public health advocates, anti-tobacco organizations, and allied politicians. The result is something of an odd-bedfellow coalition – but a formidable coalition nonetheless.

Coalitions between economic and social or moral interests – what Bruce Yandle labeled "Bootlegger and Baptist" coalitions – are not all that unusual.⁶ There is a long history of such coalitions across a range of subjects.⁷ Economic interests commonly have a significant effect on public policy, but so do normative arguments and public-spirited policymakers and interest groups. As a consequence, when such forces are aligned, they can have a particularly powerful influence on policy outcomes. Whether such cooperation is formal or

3. See, e.g., Tavernise, *supra* note 2 ("The move was applauded by public health experts who said the industry needed oversight and who had been waiting nearly seven years for the agency to provide it."); Press Release, American Lung Association, FDA Asserts Oversight Authority over Cigars, E-Cigarettes, Other Tobacco Products (May 5, 2016), <http://www.lung.org/about-us/media/press-releases/fda-asserts-oversight-tobacco-products-deeming.html>; Press Release, Campaign for Tobacco-Free Kids, Obama Administration Takes First Step to Protect Kids from E-Cigarettes, Cigars, But Must Do More to Stop Kid-Friendly Flavors in E-Cigarettes (May 5, 2016), http://www.tobaccofreekids.org/press_releases/post/2016_05_05_ecig.

4. See *infra* Section IV.B. Financial analysts also concluded the FDA's new regulations would be good for large tobacco companies. See, e.g., Guy Bentley, *Wells Fargo: FDA's E-Cigarette Regulations Are Good News For Big Tobacco*, THE DAILY CALLER (May 5, 2016), <http://dailycaller.com/2016/05/05/wells-fargo-fdas-e-cigarette-regulations-are-good-news-for-big-tobacco/#ixzz48D57kYST>.

5. See, e.g., DAVID A. KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY (2001); Yussuf Saloojee & Ross Hammond, *Fatal Deception: The Tobacco Industry's "New" Global Standards for Tobacco Marketing*, WORLD HEALTH ORG. 3 (2001), http://www.who.int/tobacco/media/en/fatal_deception.pdf.

6. Yandle pioneered the term more than thirty years ago. See Bruce Yandle, *Bootleggers and Baptists: The Education of a Regulatory Economist*, REG., May-June 1983, at 12; see also Bruce Yandle, *Bootleggers and Baptists in Retrospect*, REG., Fall 1999, at 5-7 [hereinafter Yandle, *Retrospect*] (reflecting on development of Bootlegger and Baptist framework).

7. See generally ADAM SMITH & BRUCE YANDLE, BOOTLEGGERS & BAPTISTS: HOW ECONOMIC FORCES AND MORAL PERSUASION INTERACT TO SHAPE REGULATORY POLITICS (2014). The book details examples from various episodes in the United States including, in more recent years, the Troubled Asset Relief Program bailout during the 2008 financial crisis, climate change, and the Patient Protection and Affordable Care Act of 2010 ("ObamaCare").

intentional, the combining of economic and “moral” or public-focused interest groups into a single coalition has had a substantial effect on the growth and evolution of regulation in the United States.⁸

This Article examines the political and regulatory responses to the emergence of electronic cigarettes in light of Yandle’s Bootlegger-Baptist theory of regulation. Section I summarizes Yandle’s theory and places it in the context of other positive theories of regulation and the role of interest groups in regulatory policy. With this regulatory background in hand, Section II reviews the development of tobacco regulation in the United States, focusing on the Master Settlement Agreement (MSA) that resolved state legal claims against cigarette manufacturers and subsequent federal legislation that provided the FDA with regulatory authority over tobacco products. As this section shows, the Bootlegger-Baptist theory demonstrates how advocacy by economic interests and public-interest groups aligned to create a regulatory framework that, among other things, suppressed competition to the benefit of incumbent firms in existing tobacco markets.

The emergence of electronic cigarettes disrupted the status quo in tobacco markets, creating new incentives for established firms to seek regulatory intervention. Section III describes the development of e-cigarettes, their rapid growth, and what is (and is not) known about their potential health effects. As this section highlights, the growth in demand for e-cigarettes poses a substantial threat to incumbent tobacco producers, but may also provide significant health benefits insofar as e-cigarettes pose fewer health risks than traditional tobacco products.

The push for regulation of e-cigarettes is replicating the Bootlegger-Baptist dynamic that catalyzed the development of the MSA and federal tobacco legislation. As explained in Section IV, both incumbent tobacco firms and some public health advocates support treating e-cigarettes like traditional tobacco products. Manufacturers of tobacco-cessation products (nicotine replacement therapies or NRTs) also support regulation of e-cigarettes for economic reasons. Moreover, state-level politicians are incentivized to treat e-cigarettes like traditional tobacco products because of the potential effects on state tax revenues. If this combination of interests succeeds, the likely effect will be an ever-more cartelized industry that looks much like the post-MSA cigarette industry. Whether or not any resulting regulation would benefit consumers or protect public health remains to be seen.

I. Interest Groups and the Demand for Regulation

Government regulation permeates the U.S. economy. There are few productive activities that are not subject to government regulation of one sort or

8. See *infra* Section I.B.

another.⁹ What accounts for the extent of such regulation? Why are some activities and industries regulated more than others? And why are regulatory programs designed or implemented differently at different times or in different contexts? Over the decades, political scientists, historians, and economists have struggled to develop a positive theory of regulation.¹⁰

The Baptist and Bootlegger theory, developed by economist Bruce Yandle, sought to complement prior theories of interest-group involvement in regulatory policy. Specifically, it sought to explain how economic interest groups and moral or ideological interests often align in support of common policy goals. In Yandle's view, understanding and recognizing the emergence of such alliances made it easier to understand why some regulatory policy initiatives failed and others succeeded.

A. Traditional Theories of Regulation

The oldest and perhaps most common explanation for government regulation is called the Public Interest Theory. Under this theory, government regulation is largely the product of public-spirited policymakers seeking to enhance public welfare. On behalf of the public, policymakers develop and impose various regulatory programs to address market failures, such as a failure to account for externalities, the under-provision of public goods, and information asymmetries, or tackle other perceived problems resulting from uncoordinated private activities.¹¹

The Public Interest Theory posits that most policymakers systematically attempt to serve the public interest when they enact laws, promulgate regulations, and implement government programs. Policymakers are not influenced by personal fortunes nor are they motivated to serve narrow special interests from their home territories; they are truly public servants. While the Public Interest Theory acknowledges the possibility of corruption or other problems with government policy – after all, politicians and regulators are human beings like the rest of us – the driving assumption of this theory is that those who develop, promulgate, and enforce regulations are primarily engaged in a well-intentioned effort to advance the public interest.

While the Public Interest Theory may work as a normative theory of what governments *should* do, it has obvious deficiencies as a positive theory of what governments *will* do. That is, the Public Interest Theory offers a limited

9. See, e.g., Clyde Wayne Crews, Jr., *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State*, COMPETITIVE ENTER. INST. (2015), <https://cei.org/sites/default/files/10%2C000%20Commandments%202015%20-%202005-12-2015.pdf>.

10. See generally JERRY BRITO & SUSAN E. DUDLEY, REGULATION 11-22 (2d ed. 2012) (summarizing theories of government regulation).

11. See generally STEPHEN BREYER, REGULATION AND ITS REFORM (1984) (discussing various rationales for regulation). For a discussion of social and other non-economic, yet still public-spirited, rationales for regulation, see CASS SUNSTEIN, AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE (1990).

account of the incentives faced by policymakers and, as a consequence, does not fully explain observed regulatory policies. The Public Interest Theory may offer plausible explanations for many laws and regulations that are on the books, but it fails to explain why some regulatory initiatives succeed and others fail, particularly outside of traditional economic regulation. Even if one sets aside government spending programs, which one may suspect are particularly prone to rent-seeking and pork-barrel politics, there are many regulatory decisions which cannot be explained by the Public Interest Theory, either because the regulations in question do not advance the public interest or because they are designed and implemented to achieve other ends. While the existence of market failures may provide adequate justification for regulatory interventions, the pattern of such interventions does not necessarily correspond with the existence of such justifications. Regulations persist where there is little economic justification for government intervention, while obvious cases for government involvement remain unaddressed.

As explanations of political behavior developed, seasoned observers of the political scene noticed that politicians often spoke about serving the public interest, but their actions seemed to be guided by narrow special interest groups if not by their personal career ambitions.¹² That is, what policymakers said did not line up with what policymakers did. Further, even well-intentioned government programs did not appear to be implemented in a way to achieve the public-spirited goals that may have inspired their creation. Regulators of electricity producers spent a lot of time with folks from the industry being regulated, people with experience in the railroad industry were called upon to regulate the industry, and politicians preparing labor legislation had many encounters with organized labor leaders. Put another way, politicians and regulators who might speak about serving the public interest often seemed to be captured by the industry or activity they were regulating. Thus was born the Capture Theory, an explanation elaborated by Marver Bernstein¹³ and Gabriel Kolko.¹⁴

Capture Theory provided a helpful lens for observing political behavior and, when applied, offered some useful insights into political action. But there was a problem. When there were competing interest groups struggling to affect

12. Adam Smith actually made a similar observation:

The proposal of any new law or regulation of commerce which comes from this order ought always to be listened to with great precaution, and ought never to be adopted till after having been long and carefully examined, not only with the most scrupulous, but with the most suspicious attention. It comes from an order of men whose interest is never exactly the same with that of the public, who have generally an interest to deceive and even to oppress the public, and who accordingly have, upon many occasions, both deceived and oppressed it.

ADAM SMITH, *AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS* 339 (Edwin Cannon ed., 2003).

13. See MARVER BERNSTEIN, *REGULATING BUSINESS BY INDEPENDENT COMMISSION* (1977).

14. See GABRIEL KOLKO, *THE TRIUMPH OF CONSERVATISM: A REINTERPRETATION OF AMERICAN HISTORY: 1900-1916* (1963).

an outcome – as with public health groups and tobacco companies when cigarette-advertising regulation was being formed – the theory offered nothing to predict which interest group might emerge victorious. Repairing this theoretical flaw led to Nobel Laureate George Stigler’s development of the Special Interest Theory or the Economic Theory of Regulation.¹⁵ Stigler’s theory basically says “keep your eye on the money.” The group with the most to gain or lose will make the greatest effort to capture the politician or regulator. And the larger and better organized the group, all else equal, the better the prospects for winning a cartel-like outcome. Additional research by Mancur Olson¹⁶ and Sam Peltzman,¹⁷ among others, further explicated how concentrated interest groups can influence government agencies for their own benefit at the expense of the public at large.

Stigler’s theory still left a large question unanswered. Does it matter which interest groups interact with politicians when seeking to organize regulatory agreements? Put another way, are there certain key interest groups that, when working together for a common goal, always tend to prevail? Special interest groups matter a lot, but not just any collection of interest groups seemed capable of enacting durable social regulation. Some legislative and regulatory actions were not well explained by the Public Interest Theory or the Capture Theory, which ultimately brought us to the Bootleggers and Baptists Theory.

B. Bootleggers and Baptists

Bruce Yandle’s contribution to interest-group theories of regulation was his observation that interest-group influence could be more powerful when those struggling to affect outcomes included distinctly different groups.¹⁸ Specifically, he noted that economically motivated interest groups are more likely to achieve their policy goals when supported by interest groups that provide normative justifications for the same policies. Put in more colloquial terms, the theory “tells a story of how public interest justification greases the rails for purely private pursuits.”¹⁹ As Yandle explained:

Here is the essence of the theory: durable social regulation evolves when it is demanded by both of two distinctly different groups. “Baptists” point to the moral high ground and give vital and vocal endorsement of laudable public benefits promised by a desired regulation.

15. See George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. OF ECON. & MGMT. SCI. 3 (1971).

16. See MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (1965).

17. See Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J. L. & ECON. 211 (1976).

18. See SMITH & YANDLE, *supra* note 7, at 4 (“The Bootlegger/Baptist theory provides a useful device for explaining crucial features of enduring social regulations that affect consumers and producers worldwide.”).

19. *Id.*

Baptists flourish when their moral message forms a visible foundation for political action. “Bootleggers” are much less visible but no less vital. Bootleggers, who expect to profit from the very regulatory restrictions desired by Baptists, grease the political machinery with some of their expected proceeds.²⁰

Each type of interest group is capable of influencing government policy, and does so regularly. When they are aligned, however – when moral suasion is backed or reinforced by economic muscle – they are particularly powerful and are more likely to produce durable social regulation. Among other things, allied politicians get the benefit of powerful moral rhetoric in addition to the muscle of economic interest groups. For things to work, the Bootleggers and Baptists need only pursue similar outcomes. They need not work directly together and, in many instances, have quite different ultimate policy goals and likely disdain each other.²¹

Yandle chose the Bootlegger and Baptist labels in homage to the political pairing of unlikely interests that was successful in championing laws that shuttered liquor stores on Sunday.²² Though some Bootleggers might be Baptists, and vice versa, the two interest groups would never form a visible coalition in the strict sense of the word. Yet, despite their contrasting motivations, they sought the same outcome and were willing to struggle mightily to succeed. At the height of its success, this powerful pairing entirely shut down the legal sale of alcoholic beverages in counties, states, and – during Prohibition (1920-1933) – the nation as a whole.²³

The Baptists were a moral motivating force wanting to limit alcohol sales, particularly on Sundays. The behavior engendered by alcohol created a target for moral crusaders. Their support for limiting alcohol sales is easily predictable. Laws limiting alcohol sales would satisfy the Baptists’ preferences. They also created an opportunity for Bootleggers. Limiting alcohol sales reduced competition and created profit opportunities for those willing to sell alcohol illegally (or, perhaps, in a neighboring jurisdiction without such laws). While Bootleggers obviously have no objection to the sale of alcohol (and certainly not to its consumption), they would be expected to support laws that increase their profits.

Bootleggers and Baptists did their most noteworthy work years ago, but alcohol distribution still takes place within cartel arrangements protected by

20. See Yandle, *Retrospect*, *supra* note 6, at 5. It should be noted that the original formulation was chosen for alliterative purposes, and not to single out Baptists for being particularly influential or blameworthy.

21. See SMITH & YANDLE, *supra* note 7, at viii (noting that Baptists and Bootleggers need not expressly or openly coordinate their activities to be successful).

22. Note, however, that most such jurisdictions did not restrict Sunday *consumption* of alcoholic beverages.

23. For a discussion of the role of interest groups in Prohibition and its repeal, see Donald J. Boudreaux & A.C. Pritchard, *Rewriting the Constitution: An Economic Analysis of the Constitutional Amendment Process*, 62 *FORDHAM L. REV.* 111, 119-20 (1993); SMITH & YANDLE, *supra* note 7, at 79-81.

state law. When threats arise that might disturb the cartel, seen most recently in the delivery of retail wine, Bootleggers and Baptists rise to the challenge.²⁴ State regulation of alcoholic beverages has produced a crazy-quilt set of rules. In Texas, for example, many counties and cities are dry, while others allow limited sales. Changes to the rules generate political battles among vested interests. For example, craft brewers are required by law to give away distribution rights.²⁵ Multiple parties have interests in such requirements: large, established brewers do not wish to compete at retail stores with craft brews, distributors like their protected distribution licenses, craft brewers would like to expand retail opportunities, and teetotalers may wish to keep out any new alcoholic products. The players change over time, but the battle is much the same. Having invested significant resources to obtain a beneficial political agreement, the protagonists do not go quietly into the night.²⁶ But Bootleggers never march with placards before state capital buildings petitioning for renewal of soon-to-expire Sunday closing laws.²⁷ The Baptists do that for them. Meanwhile, crafty Bootleggers may (quietly) provide campaign contributions for cooperative politicians or fund Baptist causes.

Note that Bootleggers did not support laws to limit alcohol consumption, even though their Baptist brethren might. This point is important. Successful Bootlegger/Baptist political interaction generates support for particular kinds of regulation, specifically rules that satisfy the interests of both interest groups. In the tobacco and e-cigarette context, as with alcohol, a Bootlegger/Baptist coalition is likely to favor rules that suppress competition. This raises prices, which Baptists like, but may also enable producers to capture monopoly rents. Such policies may include limits on advertising and promotion and restrictions on new market entry. The coalition is unlikely to endorse measures that directly target consumption, however. That is where the interests of the Bootleggers and the Baptists diverge.

The Bootlegger/Baptist theory helps us understand a host of regulatory episodes. For example, the theory helps explain certain features of federal clean air legislation. Environmental groups want controls on emissions. Existing emitting firms wish to avoid the regulatory costs of adopting emission controls, and prefer to reduce the risks of competition from new entrants. Both will

24. Kim Marcus, *Bizarre Coalition Opposes Direct Shipment of Wine*, WINE SPECTATOR (Feb. 14, 2005), http://www.winespectator.com/webfeature/show/id/Bizarre-Coalition-Opposes-Direct-Shipment-of-Wine_2398; SMITH & YANDLE, *supra* note 7, at 83-87.

25. The Institute for Justice represents three craft brewers challenging the distribution rules. For background, see *Texas Craft Beer*, INST. FOR JUST., <http://ij.org/case/texas-craft-beer> (last visited Apr. 10, 2016).

26. Alcohol producers routinely make contributions to election campaigns for, we presume, good business reasons. For details regarding 2015-16 contributions, see *Beer, Wine, and Liquor: Top Contributors to Federal Candidates, Parties, and Outside Groups*, OPENSECRETS.ORG <http://www.opensecrets.org/industries/indus.php?ind=N02> (last visited Apr. 10, 2016).

27. TEX. ALCO. BEV. CODE ANN. § 105.01 (West 2007) (providing details of Sunday (and other day) closing rules in Texas, which are not atypical).

support laws that impose stricter standards on newly constructed manufacturing plants than on existing plants.²⁸ Similarly, environmental groups and producers of alternative energy products will support regulations that control greenhouse gas emissions, the former due to concerns about global warming, the latter in pursuit of a competitive advantage.²⁹ Such coalitions are not only political. In some cases, the Bootleggers directly fund Baptist coffers so as to help increase their political strength. The Sierra Club, for example, received millions of dollars from natural gas interests to support the group's campaign against competing energy sources, coal in particular.³⁰

While regulatory Baptists may seek laws that are more stringent than bootleggers would support, they may settle for less stringent, or less optimal, regulatory measures if the alternative is a likely political defeat. For example, as Bruce Ackerman and William Hassler documented in *Clean Coal/Dirty Air*, environmentalist groups supported regulatory measures that advantaged the producers of high-sulfur coal as against the producers of low-sulfur coal, even though such measures would also be less effective than potential alternatives.³¹ A similar story can be told about the development of the alternative fuel and reformulated gasoline requirements of the 1990 Clean Air Act.³²

Public health and environmental regulations may provide particularly fertile ground for Baptist-Bootlegger coalitions because it can be difficult to oppose health and environmental measures openly. Instead, economic interest groups have learned that they stand to gain when policy measures that increase their bottom line can claim the support of public-spirited interest groups. Sometimes the resulting regulations produce good policy, but sometimes they do not.

In the late 1980s and early 1990s, the Hazardous Waste Treatment Council (HWTC) sought more stringent enforcement of laws governing hazardous waste treatment and disposal. Because HWTC's members operated hazardous waste incinerators and treatment facilities, they stood to benefit from an expansion of treatment requirements. The HWTC joined forces with environmentalist groups to support a range of regulatory initiatives. Yet not all of these measures were environmentally beneficial. In some cases, this

28. For examples from environmental law, see ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS (Michael Greve & Fred L. Smith, Jr. eds., 1992); Jonathan H. Adler, *Clean Politics, Dirty Profits*, in POLITICAL ENVIRONMENTALISM: GOING BEHIND THE GREEN CURTAIN 1 (Terry Anderson ed., 2000); Todd J. Zywicki, *Environmental Externalities and Political Externalities: The Political Economy of Environmental Regulation and Reform*, 73 TUL. L. REV. 845 (1999).

29. See Bruce Yandle & Stuart Buck, *Bootleggers, Baptists, and the Global Warming Battle*, 26 HARV. ENVTL. L. REV. 177 (2002).

30. Bryan Walsh, *How the Sierra Club Took Millions from the Natural Gas Industry—and Why They Stopped*, TIME (Feb. 2, 2012), <http://science.time.com/2012/02/02/exclusive-how-the-sierra-club-took-millions-from-the-natural-gas-industry-and-why-they-stopped>.

31. BRUCE A. ACKERMAN & WILLIAM T. HASSLER, CLEAN COAL/DIRTY AIR 35-37 (1981).

32. See Jonathan H. Adler, *Clean Fuels, Dirty Air*, in ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS 19 (Michael S. Greve & Fred L. Smith, Jr. eds., 1992).

Bootlegger and Baptist coalition opposed measures to reduce the generation of hazardous waste and supported regulations that could have discouraged the recycling of particular waste streams.³³ In other instances, hazardous waste incinerator companies funded environmental groups that would attack their competitors.³⁴

Just because concentrated interest groups stand to benefit economically from a given regulatory measure does not mean that such measures are bad policy. In some cases, economic interest groups may provide essential support for worthwhile measures. It is unlikely the United States would have agreed to phase out the use of chlorofluorocarbons (CFCs) when it did if doing so had not been in the economic interest of major CFC producers.³⁵ CFCs, a widely used class of propellants and refrigerants, were linked to thinning of the stratospheric ozone layer. The largest CFC producer, DuPont, opposed the CFC phase-out until it was in DuPont's interest to reverse course.³⁶ While DuPont had once enjoyed the dominant position in the CFC market, foreign producers had begun to erode DuPont's market share, and DuPont was in a strong position to market CFC substitutes. Although some groups still opposed a CFC phase-out, once significant Bootleggers joined the Baptist side, it became relatively easy to move forward with the phase-out, and the ozone layer was protected.³⁷

Bootlegger and Baptist coalitions may or may not lead to the development of sound policy. In some cases, Bootlegger interests will coincide with public welfare. In other cases, however, Bootlegger interests will distort or subvert the adoption of welfare-enhancing measures. In the case of e-cigarette regulation, that risk is real.

II. Tobacco Regulation and the Master Settlement Agreement

The history of tobacco regulation provides ample evidence of the importance of Bootlegger and Baptist coalitions. Indeed, much tobacco regulation resulted from the efforts of both Bootleggers (the tobacco companies) and Baptists (public health organizations and policymakers). One consequence of this is that tobacco regulation has often served to enhance the profits of incumbent firms as much as (if not more than) it has combated the public health harms associated with smoking.³⁸ In some cases, it even appears

33. See Adler, *supra* note 28, at 14-16; Mark K. Landy & Mary Hague, *The Coalition for Waste: Private Interests and Superfund*, in ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS 67 (Michael S. Greve & Fred L. Smith, Jr. eds., 1992).

34. See Adler, *supra* note 28, at 16-17.

35. See Daniel F. McInnis, *Ozone Layers and Oligopoly Profits*, in ENVIRONMENTAL POLITICS: PUBLIC COSTS, PRIVATE REWARDS 129, 130 (Michael S. Greve & Fred L. Smith, Jr. eds., 1992).

36. See Adler, *supra* note 28, at 21-22.

37. See *id.*

38. The tobacco companies did not want the regulations that began a half-century ago, but have played the political game very well since, so they have remained profitable. The demise of the Big Tobacco companies has been predicted for decades, but their rate of return, as seen in stock

as if tobacco industry regulation primarily served the interests of Bootleggers, though it was facilitated by a Baptist veneer.

A. Pre-Master Settlement Agreement Regulation

In the late 1950s and early 1960s, shortly before the first Surgeon General's report, news stories called attention to the harmful effects of smoking. Innovative cigarette producers responded by developing filter tips that were often accompanied with health claims for the new "safer" cigarettes.³⁹ As might be expected in a competitive marketplace, a low tar and nicotine derby developed in the industry, with producers competing at the health margin when developing and selling their wares. Consumption of higher tar and nicotine products began to fall.⁴⁰

When the Surgeon General's report of the harmful effects of smoking was released in 1964, it provided an opportunity for a new political player in the tobacco field.⁴¹ A regulatory agency, the Federal Trade Commission (FTC), soon announced a proposed requirement for a battery of warning labels to be affixed to all cigarette packages.⁴² Using dire language highlighting that smoking can cause death, the FTC proposal brought an immediate reaction from cigarette producers. Congress responded by showing a preference for a calmer, more tobacco-friendly warning.⁴³ Congress swiftly passed legislation that instructed the FTC to regulate but to ride easier on the industry and preempted state and local efforts to mandate more stringent warnings.⁴⁴

Alarmed about the misleading nature of health claims for the new low-tar and filtered cigarettes, and conscious of its responsibility for enforcing truth in

prices, generally beats the market. Paul R. La Monica, *Smoking Is Not Cool. But Cigarette Stocks Are Hot*, CNN MONEY (July 29, 2015), <http://money.cnn.com/2015/07/29/investing/cigarettes-altria-reynolds-american-stocks-earnings>.

39. For a more extensive discussion of the role of Bootleggers and Baptists in the evolution of tobacco regulation, see, Bruce Yandle et al., *Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation*, 2008 U. ILL. L. REV. 1225. For more on the history of tobacco regulation and the role of interest groups, see A. LEE FRITSCHLER, *SMOKING AND POLITICS: POLICYMAKING AND THE FEDERAL BUREAUCRACY* (2006); RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1997); PETER PRINGLE, *CORNERED: BIG TOBACCO AT THE BAR OF JUSTICE* (1998).

40. See Lynn T. Kozlowski & Richard J. O'Connor, *Dealing with Health Fears: Cigarette Advertising in the United States in the Twentieth Century*, in *TOBACCO AND PUBLIC HEALTH: SCIENCE AND POLICY* 37, 39-41 (Peter Boyle et al. eds., 2004) (discussing the "tar derby" competition among cigarette producers to offer low-tar brands).

41. See U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964); Peter D. Jacobson et al., *Historical Overview of Tobacco Legislation and Regulation*, 53 J. SOC. ISSUES 75, 85 (1997).

42. Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8325 (July 29, 1965) (to be codified at 16 C.F.R. pt. 408).

43. See Yandle et al., *supra* note 39, at 1249-51.

44. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (2012). The preemption provision is contained in section 1334.

advertising, with a blast of a Baptist trumpet, the FTC again intervened.⁴⁵ It argued that there was no meaningful difference among various cigarettes, banned the use of health claims in all advertising, and established itself and its smoking machine laboratory as the source of any data that might be used in advertising nicotine and tar content. Competition over health claims declined, as did the entry of new and perhaps safer cigarettes.⁴⁶ Innovation was chilled. Competition on this margin declined and the industry became a bit more cartelized with help from the government. But the Bootlegger/Baptist story was just beginning.⁴⁷

With health-concerns building, the Federal Communications Commission (FCC) entered the fray. In response to a citizen petition, in 1967 the FCC applied the Fairness Doctrine⁴⁸ to tobacco advertising, requiring free TV time for competing anti-tobacco public interest messages whenever a television station or network sold ad time to a tobacco company.⁴⁹ Along with the negative publicity about the health effects of smoking, the FCC mandate appeared to have an effect, as per capita smoking began to decline.⁵⁰ In 1969, responding to consumer group pressure, the FCC proposed a ban on TV advertising for cigarette and tobacco products, and the FTC proposed tougher warning labels.⁵¹ The Baptists were being heard, and the cigarette-producing bootleggers did not like what they were hearing. The anti-smoking campaign had an impact on sales, with per-capita cigarette consumption falling by 5.7 percent between 1967 and 1970.⁵²

The tobacco industry was not as enamored with these regulatory initiatives as were some health-oriented groups. Congress reacted to such concerns with new legislation that weakened the FTC's proposed label language while banning TV advertising starting in 1971.⁵³ Far from a loss for

45. See Yandle et al., *supra* note 39, at 1248.

46. John E. Calfee, *The Ghost of Cigarette Advertising Past*, REG., Summer 1997, at 35; see also John E. Calfee, *Cigarette Advertising, Health Information and Regulation Before 1970* (Fed. Trade Comm'n, Working Paper No. 134, 1985) (discussing health claims in cigarette advertising prior to 1970).

47. Yandle and Morriss, with coauthors, expanded on this in their analysis of tobacco regulation through the MSA, adding in "Televangelists" (the state attorneys general and plaintiffs' bar), players who, they argued, feigned moral indignation while having motivations more akin to the bootleggers. See Yandle et al., *supra* note 39, at 1236-40.

48. See *Red Lion Broad. Co. v. FCC*, 395 U.S. 367 (1969) (upholding constitutionality of the Fairness Doctrine). Under the Fairness Doctrine, television and radio broadcast licensees were required to cover issues of public importance and to provide "fair coverage" of such issues. *Id.* at 369.

49. See *In re TV Station WCBS-TV*, 8 F.C.C.2d 381 (1967), *recons. denied* 9 F.C.C.2d 921 (1967) (holding that the Fairness Doctrine is applicable to cigarette advertisements).

50. See Yandle et al., *supra* note 39, at 1252.

51. See FCC, Notice of Proposed Rulemaking, Advertisement of Cigarettes, 34 Fed. Reg. 1959 (Feb. 11, 1969).

52. See Yandle et al., *supra* note 39, at 1252.

53. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970); see also 15 U.S.C. § 1335 (2012) (prohibiting cigarette and cigar advertising in electronic media subject to FCC jurisdiction).

the industry, this legislation erected a substantial entry barrier for potential competitors.⁵⁴ The established brands enjoyed widespread name recognition, and new entrants would be unable to use television to establish their brands.⁵⁵ The elimination of television ads for cigarettes also brought an end to the offsetting public interest messages that attacked tobacco products and reduced cigarette company advertising costs.⁵⁶ The tobacco Bootleggers gained ground, and innovation took the back seat in what began to look like a comfortable cartel. Meanwhile, the health-care Baptists may have unwittingly cheered the new strictures that seemed to penalize bad Bootlegger behavior but actually protected their profits.

Prior to the advent of ever more stringent regulations that limited marketing practices, U.S. cigarette producers jockeyed for consumer patronage by constantly introducing heavily advertised tobacco products. There were filter tips, flavors, shorts, longs, and soft and hard packages, all designed to shape and satisfy demand for tobacco products. Over the years there have also been efforts to develop alternative nicotine products. After all, cigarettes have been called “cancer sticks” for decades for good reason. The harmful effects have long been known, but nicotine, which comes via tobacco, is addictive. The industry then rested somewhat comfortably, even as demand weakened, continuing to earn profits because of the restrictions on competition.

Despite advertising restrictions that protected established brands, Big Tobacco began losing sales to less-costly upstarts. Loss of market share became so severe that the maker of Marlboro announced a twenty percent price cut on Friday, April 2, 1993.⁵⁷ Now referred to as Marlboro Friday, due to the sharp decline in stocks of firms that relied heavily on brand name recognition, Philip Morris’s action did just what the firm hoped it would. Competition was beaten back; Marlboro recovered market share; and three years later the firm’s shares had fully recovered. Strategic response to competition and ever-rising calls for restrictions due to health concerns has long been part of cigarette makers’ struggle to survive.

B. The Master Settlement Agreement

The 1998 Master Settlement Agreement (MSA) between the nation’s largest cigarette manufacturers and state attorneys general (AGs) was a milestone in tobacco regulation. The MSA heavily influences the structure of the cigarette industry to this day. The agreement included a series of regulatory

54. See Yandle et al., *supra* note 39, at 1253-54.

55. *Id.*

56. *Id.*

57. Morgan Housel, *How Marlboro Friday Changed the World*, MOTLEY FOOL (Jan. 15, 2008), <http://www.fool.com/investing/general/2008/01/15/how-marlboro-friday-changed-the-world.aspx>.

restrictions on the industry and cemented the dominant market position of existing manufacturers.⁵⁸

The MSA was adopted to resolve a series of lawsuits filed by state AGs against cigarette manufacturers. The first suit was brought by the state of Mississippi in 1994; other states quickly followed.⁵⁹ By mid-1997, more than thirty states had filed suit. Aiding the state AGs in their efforts were numerous prominent plaintiffs' attorneys, who stood to reap substantial rewards if the suits proved successful.⁶⁰

Prior litigation against tobacco companies, typically filed by former smokers seeking damages for the health consequences of smoking, had largely failed.⁶¹ Plaintiffs found it difficult legally to claim they had been harmed by the cigarette industry's deceptions about the health risks of smoking when every package of cigarettes carried a government-mandated warning. The tobacco companies also benefited from the widespread view among potential jurors that the dangers of smoking were well known. The state lawsuits were different. The states sought reimbursement for the health care expenditures they incurred caring for smokers under the Medicaid program.⁶² Unlike the claims brought by former smokers, these suits could not be deflected by turning the focus to the smokers' choices.

The cigarette manufacturers recognized the state AG lawsuits as a potential existential threat, and sought a truce. In 1997, industry lawyers began negotiating with the AGs in an effort to bring "peace forever."⁶³ By June they had reached a tentative agreement ("the Resolution"), under which the cigarette companies agreed to pay \$10 billion initially and \$15 billion annually in perpetuity in return for protection from future lawsuits.⁶⁴ The cost of the payments would be borne by cigarette consumers in the form of higher prices.⁶⁵

58. This discussion of the MSA draws upon Yandle et al., *supra* note 39, at 1270-71.

59. See Michael DeBow, *The State Tobacco Litigation and the Separation of Powers in State Governments: Repairing the Damage*, 31 SETON HALL L. REV. 563, 566 (2001) (detailing the chronology of state suits against cigarette manufacturers); MARTHA A. DERTHICK, *UP IN SMOKE: FROM LEGISLATION TO LITIGATION IN TOBACCO POLITICS 167-70* (2d ed. 2005) (same).

60. For instance, noted plaintiff's attorney Ronald L. Motley and his partners realized fees in excess of \$1 billion for their role in the securing of the MSA. See Barry Meier, *The Spoils of Tobacco Wars; Big Settlement Puts Many Lawyers in the Path of a Windfall*, N.Y. TIMES, (Dec. 22, 1998), <http://www.nytimes.com/1998/12/22/business/spoils-tobacco-wars-big-settlement-puts-many-lawyers-path-windfall.html>; see also DAN ZEGART, *CIVIL WARRIORS: THE LEGAL SIEGE ON THE TOBACCO INDUSTRY* (2000) (discussing the role of plaintiff attorneys in tobacco litigation).

61. Yandle et al., *supra* note 39, at 1259-63.

62. *Id.* at 1261.

63. See KESSLER, *supra* note 5, at 361.

64. See Proposed Settlement Resolution Between the Tobacco Industry, State Attorneys General, and Plaintiffs' Lawyers (June 20, 1997), available at <http://stic.neu.edu/settlement/6-20-settle.pdf> [hereinafter Resolution]; see also ZEGART, *supra* note 60, at 253-71 (describing the negotiations that led to the Resolution).

65. By one estimate, as much as ninety percent of the costs of the settlement would be borne by smokers. DeBow, *supra* note 59, at 569 (citing estimates by W. Kip Viscusi); see also W. Kip Viscusi, *A Post-Mortem on the Tobacco Settlement*, 29 CUMB. L. REV. 523, 538-44 (1999) (discussing the costs of the tobacco settlement).

The Resolution also provided for limited FDA regulation of the industry, and contained requirements to protect participating cigarette companies from non-signers to the agreement and new entrants; these parties were required to contribute to the settlement fund as well.⁶⁶

Because the Resolution anticipated changes in federal law, such as legislative authorization of FDA regulation of cigarettes, it needed Congressional approval. That was not to be.⁶⁷ Although the Resolution promised total payments well in excess of \$300 billion, anti-smoking activists thought the deal was insufficient, particularly because of the limits on litigation and federal regulation.⁶⁸ Moreover, all the payments were to go to the participating states, leaving the federal government with nothing.⁶⁹ Seeking to promote its own interests, Congress added provisions to the deal that cut it in on the benefits, including a \$1.10 per pack increase in federal cigarette taxes.⁷⁰ This was too much for the industry to stomach. The cigarette companies turned against the legislation authorizing the Resolution, and it failed to pass.⁷¹

Although they failed to get legislation approving the Resolution through Congress, both the state AGs and the cigarette manufacturers still wanted a deal. Secret negotiations between several AGs, plaintiffs' lawyers, and cigarette industry attorneys produced a new agreement, the Master Settlement Agreement.⁷² After its release in late 1998, it was quickly endorsed by forty-six state AGs.⁷³ (The remaining four states had already reached separate settlements with the cigarette companies, each of which was preserved under the MSA.⁷⁴)

Like the Resolution, the MSA promised substantial payments from the then-four dominant cigarette companies to state coffers, funded by cigarette price hikes.⁷⁵ Like the Resolution, the MSA protected participating cigarette companies from competition. The firms negotiated some benefits to cushion the blow imposed by the heavy payments to which they agreed. All firms enjoyed some benefits from the cost savings imposed by restrictions on industry advertising and promotional efforts.⁷⁶ Unlike the Resolution, the MSA did not

66. See Resolution, *supra* note 64, at tit. I.E-F, tit. V.A.

67. See ZEGART, *supra* note 60, at 261-67.

68. See Yandle et al., *supra* note 39, at 1267-68.

69. *Id.* at 1270.

70. See S. REP. NO. 105-180, at 12 (1998).

71. See Nancy Gibbs, *Up in Smoke*, TIME (June 29, 1998), <http://content.time.com/time/magazine/article/0,9171,988614,00.html>.

72. For the full text of the Master Settlement Agreement, see *Master Settlement Agreement*, CAL. DEP'T OF JUST. OFF. OF THE ATT'Y GEN. (Nov. 23, 1998), <http://caag.state.ca.us/tobacco/pdf/1msa.pdf> [hereinafter *MSA*].

73. See DERTHICK, *supra* note 59, at 166.

74. *Id.*

75. See Yandle et al., *supra* note 39, at 1270-71.

76. *Id.*; see also *supra* Section II.A (discussing the original restrictions on advertising in 1971 that froze brands in place).

green-light FDA regulation or offer federal immunity from suit.⁷⁷ As a consequence, the MSA, unlike the Resolution, did not need legislative approval in Congress and so the AGs, plaintiffs' lawyers, and tobacco companies were able to cut Congress out of the deal.⁷⁸

The heart of the MSA was the promised payment of \$206 billion by the four participating cigarette companies to the participating states.⁷⁹ As under the Resolution, these payments would be tax deductible and the costs would be paid by consumers in the form of higher cigarette prices.⁸⁰ The MSA presented state legislatures with a simple choice: accept the MSA in whole and be able to spend your state's share of the billions of dollars raised from smokers, or reject the proposed statute, still have your state's smokers pay the higher prices necessary to fund the deal, and lose your state's claim on the money. Not surprisingly, every state legislature took the money.

Responsibility for the payments was allocated among the cigarette companies in proportion to their current market share, thereby reducing the incentive for the participating cigarette companies to engage in price competition amongst themselves to increase their respective market shares.⁸¹ The structure of the MSA thus provided a powerful incentive for each company to remain satisfied with the status quo.

The MSA protected the major cigarette companies from new competition.⁸² At the time of the agreement, the four participating cigarette companies accounted for all but a small fraction of domestic cigarette sales.⁸³ Increasing cigarette prices to pay for the settlement risked a loss of market share to marginal competitors or new entrants. Therefore, the MSA provided that, for every percent of market share lost by a participating cigarette manufacturer over two percent, it would be allowed to reduce its payments to the states by three percent, unless each participating state enacted a statute to prevent price competition from non-participating manufacturers, as each state did.⁸⁴ The statutes require non-participating cigarette producers to make payments equal to or greater than what they would owe had they been participants in the agreement so as to eliminate the cost advantage they might

77. See Yandle et al., *supra* note 39, at 1270.

78. *Id.*

79. *Id.*

80. Because cigarette consumption is highly price inelastic, the cost of the price increase was largely borne by consumers rather than producers. As one commentator noted, "In all but name, the payments are a national consumption tax, paid almost entirely by individual smokers (rather than the settling companies' shareholders or employees)." Michael S. Greve, *Compacts and Collusion*, AEI FEDERALIST OUTLOOK, (Apr. 2002), <http://www.aei.org/wp-content/uploads/2011/10/Compacts%20and%20Collision.pdf>.

81. Yandle et al., *supra* note 39, at 1270 n.254.

82. *Id.*

83. In 1997, Philip Morris, R.J. Reynolds, and Lorillard together held 99.6 percent of the cigarette market. See Vanessa O'Connell, *Big Tobacco Gets Favorable Ruling*, WALL ST. J. B3 (Mar. 29, 2006). This market share had dropped to 92 percent by 2003. *Id.*

84. See Yandle et al., *supra* note 39, at 1270-71 n.256.

otherwise have.⁸⁵ This was problematic, as the new entrants could not be argued to have contributed to the past harms that were the theoretical justification for the payments to the states.

The MSA included restrictions on cigarette advertising, agreed to by the participating producers.⁸⁶ The advertising limits could be portrayed as a public-health measure, particularly insofar as they reduced advertising that could be targeted at, or otherwise influence, young adults and teens. They also served to reinforce the anti-competitive nature of the MSA, as they made it more difficult for new brands or entrants to secure market share through promotional efforts.⁸⁷

As it turned out, the MSA was not quite as effective at suppressing competition as some of the signatories may have hoped.⁸⁸ Within five years, several upstart cigarette companies had captured approximately ten percent of the market, forcing the participating cigarette companies to cut prices, increase promotional expenditures, and decrease payments to the states.⁸⁹ The MSA helped cartelize the industry, but it did not provide as much insulation against new entrants into the market as industry participants would have liked.

In spite of battles with the new competition, the MSA enabled the major cigarette manufacturers to increase prices by more than was necessary to make the mandated MSA payments.⁹⁰ The MSA's cartel-reinforcing provisions sufficiently suppressed competition to enable cigarette companies to take advantage of the price inelasticity of cigarette demand and obtain record profits.⁹¹ Not only was the MSA anti-competitive, but some legal experts argued it was unconstitutional as well (although courts have not yet agreed).⁹² Nevertheless, the MSA poured competition-suppressing concrete around major tobacco companies, perhaps dulling the market spur for new product development. The stage was set for innovation from outside the industry and a delayed industry response.

C. Federal Tobacco Legislation

Although the MSA provided the dominant cigarette producers with some protection from competition, it did not have the force of federal law. In its

85. The MSA also has provisions governing the obligations of "subsequent participating manufacturers" (SPMs) — that is, cigarette companies that joined after the MSA was agreed upon. Under these provisions, SPMs are only liable for payments should they increase their market share above what they were at the time of the agreement. *Id.*

86. See *MSA*, *supra* note 72, pt. III(a)-(i).

87. Yandle et al., *supra* note 39, at 1267 n.239.

88. *Id.* at 1270.

89. *Id.* at 1270-72.

90. *Id.* at 1232.

91. Mark Curriden, *Up in Smoke*, ABA J. (Mar. 18, 2007), http://www.abajournal.com/magazine/article/up_in_smoke (noting Philip Morris's profits increased 36 percent between 1997 and 2005).

92. See, e.g., Brief of Constitutional Law Scholars as Amici Curiae Supporting the Petition for Certiorari, *S&M Brands, Inc. v. Caldwell*, 562 U.S. 1270 (2010) (No. 10-622).

wake, anti-smoking groups still wished to see increased federal regulation of cigarettes. The cigarette industry was happy to go along, if such regulation would reinforce the constraints of the MSA, deflect further tort litigation, and preempt some state and local regulation.

Altria, in particular, sought legislation granting the FDA authority to regulate cigarettes and other tobacco products.⁹³ It spent years urging the passage of a federal tobacco legislation that would authorize federal regulation.⁹⁴ While Altria did not want to grant the FDA the sweeping authority the agency attempted to claim during the Clinton Administration (and which had been rejected by the Supreme Court in *FDA v. Brown & Williamson*),⁹⁵ it supported “‘tough’ but ‘reasonable’” regulation that could preempt additional waves of tort litigation and would help to suppress competition.⁹⁶ In this sense, federal regulation would complement, and reinforce, the anti-competitive elements of the MSA.

While other tobacco companies supported some FDA regulation in principle, they split with Altria on the final legislation to give the FDA jurisdiction over tobacco products.⁹⁷ Altria prevailed. In anticipation of the law’s passage, the *New York Times* called it “the tobacco regulation that Philip Morris can live with.”⁹⁸ Anti-smoking and public health groups were also not monolithic in their support of the final legislation. Leading anti-smoking advocates such as Campaign for Tobacco-Free Kids, the American Heart Association, the American Cancer Association, and the American Lung Association joined with Phillip Morris in lobbying for the bill.⁹⁹ They believed the law was an important step in the war against smoking. However, the Center for Tobacco Control Research and Education at the University of California, San Francisco saw the health-care advocates support as capitulation to the enemy.¹⁰⁰ Senator Mike Enzi (R-WY) denounced the legislation as a “peace treaty” with Big Tobacco that Philip Morris helped write, and dubbed the bill

93. P.A. McDaniel & R. E. Malone, *Understanding Philip Morris’s Pursuit of US Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193-200 (2005).

94. See Joe Nocera, *If It’s Good for Philip Morris, Can It Also Be Good for Public Health?*, N.Y. TIMES MAG. (June 18, 2006), <http://www.nytimes.com/2006/06/18/magazine/18tobacco.html>.

95. *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120 (2000).

96. McDaniel & Malone, *supra* note 93, at 194-95; Samuel Lowenberg, *Smoke Screen: Why Is Philip Morris Supporting FDA Regulation of Cigarettes?*, SLATE (July 25, 2002), http://www.slate.com/articles/business/moneybox/2002/07/smoke_screen.html.

97. C. STEPHEN REDHEAD & VANESSA K. BURROWS, CONG. RESEARCH SERV., R40475, FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 (2009)..

98. Duff Wilson, *Philip Morris’s Support Casts Shadow over a Bill to Limit Tobacco*, N.Y. TIMES (Mar. 1, 2009), <http://www.nytimes.com/2009/04/01/business/01tobacco.html>.

99. REDHEAD & BURROWS, *supra* note 97, at 4.

100. See Kristi Keck, *Big Tobacco Down but Not Snuffed Out*, CNN (June 22, 2009), <http://www.cnn.com/2009/POLITICS/06/19/tobacco.lobby> (detailing disappointment of some tobacco-control groups with the legislation).

the “Marlboro Protection Act.”¹⁰¹ In any case, the Bootlegger/Baptist line-up in favor was overwhelming.

The resulting legislation, the Family Smoking Prevention and Tobacco Control Act of 2009, granted the FDA authority to regulate cigarettes and other tobacco products under a new regulatory regime tailored to the industry.¹⁰² The Act created a new division within the FDA, the Center for Tobacco Products, financed by fees on tobacco manufacturers.¹⁰³ The Act also barred flavoring cigarettes other than with menthol, authorized the FDA to set product standards for cigarettes, and imposed more-explicit warning labels on tobacco products.¹⁰⁴ It limited cigarette advertising generally, enacted additional specific restrictions on the marketing of “modified risk tobacco products” — that is, tobacco products, other than NRT products, that present reduced health risks — and created a mechanism through which the FDA could assert regulatory authority over nontraditional tobacco products, including e-cigarettes.¹⁰⁵ The Act also created a requirement for premarket approval of all new tobacco products, unless the manufacturer could demonstrate that the new product was substantially equivalent to a product marketed prior to February 15, 2007.¹⁰⁶

The Tobacco Control Act’s regulatory provisions apply to cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. The law provided the FDA the authority to subject other products “made or derived from tobacco” and “intended for human consumption” to its regulatory regime.¹⁰⁷ Specifically, the FDA may “deem” other such products to be regulated as “tobacco products” under the Act.¹⁰⁸ Products “deemed” to be “tobacco products” under the Act become subject to many of its requirements, including the prohibition on adulterated or misbranded products, mandatory manufacturer registration and content disclosure requirements, restrictions on modified risk claims, and mandatory premarket review of products marketed after February 15, 2007.¹⁰⁹ In the case of e-cigarettes, this latter provision

101. See, e.g., Mike Enzi, *HELP Committee Passes a “Marlboro Protection Act,”* THE HILL (Aug. 1, 2007, 2:24 PM), <http://thehill.com/blogs/congress-blog/politics/27745-help-committee-passes-a-marlboro-protection-act-sen-mike-enzi>.

102. See 21 U.S.C. § 387a (2012).

103. *Id.* at §387a(e).

104. *Id.* at §387g.

105. *Id.* at §387f (restrictions on advertising), §387f-1 (enforcement of limitations on advertising), §387k (regulation of “modified risk” tobacco products), §387a(b) (authority of FDA commissioner to “deem” other products to constitute tobacco products).

106. *Id.* at § 387j (2012).

107. *Id.* at §387a.

108. *Id.* at §387a (b).

109. *Id.* The FDA has indicated that even relatively modest changes in product design or packaging will be sufficient to identify a product as a new tobacco product, and not substantially equivalent to a product already on the market. See *Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions*, FOOD & DRUG ADMIN. (Sept. 8, 2015),

would require mandatory review of all, or nearly all, products currently on the market.

Passage of the Tobacco Control Act established the exclusive means of regulating tobacco products. In 2009, the FDA briefly sought to regulate e-cigarettes under the drug and device provisions of the Food, Drug, and Cosmetic Act.¹¹⁰ Specifically, the FDA sought to prohibit the importation of e-cigarettes by NJOY, claiming the products were adulterated, misbranded, or unapproved drug-device combinations under the FDCA.¹¹¹ Under the FDA's theory, because e-cigarettes are devices that deliver nicotine, they could be regulated as drug-device combinations. This position, had it prevailed, could have effectively prohibited e-cigarettes containing nicotine. The FDA's position was rejected in federal court after a legal challenge by NJOY, however. In *Sottera, Inc. v. FDA*, the U.S. Court of Appeals for the D.C. Circuit held that e-cigarettes, like other tobacco products, are, in the absence of therapeutic claims, only subject to FDA regulation under the Tobacco Control Act.¹¹² The FDA's attempt to extend its authority under the FDCA to e-cigarettes—like its prior effort in the 1990s to extend its regulatory authority to cigarettes—exceeded its statutory authority. Insofar as the FDA believes regulation of e-cigarettes is warranted, it would have to pursue such regulation through its authority under the Tobacco Control Act, as the agency subsequently did. In May 2016, the FDA finalized a rule deeming e-cigarettes and related products to be “tobacco products” subject to regulation under the Act.¹¹³ The e-cigarette industry will never be the same.

III. The Emergence of Electronic Cigarettes

The cartelization of the tobacco industry—first by the MSA and then by federal tobacco legislation—created opportunities for entrepreneurs. Although the MSA and federal law made things difficult for new entrants into cigarette markets, they did not close off the possibility of competing products that could substitute for cigarettes. Indeed, in some respects the MSA and federal regulations increased opportunities for firms to profit by developing alternatives. By increasing the retail price of cigarettes, the MSA made the market for cigarette alternatives more enticing to entrepreneurs. Into the void came the electronic cigarette. E-cigarettes are a potential substitute for traditional tobacco products that pose a significant threat to the tobacco industry as it exists today. E-cigarettes may also be a threat to the makers of

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf>

110. See *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

111. *Id.*

112. *Id.*

113. Deeming Tobacco Products to Be Subject to FDCA, *supra* note 1.

nicotine replacement therapies and other smoking substitutes.¹¹⁴ The development of e-cigarettes may also have implications for public health.

A. A Disruptive Technology

Electronic cigarettes, also known as “e-cigarettes” or “e-cigs,” are a “disruptive technology” that threaten the existing cigarette industry and conventional products.¹¹⁵ E-cigarettes are not cigarettes and do not contain tobacco. They are, however, a device that can be used to “mimic[] the act of smoking” and deliver the nicotine that smokers crave.¹¹⁶ For some, they have the potential to replace cigarettes (and other products) as a source of nicotine. Indeed, some suggest that e-cigarettes could make tobacco cigarettes “obsolete.”¹¹⁷ The effect of e-cigarettes on the tobacco industry could be like the effect that digital cameras had on traditional cameras and photographic film.¹¹⁸

E-cigarettes were invented in China in the early 2000s and introduced in the United States in 2006.¹¹⁹ Most production occurs in China, but the product has evolved and spread around the world. Electronic cigarettes come in multiple varieties and new products are developed with some frequency. By 2014, there were already “dozens” of e-cigarette manufacturers and “hundreds” of different models.¹²⁰

Most electronic cigarettes can be characterized as either “cigalikes,” which look like traditional cigarettes, or modular vaping devices (often referred to by the acronym VTM for “vapors, tanks, and mods”), which come in various shapes and sizes. While cigalikes, in turn, come in both disposable and rechargeable models, VTMs generally allow greater user customization.

For all electronic cigarettes, the key component is a heating device that atomizes or “vaporizes” a fluid that usually contains nicotine and flavoring of

114. See Daniela Saitta et al., *Achieving Appropriate Regulations for Electronic Cigarettes*, 5 THERAPEUTIC ADVANCES IN CHRONIC DISEASE 50, 57 (2014) (“[T]he growing popularity of e-cigarettes is a threat to the interests of the tobacco industry, the pharmaceutical industry and to their associated stakeholders due to the substantial decrease in cigarette consumption and NRT sales.”).

115. See David B. Abrams, *Promise and Peril of e-Cigarettes*, 311 J. AM. MED. ASS’N 135 (2014).

116. Cahn & Siegel, *supra* note 1, at 17.

117. Abrams, *supra* note 115, at 136; see also *id.* at 135 (“[T]he increasing evidence to date points to an opportunity of a new class of safer, but very appealing, nicotine delivery technologies that could favor the speedy obsolescence of conventional cigarettes.”).

118. *Id.*

119. See Peter Hajek et al., *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801 (2014); Barbara Demick, *A High Tech Approach to Getting a Nicotine Fix*, L.A. TIMES (Apr. 25, 2009), <http://articles.latimes.com/2009/apr/25/world/fg-china-cigarettes25>. Various patents for smokeless delivery of nicotine were filed as early as 1965. See Jordan Paradise, *No Sisyphian Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL’Y L. & ETHICS 326, 352-53 (2013).

120. See Hajek et al., *supra* note 119, at 1801.

some sort; the user then inhales the vapor (hence the name “vaping”).¹²¹ Almost anything can be transformed into breathable vapor this way. There is a growing market for flavors and assorted devices that allow users to “vape.” As of early 2014, the domestic e-cigarette market was estimated to be worth \$2.2 billion, with the cigalike and VTM markets valued at \$1.4 billion and \$800 million, respectively.¹²² By 2015, estimated sales of electronic cigarettes and associated paraphernalia hit \$3.5 billion.¹²³

For smokers who would like to quit smoking but still receive doses of nicotine, e-cigarettes are a major potential substitute.¹²⁴ E-cigarettes can look like cigarettes, produce a vapor that shares the mouth feel of smoking, and involve the same hand-to-mouth process, but avoid the health hazards caused by the byproducts of combustion, such as tar and other substances.¹²⁵ While e-cigarettes cannot be characterized as “risk-free,” they appear to be far less risky to users than conventional cigarettes, and may be less risky than various forms of smokeless tobacco as well.¹²⁶ Smokers who do not wish to quit smoking may use e-cigarettes in locations where they need to reduce secondhand smoke. It is thus no surprise that many e-cigarette users are smokers or former smokers,¹²⁷ and it appears that at least some use e-cigarettes to reduce their overall cigarette consumption or to help them quit.

The newness of the industry means it does not have an extensive financial history. Wells Fargo Securities produces detailed analyses of the markets for traditional tobacco and e-cigarettes. It estimated world e-cigarette revenues for manufacturers at a half billion dollars in 2012. That almost tripled by 2013 and

121. See Cahn & Siegel, *supra* note 1, at 17; Hajek et al., *supra* note 119, at 1801.

122. See *Equity Research: Vape Shops-Springing Up Across the Country*, WELLS FARGO SEC. 2 (Apr. 14, 2014), available at http://www.vaporworldexpo.com/PDFs/Tobacco_%20Vape_Shop_Visit_Apri_2014.pdf; see also *Equity Research-Tobacco Talk: Vapors/Tanks Driving Next Wave of E-Vapor Growth*, WELLS FARGO SEC. (Mar. 24, 2014), available at http://www.vaporworldexpo.com/PDFs/Tobacco_Talk_Vapors_Tanks_%20March%202014.pdf (discussing growth of VTM market); *Equity Research-Tobacco: Vapor World Expo*, WELLS FARGO SEC. (May 12, 2014), available at http://www.vaporworldexpo.com/PDFs/Vapor_World_Expo_Key_Takeaways.pdf (same).

123. Jilian Mincer, *The U.S. Vaporizer Market Is Booming*, BUS. INSIDER (July 29 2015), <http://www.businessinsider.com/r-in-rise-of-us-vape-shops-owners-eye-new-marijuana-market-2015-7>.

124. See Cahn & Siegel, *supra* note 1.

125. Hajek et al., *supra* note 119, at 1806.

126. The health evidence will be discussed more below. For an overview favorable to the e-cigarette industry, see Joel L. Nitzkin, *E-Cigarette Primer for State and Local Lawmakers*, R ST. INST. (2014), <http://www.rstreet.org/wp-content/uploads/2014/06/RSTREET25.pdf>.

127. See, e.g., Sarah E. Adkinson et al., *Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey*, 44 AM. J. PREVENTIVE MED. 207, 208 (2013); *Use of Electronic Cigarettes (Vapourisers) Among Adults in Great Britain*, ACTION ON SMOKING & HEALTH (May 2015), http://www.ash.org.uk/files/documents/ASH_891.pdf. Both studies, like many others, find the overwhelming majority of e-cigarette users to be current or former cigarette smokers.

may reach \$20 billion by 2021.¹²⁸ In less than a decade, profits from e-cigarettes could eclipse profits from traditional cigarettes.

Not surprisingly, the major tobacco producers saw the need to respond to this new competition. They did this by developing (or acquiring) their own electronic cigarette brands,¹²⁹ as well as by supporting regulation that could reduce the threat posed by this disruptive technology.¹³⁰ Existing tobacco companies have “war chests of cash to invest,” a distribution system tied to tobacco retailers, expertise in building brands, and deep knowledge of tobacco consumers.¹³¹ The CEO of Reynolds uses e-cigarettes and has suggested they are a large part of Reynolds’ future.¹³² At the same time, Reynolds has called for the FDA to prohibit “open-system” vapor e-cigarettes (i.e. VTMs), which are primarily made by smaller companies and allow consumers to mix inputs to customize their vapor devices.¹³³

The Wells Fargo analysis makes reasonable assumptions: e-cigarettes are substitutes for conventional cigarettes, and consumers are now learning about e-cigarettes and how they work as substitutes. The e-cigarettes model will be much like the razor and razor blade model: the razor handle has a small profit margin, made up for by higher margins on razor refills. Similarly, the cartridges for e-cigarettes and VTM e-liquids could have higher margins than starter kits or vaping devices in which cartridges or fluid may be used. Many VTM users also appear to be former cigarette smokers who switched because VTMs offer a “superior vaping experience.”¹³⁴

128. *Equity Research: e-Cigarettes Revolutionizing the Tobacco Industry*, WELLS FARGO SEC. 2 (June 12, 2013), available at <http://www.smallcapfinancialwire.com/wp-content/uploads/2013/11/E-Cigs-Revolutionizing-the-Tobacco-Industry-Interactive-Model.pdf>. More recent figures indicate the growth of e-cigarettes is not as meteoric as was thought. See Tripp Mickle, *Reynolds’s New Cigarette Merely Heats Tobacco*, WALL ST. J. (Nov. 17, 2014), <http://online.wsj.com/articles/reynolds-american-plans-new-cigarette-which-wont-burn-tobacco-1416256130>.

129. See WELLS FARGO SEC., *supra* note 128, at 1 (discussing efforts by “Big 3” cigarette companies to compete in e-cigarette market).

130. See *infra* Section IV.B.

131. WELLS FARGO SEC., *supra* note 128, at 1.

132. Mike Esterl, *A Tobacco CEO Who ‘Vapes’ Could Alter the Industry*, WALL ST. J. (July 14, 2014), <http://online.wsj.com/articles/a-tobacco-ceo-who-vapes-could-alter-the-industry-1405297837>.

133. Richard Craver, *Reynolds American Wants FDA to Ban Vapor e-Cigarettes*, WINSTON-SALEM J. (Sept. 7, 2014), http://www.journalnow.com/business/business_news/local/reynolds-american-wants-fda-to-ban-vapor-e-cigarettes/article_77b131f5-540d-5f02-927c-733bac751529.html. For a copy of Reynolds’s official comments on the proposed rule, see RAI Services Co., Comment Letter on Proposed Rule to Deem Tobacco Products Subject to Federal Food, Drug, and Cosmetic Act (Aug. 8, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-76048>. Reynolds is also launching a cigarette that heats, not burns tobacco, in an effort to keep cigarette smokers who are not keen on e-cigarettes but would like a safer product. See Mickle, *supra* note 128.

134. Ted Cooper, *Why a Major e-Cigarette Company Is Lobbying for More Regulation*, MOTLEY FOOL (Sept. 17, 2014), <http://www.fool.com/investing/general/2014/09/17/why-a-major-e-cigarette-company-is-lobbying-for-mo.aspx>.

As often occurs in an emerging industry, particularly one based on a disruptive technology, there is rapid change in the position of firms. As of 2013, there were as many as three hundred companies in the United States selling mostly Chinese-made e-cigarettes, many over the Internet.¹³⁵ In 2012, Ballantyne Brands' Mistic e-cigarette was the leader in domestic unit sales and second in revenue.¹³⁶ By early 2013, NJOY had become the leader in both categories, but by May of that year it was overtaken by Lorillard's blu brand. By the summer of 2014, Logic (Logic Technologies) was number one in convenience store sales (24.3 percent).¹³⁷ At that time, the top four firms accounted for approximately ninety percent of sales and revenue. In this sense, the market is like the domestic cigarette market, which is dominated by what was the Big 3 – Reynolds, Lorillard, and Altria – and is now the Big 2 since Reynolds and Lorillard merged. Unlike the cigarette market, which has severe restrictions on entry of new competition and marketing practices, however, the e-cigarette market has been wide open with many entrants. In 2015, yet another market leader emerged, as Reynolds' Vuse brand became the top-selling electronic cigarette brand, even as sales of VTMs continued to increase.¹³⁸ By 2015, there were an estimated 8,500 "vape shops" in the United States, in addition to online vendors of VTMs.¹³⁹ Sales from such sources are difficult to track and are not always included in industry sales estimates.¹⁴⁰

The dominant tobacco companies have sought to maintain the profitability of their core business and enter into the growing e-cigarette market — albeit on terms that work to the large manufacturers' comparative advantage.¹⁴¹ Cigarettes are particularly profitable, as Altria and Reynolds are protected from competition by the MSA. Domestically, however, these companies face a shrinking market as a declining and aging share of the population smokes. From 2005 to 2014, the percent of the population that smokes declined from

135. See Shannon Bond, *Big Tobacco Bets a Packet on e-Cigarettes*, FIN. TIMES (June 6, 2013), <http://www.ft.com/cms/s/0/1bee7f5c-cec6-11e2-ae25-00144feab7de.html>.

136. See Bea Quirk, *Smokers' Market Enjoys a Breath of Fresh Air*, CHARLOTTE BUS. J. (Sept. 12, 2014), <http://www.bizjournals.com/charlotte/print-edition/2014/09/12/smokers-market-enjoys-a-breath-of-fresh-air.html>.

137. Melissa Vonder Haar, *In Face of e-Cigarette Challenges, Logic Rises to No. 1*, CSP DAILY NEWS (Aug. 14, 2014), <http://www.cspnet.com/category-news/tobacco/articles/face-e-cigarette-challenges-logic-rises-no-1>.

138. See Melissa Vonder Haar, *Nielsen: Electronic Cigarette Sales Growth Declines*, TOBACCO E-NEWS (Aug. 18, 2015), <http://www.cspnet.com/category-news/tobacco/articles/nielsen-electronic-cigarette-sales-growth-declines>.

139. See Mincer, *supra* note 123.

140. See Vonder Haar, *supra* note 138 (noting the difficulty of accounting for vape shop and online sales).

141. Nicotine gum and nicotine patches, generally used by people wanting to quit smoking, were developed by pharmaceutical firms; the nicotine is a tobacco extract, but the delivery mechanism and distribution is distinct from tobacco sales and dominated by a separate industry. The advantage for the Big 2 (formerly the Big 3) is their distribution expertise and network that can be employed for e-cigarettes.

20.9 percent to 16.8 percent.¹⁴² Industry analysts believe the fall in cigarette sales will continue and recent data suggest they are correct: for example, Lorillard's domestic shipments of traditional cigarettes fell 1.9 percent in the third quarter of 2014.¹⁴³ Altria is similarly seen as threatened by "deeper secular declines in U.S. cigarettes than anticipated."¹⁴⁴

Insofar as e-cigarettes are a substitute for traditional cigarettes, cigarette makers would be expected to attempt to participate in the e-cigarette market. Financial analysts following the cigarette industry make clear their view that the major cigarette companies must be in the e-cigarette market and may come to dominate it. Lorillard, the smallest of what was the Big 3, had a top-selling e-cigarette, blu, that it acquired in 2012.¹⁴⁵ Reynolds introduced Vuse in 2013, which it markets as a superior quality product that will have less of an impact on the environment than traditional cigarettes.¹⁴⁶ Philip Morris International bought Nicocigs, one of the U.K.'s largest e-cigarette makers, in 2014.¹⁴⁷ Altria launched MarkTen e-cigarettes nationally in 2014 and also bought an independent firm, Green Smoke.¹⁴⁸ Lorillard bought one of the largest e-cigarette companies in the U.K.¹⁴⁹ Industry analysts are not surprised by such investments, as some forecast that sales revenues from e-cigarettes could surpass sales revenues from cigarettes sometime between 2017 and 2023. Cigarette sales are falling; meanwhile, e-cigarette sales are growing rapidly and

142. *Current Cigarette Smoking Among Adults in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 23, 2015), www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking. The share of adults aged 19-24 who smoke is about ten percent lower than for the rest of the adult population.

143. *Lorillard Growth Comparisons*, CSIMARKET, <http://csimarket.com/stocks/growthrates.php?code=LO> (last visited Apr. 10, 2016).

144. BANK OF AM.-MERRILL LYNCH, ALTRIA GROUP 2 (May 7, 2014) (on file with the Yale Journal on Regulation).

145. Lorillard trumpeted its move into the e-cigarette market by its purchase of blu in 2012, as its press release indicates. Press Release, Lorillard Inc., *Lorillard Inc. Reports First Quarter 2012 Results and Acquisition of blu E-cigs* (Apr. 25, 2012), <http://investors.lorillard.com/investor-relations/news/news-details/2012/Lorillard-Inc-Reports-First-Quarter-2012-Results-and-Acquisition-of-blu-e-cigs/default.aspx>. Lorillard agreed to sell blu to Imperial Tobacco in 2014 as part of the merger of Lorillard with Reynolds. Even without the merger issue, the divestiture of blu suggests that the period of glory for blu may have been temporary due to consumers' move toward open systems. Rapid change in technology is not uncommon in emerging markets. See Rich Duprey, *Is This the Real Reason Lorillard Is Willing to Sell blu Cigs*, THE MOTLEY FOOL (Aug. 19, 2014), <http://www.fool.com/investing/general/2014/08/19/is-this-the-real-reason-lorillard-is-willing-to-se.aspx>.

146. For a copy of the advertisement, see VUSE VAPOR, <https://vusevapor.com/modules/Security/Landing.aspx> (last visited Apr. 10, 2016).

147. Eise Erheriene, *Philip Morris Strikes U.K. e-cigarette Deal*, WALL ST. J. (June 26, 2014), <http://online.wsj.com/articles/philip-morris-strikes-u-k-e-cigarette-deal-1403783669>.

148. Mike Esterl, *Altria Expands in e-Cigarettes with Green Smoke*, WALL ST. J. (Feb. 3, 2014), <http://online.wsj.com/articles/SB10001424052702304626804579360552508696542>; Mike Esterl, *Altria to Launch MarkTen e-Cigarette Nationally*, WALL ST. J. (Feb. 19, 2014), <http://online.wsj.com/news/articles/SB10001424052702304914204579393083711733854>.

149. Lorillard bought SKYCIG, a U.K. e-cigarette company, in 2013. Press Release, Lorillard, Inc. *Acquires British-based SKYCIG, Expanding its Electronic Cigarette Business* (Oct. 1, 2013), <http://www.prnewswire.com/news-releases/lorillard-inc-acquires-british-based-sky cig-expanding-its-electronic-cigarette-business-225948541.html>.

thus could become the primary income and profit source for Altria and Reynolds. Even if such projections are overly optimistic, the moves being made by the two dominant firms and investments by independent e-cigarette makers indicate that the market for e-cigarettes is expected to grow. The big tobacco companies continue to be profitable and are considered, at least by some analysts, to be good investments, particularly after the FDA's decision to regulate e-cigarettes as tobacco products.¹⁵⁰

B. E-Cigarettes and Public Health

E-cigarettes mimic traditional tobacco products, but they do not produce smoke and do not involve combustion. For these reasons, "vaping" is likely to pose a lower risk to e-cigarette users and third-parties than smoking.¹⁵¹ Preliminary research on e-cigarettes supports this conclusion.¹⁵² For this reason, some public health experts and organizations like the Royal College of Physicians believe e-cigarettes can represent a form of "harm reduction" for tobacco.¹⁵³ Some anti-smoking groups, on the other hand, fear that widespread "vaping" could renormalize smoking, prolong rates of nicotine addiction, encourage teen tobacco use, and pose additional health threats that have not yet been uncovered.¹⁵⁴

While much is still unknown about the full public health effects of e-cigarettes, the evidence to date suggests that e-cigarettes are substantially less dangerous than traditional tobacco products, cigarettes in particular.¹⁵⁵ Tar and

150. See, e.g., Rupert Hargreaves, *Tobacco is Still an Extremely Profitable Business, and This Won't Change Soon*, MOTLEY FOOL (Apr. 8, 2014), <http://www.fool.com/investing/general/2014/04/08/tobacco-is-still-an-extremely-profitable-busines-2.aspx>; Penny Morgan, *2Q15 Revenue Results of Tobacco Companies Sent Strong Signals*, MKT REALIST (Dec. 21, 2015), <http://marketrealist.com/2015/12/3q15-revenue-results-of-tobacco-companies-sent-strong-signals/>; Bentley, *supra* note 4.

151. Cahn & Siegel, *supra* note 1, at 17 ("Theoretically, we would expect *vaping* to be less harmful than smoking as it delivers nicotine without the thousands of known and unknown toxicants in tobacco smoke.").

152. See, e.g., Hajek et al., *supra* note 119; A. McNeill et al., *E-Cigarettes: An Evidence Update—A Report Commissioned by Public Health England*, PUB. HEALTH ENG. (2015), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

153. See, e.g., Cahn & Siegel, *supra* note 1; McNeill et al., *supra* note 152, at 14; ROYAL COLLEGE OF PHYSICIANS. NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION (2016), <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> (urging encouragement of e-cigarettes and other tobacco alternatives as a means of curbing smoking).

154. See *infra* notes 175-181 and accompanying text.

155. See Cahn & Siegel, *supra* note 1, at 18 ("Although the existing research does not warrant a conclusion that electronic cigarettes are safe in absolute terms and further clinical studies are needed to comprehensively assess the safety of electronic cigarettes, a preponderance of the available evidence shows them to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products."). See generally Hajek et al., *supra* note 119 (concluding that e-cigarettes are likely to be much less harmful to users and bystanders than cigarettes); McNeill et al., *supra* note 152, at 80 ("While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger.").

other chemicals inhaled when smoking cigarettes are a cause of lung cancer and other health problems associated with smoking.¹⁵⁶ E-cigarettes eliminate these chemicals, which are the primary health dangers to smokers. The problems caused by secondhand smoke are also greatly reduced because e-cigarettes produce vapor, as opposed to smoke, and do not deliver “side-stream” smoke.¹⁵⁷ Most e-cigarettes deliver measured doses of nicotine, the addictive substance in tobacco to users. The levels of nicotine delivered in cigarettes and e-cigarettes are not toxic, however.¹⁵⁸ Users also can, depending on the brand purchased, choose the dose level preferred.¹⁵⁹ Furthermore, some e-cigarette products are available that lack any nicotine content. Various smoking cessation products, such as gums, lozenges and other NRTs, also contain nicotine.

A comprehensive report about e-cigarettes produced by Public Health England (the research arm of the UK’s Department of Health), found e-cigarettes significantly less harmful than other tobacco products.¹⁶⁰ A follow-up report in 2015, surveying the available medical research, reaffirmed this conclusion.¹⁶¹ A separate international expert panel evaluating the relative harms posed by various nicotine-containing products concluded that e-cigarettes pose no more than five percent of the risk posed by traditional cigarettes.¹⁶² Some preliminary studies also appear to show relatively rapid health benefits for smokers who switch from cigarettes to e-cigarettes.¹⁶³ One

156. Cigarette smoking is estimated to cause almost a half million deaths annually; about ten percent of those are from secondhand smoke. See *Tobacco-Related Mortality*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 6, 2014), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality; see also Saitta et al., *supra* note 114, at 53 (“[N]early all the health risks come from tar, chemicals, and other substances found in the smoke, not from nicotine.” (citation omitted)).

157. See McNeill et al., *supra* note 152, at 76 (noting that “the health risks of passive exposure to electronic cigarette vapour are likely to be extremely low”). Side-stream smoke is one component of secondhand smoke. Different from mainstream smoke, which is secondhand smoke that is exhaled by a smoker, side-stream smoke is produced by the combusting tip of a cigarette or other tobacco product. See *Health Risks of Secondhand Smoke*, AM. CANCER SOC’Y, <http://www.cancer.org/cancer/cancercauses/tobaccocancer/secondhand-smoke> (last updated Nov. 13, 2015).

158. The WHO attack on e-cigarettes resulted in backlash. A large number of health researchers replied to WHO that e-cigarettes could be a tobacco harm reducer. See Letter from Specialists in Nicotine Science and Public Health Policy to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 26, 2014), <http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>.

159. For example, the blu e-cigarette brand offers cartridges with a range of nicotine levels, and also offers “Non-Nicotine” cartridges. See *Flavor Cartridges*, BLU, <http://www.blucigs.com/product/flavor-cartridges> (last visited Apr. 10, 2016).

160. John Britton & Ilze Bogdanovica, *Electronic Cigarettes*, PUB. HEALTH ENG. (2014), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf.

161. See McNeill et al., *supra* note 152.

162. See David J. Nutt et al., *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 EUR. ADDICTION RES. 218 (2014). The 2015 Public Health UK report concluded this was a “reasonable estimate.” McNeill et al., *supra* note 152, at 80.

163. Stephen S. Hecht et al., *Evaluation of Toxicant and Carcinogen Metabolites in the Urine of E-Cigarettes Users Versus Cigarette Smokers*, 17 NICOTINE TOBACCO RES. 704 (2015); Riccardo Polosa, *Electronic Cigarette Use and Harm Reversal: Emerging Evidence in the Lung*, 13

study, for example, found significant improvements in measures such as airway inflammation and obstruction in as little as three months.¹⁶⁴

Nonetheless, e-cigarettes are not risk free. Among the problems identified by the Public Health England report are several related to quality control, particularly with smaller brands. Some e-cigarettes are not consistent in the level of nicotine doses delivered. The Parliament Office of Science and Technology found e-cigarettes to be a good alternative to cigarettes from a public health standpoint¹⁶⁵ but noted that some brands of e-cigarettes tended to be unreliable in dosage and had inadequate labels.¹⁶⁶ Some are also concerned that celebrity endorsement of e-cigarettes may induce usage by non-smoking youth.¹⁶⁷

Most electronic cigarettes contain nicotine. While nicotine can be quite addictive, nicotine itself is not a significant source of the health problems caused by cigarettes. Public Health England, a government agency that funds campaigns against tobacco use, explains: “nicotine is not a significant health hazard. Nicotine does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease, and is not carcinogenic.”¹⁶⁸ That is, the primary health hazards from tobacco are from substances other than nicotine. In cigarettes, a multitude of substances are under combustion.¹⁶⁹ On the other hand, as a recent review of the available scientific literature concluded, e-cigarettes “contain some toxicants in concentrations much lower than in tobacco smoke and negligible concentrations of carcinogens.”¹⁷⁰

The growth in e-cigarette usage to date seems to be an advance for public health. The majority of e-cigarette users appear to switch to the product away from cigarettes, thereby reducing exposure to the harmful content of cigarettes. A survey in the U.K found that “three out of five [e-cigarette users] are current

BMC MED. 54, 54 (2015) (“[S]mokers completely switching to regular EC use are likely to gain significant health benefits.”).

164. See Polosa, *supra* note 163, at 56.

165. That office is akin to the Congressional Research Service (CRS) in the United States.

166. Britton & Bogdanovica, *supra* note 160, at 7.

167. See, e.g., Rachel Grana et al., *E-Cigarettes: A Scientific Review*, 129 CIRCULATION 1972 (2014). On the question of whether e-cigarettes are a “gateway to smoking,” the evidence is lacking. See Michael B. Siegel, *The e-Cigarette Gateway Myth*, WALL ST. J (AUG. 5, 2014), <http://www.wsj.com/articles/michael-b-siegel-the-e-cigarette-gateway-myth-1407283557>.

168. Britton & Bogdanovica, *supra* note 160, at 7.

169. Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List, 77 Fed. Reg. 20034 (Apr. 3, 2012); Jeff Fowles & Erik Dybing, *Application of Toxicological Risk Assessment Principles to the Chemical Constituents of Cigarette Smoke*, 12 TOBACCO CONTROL 424 (2003). The FDA lists nicotine as a reproductive or developmental toxicant and addictive, but not a carcinogen like dozens of other chemicals identified in tobacco products and tobacco smoke.

170. Hajek et al., *supra* note 119, at 1801.

smokers” and most of the rest are ex-smokers.¹⁷¹ Similarly, a Canadian study found “64 per cent of those who vape also smoke. Another 27 per cent used to smoke tobacco but quit, while 9 per cent of vapers never smoked.”¹⁷² In this regard, e-cigarettes and other ENDS may be a viable form of “harm reduction.”¹⁷³

No doubt more will be learned from more research. E-cigarettes are new, so long-term health consequences cannot yet be known. The nicotine content of e-cigarettes also varies more than is likely acceptable.¹⁷⁴ Health issues may well be attached to the use of e-cigarettes,¹⁷⁵ but, based on the evidence to date, the dangers appear to be much smaller than those posed by tobacco use. Nonetheless, there is virulent opposition to e-cigarettes from a variety of health researchers and advocacy groups who would, at a minimum, like e-cigarettes to be subject to strong regulation and taxation so as to discourage their use. These public health advocates are the Baptists in our story.¹⁷⁶

C. Regulating E-Cigarettes

Prior to 2016, e-cigarettes were not subject to federal regulation as currently marketed and sold. As noted above, the FDA had sought to regulate e-cigarettes as drug-device combinations, only to have that effort rejected in federal court.¹⁷⁷ Under current law, e-cigarettes are only subject to regulation

171. *Use of Electronic Cigarettes in Great Britain*, ACTION ON SMOKING AND HEALTH (May 2015), http://www.ash.org.uk/files/documents/ASH_891.pdf

172. Andre Picard, *Ex-Smokers Credit E-Cigarettes for Helping Them Quit*, *Poll Finds*, THE GLOBE & MAIL (Dec. 18, 2014), <http://www.theglobeandmail.com/life/health-and-fitness/health/ex-smokers-credit-e-cigarettes-for-helping-them-quit-poll-finds/article22135601>. Other surveys also find most e-cigarette users to be current or former cigarette smokers. Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control*, 32 J. PUB. HEALTH POL'Y 15, 16, 26 (2011) (“[E]lectronic cigarettes show tremendous promise in the fight against tobacco-related morbidity and mortality.”).

173. See Cahn & Siegel, *supra* note 1; Michael L. Marlow, *Regulating a Less Unhealthy Cigarette*, REG., Fall 2014, at 28; Nicole D. White, *E-Cigarettes for Smoking Cessation: Helpful or Harmful*, 9 AM. J. LIFESTYLE MED. 109 (2014); ROYAL COLLEGE OF PHYSICIANS, *supra* note 153.

174. Joseph G. Lisko et al., *Chemical Composition and Evaluation of Nicotine, Tobacco Alkaloids, pH, and Selected Flavors in e-Cigarette Cartridges and Refill Solutions*, 10 NICOTINE TOBACCO RES. 17 (2015).

175. Most e-cigarette opponents attack the product as a gateway to tobacco use or assert that nicotine use is a danger. The vaping process itself may involve some hazards. See R. Paul Jensen et al., *Hidden Formaldehyde in e-Cigarette Aerosols*, 372 NEW ENG. J. MED. 392 (2015).

176. An interesting twist has arisen in the analysis of tobacco regulations. The FDA has recognized, perhaps for the first time formally, that some smokers like smoking, so consideration should be given to the pleasure they receive from it. That point is obvious but has generally been dismissed as irrelevant when discussing something that has negative health effects. For an analysis of the FDA regulation in question, see Deeming Tobacco Products to Be Subject to FDCA, *supra* note 1. For news coverage of the controversy, see Sabrina Tavernise, *In New Calculus on Smoking, It's Health Gained vs. Pleasure Lost*, N.Y. TIMES (Aug. 6, 2014), <http://www.nytimes.com/2014/08/07/health/pleasure-factor-may-override-new-tobacco-rules.html>.

177. See *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010); see also *supra* notes 110-113 and accompanying text.

as drug-devices if they are advertised or sold for therapeutic uses. As this would entail going through an extensive regulatory approval process, no e-cigarette maker markets and sells e-cigarettes in this fashion. If e-cigarettes are to be regulated under existing federal law, it can only occur under the Family Smoking Prevention and Tobacco Control Act of 2009.

In May 2016, the FDA asserted its authority to regulate e-cigarettes by deeming e-cigarettes containing nicotine to be “tobacco products” subject to FDA authority.¹⁷⁸ The resulting regulations define the next e-cigarette regulatory environment. Under these regulations, sales to minors are prohibited and advertising and promotional efforts are limited. The rules also subject e-cigarettes to stringent premarket review requirements. As noted above, these requirements apply to all tobacco products that are not substantially equivalent to products that were marketed before 2007, at which time there were few e-cigarettes on the market. These policy changes will increase the cost of bringing new cigarette alternatives to market while still offering opportunities to expand the market and establish new brands.¹⁷⁹ Moreover, the FDA appears to be applying the “substantial equivalent” requirement quite stringently, imposing significant costs on producers that will be borne most readily by larger firms. These requirements are likely to impose substantial burdens on smaller manufacturers and distributors and further enhance the competitive advantage of traditional cigarette manufacturers that seek to make inroads within the e-cigarette market.

The FDA’s new regulations do not address the MSA revenue problem or the federal tobacco tax problem, however. To bring e-cigarettes under the MSA will require actions by the state attorneys general deeming e-cigarettes as cigarettes under the agreement because they “contain . . . tobacco,” insofar as they contain nicotine that is derived from tobacco, and are “heated under ordinary conditions of use.” If e-cigarettes are to be subject to federal excise taxes now applied to tobacco products, Congressional action will be required. Thus, it is unlikely that the FDA’s new regulations will end the jockeying to define the e-cigarette regulatory framework.

The FDA is not the only regulator of e-cigarettes and other tobacco alternatives. Many state and local governments have begun to regulate e-cigarettes sale and use, either as part of existing smoking regulations or separately enacted rules.¹⁸⁰ State legislatures have also begun to consider whether e-cigarettes and other cigarette alternatives should be subject to tobacco taxes or substitute levies.

178. Deeming Tobacco Products to Be Subject to FDCA, *supra* note 1.

179. See Mickle, *supra* note 2 (citing estimated costs of \$2 million to \$10 million per product for premarket approval).

180. See Tripp Mickle, *States Dash to Regulate E-Cigarettes*, WALL ST. J. (Jan. 30, 2015), <http://www.wsj.com/articles/states-dash-to-regulate-e-cigarettes-1422668141>; *States and Municipalities with Laws Regulating Use of Electronic Cigarettes*, AM. NONSMOKERS’ RTS. FOUND. (Apr. 4, 2016), www.no-smoke.org/pdf/ecigslaws.pdf.

IV. Baptists, Bootleggers & E-Cigarettes

The chaotic competitiveness of the rapidly growing e-cigarette dispensing industry is not surprising. When there is new low-cost technology, start-up firms enter, exit, and, in some cases, become acquired by more seasoned competitors. We doubt that the current competitiveness will be the industry equilibrium. All firms prefer cartels that coordinate pricing and output to chaotic competition. Firms that are already a part of a Bootlegger/Baptist agreement with regulators will surely seek to enlist new, worrisome competitors into the cartel camp. As discussed more below, e-cigarette producers, be they newly formed firms or members of the Big 2, could be lured or dragooned into the MSA fold, as some members of Congress have already suggested.¹⁸¹ This is a possibility because critically important interest groups have much to gain by making e-cigarette producers contributors to MSA revenues. In particular, a coalition of Bootleggers and Baptists who prefer to see greater regulation of and rent extraction from e-cigarettes could seek to draw traditional cigarettes' greatest competitive threat into the MSA cartel.

In the case of e-cigarettes, a Bootleggers and Baptists coalition is forming. As we discuss next, the coalition is composed of the tobacco companies (Bootleggers) and makers of nicotine replacement therapies that see their markets threatened by a new product. Some public health advocates (Baptists) oppose e-cigarettes and wish to see them strictly regulated or prohibited. State governments, that enjoy tobacco tax revenue and have sold bonds backed by tobacco tax revenue now threatened by the decline in cigarette sales, are also Bootleggers. Alone, each interest may be too weak to control the future of the e-cigarette market, but the coalition of diverse interests, even if not directly collaborative, could well impose significant controls on e-cigarettes.

A. Baptists: Those Who Want E-cigarettes Regulated or Banned

Private and public health officials have long assailed cigarettes, as the MSA attests. They are the Baptists in this story—those concerned for the health of others. Many anti-smoking groups, such as the Campaign for Tobacco-Free Kids, have called for greater regulation of e-cigarettes including, but not limited to, measures to control access to such products by children.¹⁸²

181. Press Release, H. Comm. on Energy & Commerce, Democratic Leaders Urge State Attorneys General to Bring e-Cigarettes Under Tobacco Master Settlement Agreement (Feb. 12, 2014). This call for action was reiterated late in 2014. See Press Release, H. Comm. on Energy & Commerce, Democratic Leaders Urge FDA Action, Call for State Attorneys General to Classify e-cigarettes Under the Master Settlement Agreement (Dec. 19, 2014).

182. See *E-Cigarettes and Lung Health*, AM. LUNG ASS'N (2015), <http://www.lung.org/stop-smoking/tobacco-control-advocacy/federal/e-cigarettes.html>; Matthew L. Meyers, *FDA Oversight is Key to Minimizing Risks of e-Cigarettes, Especially to Kids, and Realizing Potential*, CAMPAIGN FOR TOBACCO-FREE KIDS (Oct. 24, 2015) http://www.tobaccofreekids.org/tobacco_unfiltered/tag/e-cigarettes; *Position Statement on Electronic*

Past anti-smoking coalitions, including the iconic American Heart Association, American Cancer Association, and American Lung Association have been successful in lobbying for legislative and regulatory changes that restrict advertising and marketing practices, especially when their sought-after changes have accommodated the long-run strategies of dominant tobacco industry bootleggers. Only now, the debate is a bit more complex than past struggles that had to do with limiting the sale of cigarettes to young people. After all, e-cigarettes can be viewed as forming an avenue that reduces smoking.

Based on what is known about the health effects of e-cigarette use, it would seem e-cigarettes might be hailed as an advance in public health insofar as they attract cigarette smokers to a safer product. Even small reductions in the number of smokers or even in the amount of tobacco products that smokers consume, would likely produce substantial gains for public health. Yet e-cigarettes have been greeted with scorn in some quarters or, at a minimum, suspicion, by health researchers. Even those that acknowledge the potential benefits of e-cigarettes call for increased federal regulation.¹⁸³

Critics of e-cigarettes note that little is known about the health effects of these products, and long-term effects in particular. As the FDA acknowledged when proposing its deeming rule, the agency does “not currently have sufficient data about these products to determine what effects e-cigarettes have on public health.”¹⁸⁴ Some studies have confirmed that e-cigarettes themselves or e-cigarette vapor do contain potentially dangerous substances, even if at lower levels than are found in cigarette smoke.¹⁸⁵ Therefore, some researchers are

Cigarettes [ECs] or Electronic Nicotine Delivery Systems [ENDs], INT’L UNION AGAINST TUBERCULOSIS & LUNG DISEASE, (Oct. 2013), http://www.theunion.org/what-we-do/publications/official/body/E-cigarette_statement_FULL.pdf; see also *infra* notes 184-90 and accompanying text (discussing health concerns about use of e-cigarettes).

183. See, e.g., Aruni Bhatnagar et al., *Electronic Cigarettes: A Policy Statement from the American Heart Association*, 130 CIRCULATION 1418 (2014).

184. Deeming Tobacco Products to Be Subject to FDCA, *supra* note 2, at 23144. In the *Federal Register* notice accompanying the final rule, the FDA disclaimed any legal obligation to only deem products where such action is necessary to protect public health, but also argued that “regulation of the newly deemed products will be beneficial to public health.” Deeming Tobacco Products to Be Subject to FDCA, *supra* note 1, at 28983.

185. See, e.g., Vicky Yu et al., *Electronic Cigarettes Induce DNA Strand Breaks and Cell Death Independently of Nicotine in Cell Lines*, 52 ORAL ONCOLOGY 58 (2015) (finding that e-cigarette vapor is potentially cytotoxic). In response to news reports, the study authors noted, “Contrary to what was stated or implied in much of the news coverage resulting from this news release, the lab experiments did not find that e-cigarette vapor was as harmful to cells as cigarette smoke. In fact, one phase of the experiments, not addressed in the news release, found that cigarette smoke did in fact kill cells at a much faster rate.” Press Release, Veterans Affairs Research Comm’ns, Cell Harm Seen in Lab Tests of E-Cigarettes (Dec. 28, 2015), http://www.eurekalert.org/pub_releases/2015-12/varchs122815.php; see also Joseph G. Allen et al., *Flavoring Chemicals in e-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored e-Cigarettes*, 2015 ENVTL. HEALTH PERSP. 1 (finding presence of contaminant linked to “popcorn lung”); R. Paul Jensen et al., *Hidden Formaldehyde in e-Cigarette Aerosols*, 372 N. ENG. J. MED. 392 (2015). But see Clive D. Bates & Konstantinos E. Farsalinos, *Research Letter on e-Cigarette Cancer Risk Was So Misleading It Should Be Retracted*, 110 ADDICTION 1686 (2015); Michael Siegel, *New*

concerned that e-cigarettes may turn out to be more dangerous than some suppose, or may replace the risks of smoking with other risks.¹⁸⁶ Additionally, given the degree of innovation and churn within the industry, there is relatively little standardization of products, especially among smaller producers. Thus, even if the most commonly marketed e-cigarettes are generally safe, the same may not be so of products made by independent producers or individual vape shops.¹⁸⁷ There are also independent concerns about the safety, labeling, and packaging of nicotine-containing vaping fluid sold in bottles or cartridges.¹⁸⁸

A particularly powerful concern is that e-cigarette use could encourage nicotine addiction and either prolong nicotine addiction among smokers that might otherwise have quit or serve as a “gateway” to use of traditional tobacco products, among children especially.¹⁸⁹ Dr. Tom Frieden of the Centers for Disease Control and Prevention (CDC), for example, opposes e-cigarettes because he believes they will attract young people, who will then migrate to cigarettes, and that e-cigarettes will also lead former smokers back to smoking.¹⁹⁰ The 2014 National Youth Tobacco Survey found that e-cigarette use among high school students increased substantially from 2013 to 2014.¹⁹¹ At the same time, cigarette and cigar use among high school students declined significantly.¹⁹² As the CDC noted, 2014 was the first year in which teen use of

Study Finds that Average Diacetyl Exposure from Vaping is 750 Times Lower than from Smoking, THE REST OF THE STORY: TOBACCO ANALYSIS & COMMENT. (Dec. 10, 2015, 9:37 AM), <http://tobaccoanalysis.blogspot.com/2015/12/new-study-finds-that-average-diacetyl.html>.

186. See, e.g., M. Zeller & D. Hatsukami, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the U.S.*, 18 TOBACCO CONTROL 324 (2009).

187. Some critics are particularly concerned about the quality control of vaping fluid and e-cigarette components imported from China. See Matt Richtel, *Selling a Poison by the Barrel: Liquid Nicotine for e-Cigarettes*, N.Y. TIMES (Mar. 23, 2014), <http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html> (discussing quality control problems with imported vaping fluid). See generally David Barboza, *China's e-Cigarette Boom Lacks Oversight for Safety*, N.Y. TIMES (Dec. 13, 2014), <http://www.nytimes.com/2014/12/14/business/international/chinas-e-cigarette-boom-lacks-oversight-for-safety-.html> (discussing concerns about lack of oversight of imported e-cigarette products, including vaping fluid).

188. These concerns have led to the FDA considering a regulation that would specifically address the safety of nicotine-containing fluid. See Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco products; Request for Comments, 80 Fed. Reg. 37,555 (proposed July 1, 2015).

189. Kelvin Choi & Jean Forster, *Characteristics Associated with Awareness, Perceptions, and Use of Electronic Nicotine Delivery Systems Among Young U.S. Midwestern Adults*, 103 AM. J. PUB. HEALTH 556 (2013); Lauren M. Dutra & Stanton A. Glantz, *Electronic Cigarettes and Conventional Cigarette Use Among U.S. Adolescents*, 168 J. AM. MED. ASS'N PEDIATRICS 610 (2014); see also John P. Pierce, *Harm Reduction or Harm Maintenance?*, 4 NICOTINE & TOBACCO RES. S53 (2002) (discussing concerns with harm reduction approach to tobacco use).

190. Karen Kaplan, *CDC Director Explains What He Hates About Electronic Cigarettes*, L.A. TIMES (Apr. 29, 2014), <http://www.latimes.com/science/sciencenow/la-sci-sn-why-tom-frieden-hates-electronic-cigarettes-cdc-20140429-story.html>.

191. Rene A. Arrazola et al., *Tobacco Use Among Middle and High School Students—United States, 2011–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 381, 383 (Apr. 17, 2015).

192. *Id.*; see also Jacob Sullum, *Smoking and Vaping Keep Moving in Opposite Directions*, REASON: HIT & RUN BLOG (Apr. 16, 2015, 10:31 PM),

e-cigarettes was greater than teen use of traditional tobacco products.¹⁹³ One possible explanation of this trend is that teens who would otherwise have smoked cigarettes are using e-cigarettes instead.¹⁹⁴ Interestingly enough, recent research suggests that restrictions on youth access to e-cigarettes can increase youth smoking rates.¹⁹⁵ This is further evidence that, at least for some users, e-cigarettes are substitutes for traditional tobacco products.

The World Health Organization (WHO) has also expressed grave concern.¹⁹⁶ It declared early after the introduction of e-cigarettes: “Nicotine is a highly toxic and addictive substance that poses a serious risk to health.”¹⁹⁷ However, as noted above, this statement is not consistent with the evidence. Nicotine can be toxic — almost everything is at some level. WHO recommended that e-cigarettes be regulated under tobacco laws, and that there should be prohibitions against use in public and restrictions on advertising and promotions.¹⁹⁸ In 2012, WHO said more study of the matter is needed but that controls similar to tobacco products are needed.¹⁹⁹ Similarly, the European Parliament recommends consistent regulation of e-cigarettes across EU countries, including advertising restrictions, controls on product design, and other controls similar to those on tobacco.²⁰⁰

<http://reason.com/blog/2015/04/16/smoking-and-vaping-are-still-moving-in-o> (dismissing claims that e-cigarette use leads to tobacco use); Graham Moore, et al., *Electronic-cigarette use among young people in Wales: evidence from two cross-sectional surveys*, 5 *BMJ OPEN* (2015) <http://bmjopen.bmj.com/content/5/4/e007072> (“e-cigarettes are unlikely to make a major direct contribution to adolescent nicotine addiction.”).

193. Press Release, Ctrs for Disease Control, E-Cigarette Use Triples Among Middle and High School Students in Just One Year (Apr. 16, 2015), <http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html>.

194. See, e.g., Sullum, *supra* note 192.

195. See Abigail S. Friedman, *How Does Electronic Cigarette Access Affect Adolescent Smoking?*, 44 *J. HEALTH ECON.* 300 (2015); Michael Pesko et al., *The Influence of Electronic Cigarette Age Purchasing Restrictions on Adolescent Tobacco and Marijuana Use*, 2016 *PREVENTIVE MEDICINE* 1.

196. See Grana et al., *supra* note 167 (summarizing report of the WHO Tobacco Free Initiative); see also Ann McNeill et al., *A Critique of a World Health Organization-Commissioned Report and Associated Paper on Electronic Cigarettes*, 109 *ADDICTION* 2128 (2014) (critiquing WHO report).

197. Framework Convention on Tobacco Control, *Control and Prevention of Smokeless Tobacco Products and Electronic Cigarettes*, *FCTC/COP/4/12*, WORLD HEALTH ORG., 6, (Sept. 15, 2010), http://apps.who.int/gb/ftc/PDF/cop4/FCTC_COP4_12-en.pdf.

198. *WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation*, WORLD HEALTH ORG. TECHNICAL REP. S. 39-40 (2010), http://apps.who.int/iris/bitstream/10665/44213/1/9789241209557_eng.pdf.

199. Framework Convention on Tobacco Control, *Electronic Nicotine Delivery Systems, Including Electronic Cigarettes*, *FCTC/COP/5/13*, WORLD HEALTH ORG. (June 18, 2012), http://apps.who.int/gb/ftc/PDF/cop5/FCTC_COP5_13-en.pdf.

200. The Directive asserts that competition will be enhanced if all EU members adopt identical regulations. Council Directive 2014/40, 2014 O.J. (L 127) 1, 7 (EC), http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf.

B. Bootleggers: Those Who Profit from Restrictions on E-Cigarettes

There are substitutes in every market. E-cigarettes are a substitute for traditional cigarettes for some smokers. This makes e-cigarettes a threat to the traditional cigarette industry. For this reason, traditional cigarette manufacturers have an incentive to either enter the e-cigarette market themselves, suppress competition from upstart e-cigarette manufacturers, or both.²⁰¹ As one would predict, cigarette manufacturers have pursued both strategies, developing or acquiring their own lines of e-cigarette products and supporting regulatory measures that could suppress competition.

Altria, the nation's largest cigarette manufacturer and the producer of MarkTen e-cigarettes, urged the FDA to regulate "all currently unregulated tobacco products."²⁰² Among other things, Altria urged the FDA to subject all such products to premarket review requirements.²⁰³ Such requirements will particularly burden smaller firms and new market entrants, to the advantage of the major cigarette producers. Reynolds has also urged greater federal regulation and supported the FDA's assertion of authority over e-cigarettes. Specifically, Reynolds called upon the FDA to prohibit all "open-system vapor products."²⁰⁴ Even though such systems can be used without nicotine, Reynolds argues that such products "create unique public health risks."²⁰⁵ Such products also appear to be increasingly popular and to pose the greatest competitive risk to established market players.²⁰⁶

Just as the MSA has served to protect the dominant cigarette manufacturers from smaller producers and new market entrants, extensive regulation of e-cigarettes — including limits on advertising and requirements that new e-cigarette brands or products become subject to an extensive permitting or pre-approval regime — may make it more difficult for newer and smaller e-cigarette manufacturers to compete. Larger, more-established firms will have an easier time affording and navigating such requirements than their newer and smaller competitors. They also benefit from an existing distribution system that is likely to give them preferential shelf space in smoke shops, convenience stores, and the like.

Despite the lack of evidence that e-cigarette use poses significant health risks, large cigarette manufacturers have begun to place detailed health

201. As noted above, some research already indicates that restrictions on e-cigarettes may lead to greater smoking rates. See Friedman, *supra* note 195.

202. Letter from James E. Dillard III, Senior Vice President, Regulatory Affairs, Altria Client Servs., Inc., to Dr. Margaret A. Hamburg, Comm'r, Food & Drug Admin. (Oct. 10, 2013), <http://www.altria.com/About-Altria/Federal-Regulation-of-Tobacco/Regulatory-Filing/FDAFilings/Support-of-Unregulated-Tobacco-%20Products.pdf>.

203. *Id.*

204. Craver, *supra* note 133.

205. *Id.*

206. See Cooper, *supra* note 134 ("[T]he open devices are a platform for flavor innovation that could make it difficult for big tobacco companies to keep up.").

warnings on their e-cigarette products, including messages that warn of the potential dangers of nicotine.²⁰⁷ Altria, for instance, has a warning that reads, in part, “Nicotine is addictive and habit forming, and is very toxic by inhalation, in contact with the skin, or if swallowed.”²⁰⁸ These warnings are far more explicit than those currently required on cigarette packages, leading some to believe they are part of a “cynical business strategy.”²⁰⁹ The adoption of such labels may make the larger companies appear to be more responsible than other, smaller companies that do not place equivalent labels on their products and could help build support for competition-limiting regulation of e-cigarettes — regulation that could work to larger cigarette manufacturers’ advantage.²¹⁰

E-cigarettes are also a potential substitute for other products that may satisfy smokers’ desire for nicotine. Quitting smoking is not easy, so firms have invented products to help wean smokers away from traditional cigarettes. For some years now, nicotine gum, lozenges, patches, and inhalers (all NRTs) have been the primary ways smokers can continue to get nicotine doses without exposing themselves to the unhealthy side products present in traditional cigarettes. The WHO, which is hostile to e-cigarettes as just discussed, lists nicotine gum and patches on its essential medicines list for “disorders due to psychoactive substance use.”²¹¹ Many of these products are available over-the-counter and are encouraged by public health officials.

Pharmaceutical companies that make NRT products, such as GlaxoSmithKline (GSK), are among the Bootleggers in our story. They have benefitted from government’s encouragement of smokers to use their products to aid in smoking cessation as well as from government limitations on information on tobacco harm reduction through the use of e-cigarettes or smokeless tobacco products. Insofar as e-cigarettes are an alternative way for smokers to satisfy their nicotine cravings, they are a threat to the profitability of NRT products. This is particularly so given recent research suggesting that NRT products do not help many smokers quit.²¹²

207. Matt Richtel, *Dire Warnings by Big Tobacco on E-Smoking*, N.Y. TIMES (Sept. 28, 2014), <http://www.nytimes.com/2014/09/29/business/dire-warnings-by-big-tobacco-on-e-smoking-.html>.

208. *Id.*

209. *Id.*

210. No doubt such a warning gladdens the CDC director who, as noted above, greatly dislikes e-cigarettes. His agency reported that e-cigarette use among teens has increased. See *Tobacco Use Among Middle and High School Students—United States, 2013*, CTDS FOR DISEASE CONTROL & PREVENTION (2014), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a2.htm?s_cid=mm6345a2_w. It should not be surprising that experimentation with a new product is occurring. Despite experimenting with e-cigarettes, smoking among that age group continues to decline.

211. *WHO Model List of Essential Medicines*, WORLD HEALTH ORG., 32 (18th ed. 2013), http://apps.who.int/iris/bitstream/10665/93142/1/EML_18_eng.pdf?ua=1.

212. There is relatively limited evidence that NRTs are an effective means of helping smokers to quit. See, e.g., David Moore et al., *Effectiveness and Safety of Nicotine Replacement Therapy Assisted Reduction to Stop Smoking: Systematic Review and Meta-Analysis*, 338 BRIT. MED. J. 867 (2009); Shu-Hong Zhu et al., *Interventions to Increase Smoking Cessation at the Population Level: How*

GSK's chief executive has admitted that e-cigarettes have cut into NRT sales.²¹³ Unsurprisingly, GSK and other NRT manufacturers pushed for greater regulation of e-cigarettes, in some cases calling for e-cigarettes to be as extensively regulated as medical devices.²¹⁴ In comments to the FDA, GSK contended that e-cigarettes are "recreational" and "have not been proven to help smokers quit." (GSK's products, on the other hand, are described as "medicine.")²¹⁵ GSK urged the FDA to treat e-cigarettes as the equivalent of cigarettes for regulatory purposes and subject them to the same advertising and other restrictions as traditional tobacco products.²¹⁶

The Patient Protection and Affordable Care Act of 2010 (ACA/ "ObamaCare") provides a financial incentive for smokers to quit and encourages the use of NRT products as part of smoking cessation efforts. Whereas the ACA generally prohibits medical underwriting — the practice of pricing health insurance based upon the insured's health status and other indicators of expected risk — it allows insurance companies to charge current smokers as much as 50 percent more for health insurance coverage, unless the smoker enrolls in an approved smoking cessation program. The imposition of any such surcharges, however, is conditioned on state approval, and some states have prohibited or limited the surcharges. In addition, the ACA requires insurance plans to cover comprehensive smoking cessation treatments as a form of preventative care. As with the contraception mandate, this coverage must be offered without cost-sharing by the insured and is meant to include all FDA-

Much Progress Has Been Made in the Last Two Decades?, 21 TOBACCO CONTROL 110 (2012). An older survey article indicates the low success rate of NRTs. See J.R. Hughes et al., *A Meta-Analysis of the Efficacy of Over-the-Counter Nicotine Replacement*, 12 TOBACCO CONTROL 21 (2003). For critical commentary on the usefulness of NRT products, and the active political role played by the pharmaceutical companies that promote them, see Michael Siegel, *THE REST OF THE STORY: TOBACCO NEWS ANALYSIS & COMMENT.*, tobaccoanalysis.blogspot.com. See, e.g., Michael Siegel, *New Study Finds No Benefits to Use of Over-the-Counter NRT for Smoking Cessation*, THE REST OF THE STORY (Oct. 14, 2014, 6:33 AM), <http://tobaccoanalysis.blogspot.com/2014/10/new-study-finds-no-benefits-to-use-of.html>; Michael Siegel, *Big Pharma Gets its Money's Worth: Study by Pharma-Funded Researchers Reports Invalid Data to Show that NRT Works When the Correct Study Data Shows No Effect*, THE REST OF THE STORY (Jun. 24, 2013, 6:24 AM), <http://tobaccoanalysis.blogspot.com/2013/06/big-pharma-gets-its-moneys-worth-study.html>.

213. Nic Fides, *Glaxo Boss Bemoans Rise of 'Vaping'*, THE TIMES (Jan. 17, 2015), <http://www.thetimes.co.uk/tto/business/industries/health/article4325917.ece>.

214. See, e.g., Timothy P. Carney, *Big Pharma, Not Tobacco Companies, Wages War on Electronic Cigarettes*, WASH. EXAMINER (Nov. 19, 2013), <http://washingtonexaminer.com/big-pharma-not-tobacco-companies-wages-war-on-electronic-cigarettes/article/2539441>; Makiko Kitamura, *Glaxo Memo Shows Drug Industry Lobbying on e-Cigarettes*, BLOOMBERG BUS. (Feb. 19, 2014), <http://www.bloomberg.com/news/2014-02-19/glaxo-memo-shows-drug-industry-lobbying-on-e-cigarettes.html>.

215. Letter from Erin Oliver, Head, U.S. Regulatory Affairs, GlaxoSmithKline Consumer Healthcare, to Food & Drug Admin. (Aug. 8, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-62796> (concerning the proposed rule that tobacco products be subject to FDA control).

216. *Id.*

approved forms of smoking cessation medications and over-the-counter NRTs.²¹⁷

Even with the financial incentive for greater NRT use, existing NRT product makers are threatened by the emergence of e-cigarettes. E-cigarettes are cutting into NRT product sales.²¹⁸ Compounding the threat posed by a new entrant in the NRT market would be evidence that e-cigarettes are more effective than traditional NRT products at helping smokers quit or reduce cigarette consumption, as at least one large scale study found.²¹⁹ Another study found evidence that e-cigarettes may be superior to traditional NRT for methadone-maintained smokers.²²⁰ Another study found that e-cigarette users liked the product more than did the users of other NRT products and that there were fewer withdrawal problems for e-cigarette users.²²¹ Given such research, there seems to be good reason for the makers of traditional NRT products to be concerned about the emergence of e-cigarettes.

C. Bootleggers & Politicians

State governments are Bootleggers in our story as well. But they are not just run-of-the mill Bootleggers. Their voices are loud and their influence is deep. They are “a player in the political process who will assist Bootleggers and Baptists in expanding their regulatory gains.”²²² Huge amounts of tax revenues are at stake in regulating e-cigarettes. Tobacco sellers have become global tax collectors for states and the national governments. Philip Morris International pays more than sixty percent of its gross revenues to governments

217. *FAQs About Affordable Care Act Implementation (Part XIX)*, DEP'T OF LABOR, <http://www.dol.gov/ebsa/faqs/faq-aca19.html> (last updated May 2, 2014). According to news reports, coverage of smoking cessation programs, medications, and NRTs has been inconsistent to date. Ferdous Al-Faruque, *Trying to Quit Smoking? Administration Clarifies ObamaCare Rules*, THE HILL (May 4, 2014), <http://thehill.com/policy/healthcare/205090-administration-clarifies-o-care-tobacco-cessation-requirements>.

218. *How e-Cigarettes Are Killing the Nicotine Patch Market in Europe*, VAPE RANKS (Jan. 27, 2014), <http://vaperanks.com/how-e-cigarettes-are-killing-the-nicotine-patch-market-in-europe>.

219. E-cigarettes may be the most effective NRT, although all work better with coincident behavioral therapy. A study involving almost 6,000 smokers found e-cigarettes to be significantly more effective than over-the-counter NRT in producing abstinence from smoking tobacco. See Jamie Brown et al., *Real-World Effectiveness of e-Cigarettes When Used to Aid Smoking Cessation*, 109 ADDICTION 1531 (2014).

220. Michael D. Stein et al., *An Open Trial of Electronic Cigarettes for Smoking Cessation Among Methadone-Maintained Smokers*, 18 NICOTINE TOBACCO RES. 1157 (2015).

221. Victoria A. Nelson et al., *Comparison of the Characteristics of Long-Term Users of Electronic Cigarettes Versus Nicotine Replacement Therapy*, 153 DRUG ALCOHOL DEPENDENCE 300 (Aug. 1, 2015). See also Cristina Russo et al., *Evaluation of Post Cessation Weight Gain in a 1-Year Randomized Smoking Cessation Trial of Electronic Cigarettes*, SCI. REP. (2016), <http://www.nature.com/articles/srep18763> (finding evidence use of e-cigarettes may help limit post-smoking cessation weight gain).

222. Yandle, et al., *supra* note 39, at 1230.

around the world.²²³ But consider the critical position of the states. As discussed earlier, the 1998 MSA established a large and continual flow of revenues to the jurisdictions it covered.²²⁴ On the date of the settlement, it was estimated that a total of \$229 billion would be paid to the state treasuries across the years 1998-2025, although there was no end-point to the stream of payments.²²⁵ Payments are to be made annually on April 15. The amount paid to each state is based on a negotiated formula that reflected individual state smoking rates, the level of cigarette taxes, Medicaid, and other health care expenditures.²²⁶

For any given year, tobacco company cigarette sales revenues determine the total allocated to the states. Rising and falling revenues bring variations in the amounts paid to individual states in a given year. In 2002, MSA payments to the states were \$7 billion. Added to that were state tobacco excise tax revenues of \$9.2 billion. By 2012, MSA payments fell to \$6.2 billion, but excise revenues were up to \$17 billion.²²⁷ This reflected a combination of factors. First, in an effort to obtain revenues for government operations and to reduce smoking, states nationwide raised tobacco excise taxes markedly. Second, the MSA called for higher payments beginning in 2008 and continuing thereafter. Third, the MSA included an inflation adjustment of three percent annually or the increase in the CPI, whichever was larger. And fourth is the effect of the decline in cigarette consumption, which now more than offsets the annual inflation adjustment. As a result of these forces, total tobacco-related state revenues appear to have peaked and seem likely to fall further in the future. Declining revenues raise serious issues regarding payments that must be made by the states to holders of bonds securitized with tobacco MSA revenues, a topic we address more fully below.²²⁸

223. Daniel Fisher, *Philip Morris International Bets Big on the Future of Smoking*, FORBES (May 28, 2014), <http://www.forbes.com/sites/danielfisher/2014/05/28/philip-morris-international-bets-big-on-the-future-of-smoking>.

224. U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-502, TOBACCO SETTLEMENT: STATES' ALLOCATION OF FISCAL YEAR 2005 AND EXPECTED FISCAL YEAR 2006 (2006), <http://www.gao.gov/assets/250/249651.pdf>.

225. Craig L. Johnson et al., *Tobacco Securitization and Public Spending*, 6 ALBANY GOV'T L. REV. 21, 22 (2013).

226. Kip Viscusi & Joni Hersch, *Tobacco Regulation through Litigation: The MSA Agreement*, in REGULATION VERSUS LITIGATION 71, 78 (Daniel P. Kesler ed., 2011).

227. For tax revenue data, see *Tobacco Tax Revenue*, TAX POL'Y CTR., URB. INST. & BROOKINGS INST. (Nov. 24, 2015), <http://www.taxpolicycenter.org/statistics/tobacco-tax-revenue>. For tax revenue information from 2012, see *Michigan's Cigarette & Tobacco Taxes, 2012 Statistical Update*, MICHIGAN.GOV, http://www.michigan.gov/documents/treasury/CigaretteTobaccoTaxes2012StatisticalUpdate_432536_7.pdf. For data on MSA payments, see *Actual Tobacco Settlement Payments Received by the States, 2002-2014*, CAMPAIGN FOR TOBACCO-FREE KIDS (Dec. 23, 2014), <http://www.tobaccofreekids.org/research/factsheets/pdf/0365.pdf>. MSA payments include less than \$100 million annually in total to American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands. *Id.*

228. See *infra* notes 230-245 and accompanying text.

The MSA did not stipulate how the windfall revenues should be spent. Health care advocates in state legislative bodies pressed for a significant amount to be allocated toward smoking cessation programs and other activities that would help reduce the consumption of cigarettes and other tobacco products. But support for the health-care position was far from monolithic. There were other state politicians who simply wanted more revenue for favorite projects like roads, schools, higher teacher salaries, and improved legislator pay. The health-care Baptists have been disappointed.

According to CDC studies reported by the Campaign for Tobacco-Free Kids, “[o]ver the past 15 years, the states have received \$390.8 billion in tobacco-generated revenue—\$116.3 billion from the tobacco settlement and \$274.5 billion from tobacco taxes. But they have spent only 2.3 percent of their tobacco money—\$8.9 billion—on tobacco prevention programs.”²²⁹ In fiscal year 2014, the states collected an estimated \$25 billion from the tobacco settlement and tobacco taxes, but planned to spend only 1.9 percent of it — \$481.2 million — on tobacco prevention and cessation programs. States, now addicted to cigarette sales revenues, have become regulatory Bootleggers—they do not wish for tobacco sale revenues to fall and fear the possible impact of e-cigarettes. Of course, like other regulatory Bootleggers, they must never speak this publicly.

In the wake of the settlement, some state politicians saw a short-run opportunity to get control of even more revenue by securitizing all or part of the MSA cash flow by selling tobacco revenue bonds so they could immediately spend the present value of the future revenue. This was done in some cases by establishing a special purpose vehicle, such as a trust or separate state corporation, created for the specific purpose of issuing and managing the tobacco bonds.²³⁰ Selling bonds gave incumbent politicians the opportunity to dispense largess to benefit their supporters immediately.²³¹ The sale of tobacco bonds also generated a new group of Bootleggers with intense interest in the future fortunes of the tobacco companies, their sales, and any competitor that might carve away part of the tobacco market: the bondholders and the state agencies that issued the bonds.

Once tobacco bonds were sold, issuing states were not technically liable for payment to the bondholders, unless they had included in the bonds state

229. Press Release, Campaign for Tobacco-Free Kids, *Fifteen Years after Tobacco Settlement Report Finds Most States Continue to Shortchange Prevention Programs* (Dec. 9, 2013), http://www.tobaccofreekids.org/press_releases/post/2013_12_09_staterport.

230. See Frank Sloan & Lindsey Chepke, *Litigation, Settlement, and the Public Welfare: Lessons from the Master Settlement Agreement*, 17 WIDENER L. REV. 159, 219 (2011).

231. What happened with tobacco bond money after the bonds were sold has not always been consistent with high-minded promises. See Cory Eucalitto, *Tobacco Settlement Fund Gimmicks Alive and Well*, ST. BUDGET SOLUTIONS (Apr. 15, 2013), <http://www.statebudgetsolutions.org/publications/detail/tobacco-settlement-fund-gimmicks-alive-and-well>.

general fund guarantees, which some states did.²³² However, in the event of a tobacco company bankruptcy or other payment default, credit markets would likely still punish a state involved in bond issuance. It seems impossible for a state to completely separate itself from any debt issue that bears the state's name. Tobacco bonds were issued by eighteen states and the District of Columbia, through thirty-four separate bond issues that generated \$46 billion.²³³ As of 2014, debt outstanding, which includes subsequent issues for refinancing old debt, is reported to be \$94 billion.²³⁴ Included in the total is a special bond category called capital appreciation bonds (CABs), which require low annual payments until maturity when a large balloon payment must be made. CABs, issued by nine states, the District of Columbia, and a number of counties, will require a \$64 billion payoff when they mature.²³⁵ Some states that issued CABs have already experienced reduced credit ratings, based partly on declining tobacco revenues, according to a recent assessment.²³⁶

From 2005 to 2012, the percent of the adult population that smokes fell 13.4 percent.²³⁷ With cigarette sales falling due to new restrictions on smoking, higher cigarette taxes, increased health care concerns, and booming e-cigarette sales, tobacco bondholders have good reason to be more than a bit nervous.²³⁸ In May 2014, Moody's indicated that "[f]rom 65 percent to 80 percent of tobacco securities may fail to pay principal on time as demand for cigarettes falls short of assumptions."²³⁹

The growth of e-cigarettes further threatens tobacco bonds. It should be no surprise that there is pressure to revise the MSA to include e-cigarettes.²⁴⁰ Longtime Congressional supporters of tobacco regulation have urged states to

232. See Viscusi & Hersch, *supra* note 226, at 85.

233. Gary Ellis, *Analysis of Tobacco Revenue Settlement Bonds: Assessing Cigarette Consumption Decline Estimates*, 13 J. STRUCTURED FIN. 60, 60-62 (2006); Johnson, *supra* note 225, at 31.

234. Robin Respaut, *E-Cigarettes Could Stub Out Tobacco Bonds Sooner Than Thought*, REUTERS (June 24, 2014), <http://www.reuters.com/article/2014/06/24/us-tobacco-bonds-ecigs-insight-idUSKBN0EZ0CZ20140624>.

235. Cezary Podkul, *How Wall Street Tobacco Deals Left States with Billions in Toxic Debt*, PROPUBLICA (Aug. 7, 2014), <http://www.propublica.org/article/how-wall-street-tobacco-deals-left-states-with-billions-in-toxic-debt>.

236. *Id.*

237. As of 2012, 18.1 percent of the adult population smoked. *Current Cigarette Smoking Among Adults—United States, 2005-2012*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 17, 2014), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6302a2.htm?s_cid=mm6302a2_w. A survey of teens indicates a continued decline in smoking also. See Institute for Soc. Research, *Teen Smoking Continues to Decline in 2013, Annual Survey Shows*, UNIV. REC. (Dec. 18, 2013), <http://record.umich.edu/articles/teen-smoking-continues-decline-2013-annual-survey-shows>.

238. Aaron Kuriloff, *Tobacco Bonds May Feel Heat from e-Cigarettes*, WALL ST. J. (June 24, 2014), <http://online.wsj.com/articles/tobacco-bonds-feel-heat-from-e-cigarettes-1403648086>.

239. Brian Chappatta, *Gross's Tobacco Bond Gain Shows Default Risk Defied*, BLOOMBERG (May 20, 2014), <http://www.bloomberg.com/news/2014-05-20/gross-s-tobacco-bond-gain-shows-default-risk-defied-muni-credit.html>.

240. See Respaut, *supra* note 234.

classify e-cigarettes as tobacco products under the MSA.²⁴¹ According to these legislators, in letters to twenty-nine AGs, the reason for this is to protect “America’s youth” from e-cigarettes.²⁴² They contend that e-cigarettes meet the definition of “cigarettes” under the MSA because they contain tobacco (insofar as they contain nicotine derived from tobacco), are “heated under ordinary conditions of use,” and are “likely to be offered to, or purchased by, consumers as a cigarette.”²⁴³ Doing so would bring e-cigarettes under the same cartel-reinforcing and tax-revenue generating regime as traditional tobacco products, including limitations on advertising. The Baptists share in this regulatory zeal in the name of protecting youth. As a legal matter, however, it is not entirely clear how the MSA could be applied to e-cigarettes or VTM systems that do not contain nicotine, particularly if not manufactured by a company that is already subject to the MSA’s restrictions.

Tobacco bond trouble has therefore generated a powerful coterie of Bootleggers who would favor capturing e-cigarette revenues for the MSA cartel: the state agencies that issued the bonds, the investors holding the bonds, and the state governments that must trim possible spending. Alternatively, it is in the interest of state governments and bondholders to suppress the competitive threat posed by e-cigarettes to traditional cigarettes and to the source of revenue cigarettes provide. Thus it is not surprising that over two dozen state AGs have urged the FDA to adopt regulations, such as a prohibition on the use of flavorings in e-cigarettes, that would make e-cigarettes a less attractive alternative to cigarettes for current and former smokers.²⁴⁴ While state governments seem to be playing a Bootlegger role, the public may well see them as Baptists when politicians argue that vital state services that serve the public interest are being threatened by e-cigarette sales.²⁴⁵ Because of this

241. Editorial Board, *E-Cigarettes Cloud Progress on Teen Smoking: Our View*, USA TODAY (Dec. 16, 2014), <http://www.usatoday.com/story/opinion/2014/12/16/e-cigarettes-teen-smoking-university-of-michigan-editorials-debates/20485297>.

242. Press Release, Sen. Dick Durbin, Democratic Leaders Urge FDA Action, Call for State Attorneys General to Classify E-Cigarettes Under the Master Settlement Agreement (Dec. 22, 2014), <http://www.durbin.senate.gov/newsroom/press-releases/democratic-leaders-urge-fda-action-call-for-state-attorneys-general-to-classify-e-cigarettes-under-the-master-settlement-agreement>.

243. *Id.*

244. Elizabeth A. Harris, *29 States Seek Tighter e-Cigarette Regulations*, N.Y. TIMES (Aug. 8, 2014), <http://www.nytimes.com/2014/08/09/business/29-states-seek-tighter-e-cigarette-regulations.html>. For a copy of the letter from the attorneys general to the FDA, see Lisa Madigan et al., Comment Letter on Proposed Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act (Aug. 8, 2014), available at <http://online.wsj.com/public/resources/documents/fdaletter20140808.pdf>.

245. We see a similar dual Bootlegger and Baptist role being played by states under the 2010 Prevent All Cigarette Trafficking (PACT) Act, with the MSA signatories taking the straight Bootlegger position. The legislation requires tobacco product shippers to show proof that state excise taxes have been paid on tobacco products excluding cigars. Prior to PACT, states with high excise taxes (New York) were losing large amounts of revenue by way of the illegal sale of cigarettes from low tax states (North Carolina) as well as through Internet sales. Playing Baptists, the states argued that important public services were put at risk due to the leakage. We argue that the MSA signers, the straight Bootleggers in our interpretation, were also vitally interested in strengthening their revenue-

multifaceted performance, we have labeled state governments as possible televangelists. Indeed, they may be Bootleggers wearing Baptist clothing, or at least they appear to act that way, and have every incentive to do so.

D. E-Cigarettes & Excise Tax Revenues

Expanding e-cigarette sales provides a second reason for state governments, along with a few tobacco companies, to enter the “let’s regulate e-cigarettes” discussion. With the exception of Minnesota and North Carolina, where e-cigarettes are taxed, state revenues fall each time a consumer substitutes e-cigarettes for regular smokes. The average state excise tax per cigarette pack is \$1.54; in July 2014, state taxes per pack ranged from \$0.17 in Missouri to \$4.35 in New York.²⁴⁶ Some municipal governments add another layer of tax. For example, New York City imposes a \$1.50 per pack tax. The federal government adds an additional \$1.01 per pack nationwide.²⁴⁷ Thus, cigarette consumers in New York City pay \$6.86 per pack in taxes while e-cigarette consumers pay no excise taxes.²⁴⁸ As of this writing, several bills have been introduced in Congress that would impose federal excise taxes on e-cigarettes, but none has been acted upon.²⁴⁹ Because of differences in state and local excise taxes, the price of a package of Marlboro Reds ranges from a low of \$4.50 in Kentucky to \$14.50 in New York City.²⁵⁰ This prompts some actual bootlegging of cigarettes across state lines to evade the higher excise taxes.

The total of all these taxes and the MSA payments provide substantial government revenue. According to Reynolds, from 1998 — the time of the MSA — through 2013, tobacco companies transmitted \$528 billion to governments at all levels.²⁵¹ In fiscal year 2013, taxes collected on cigarettes included \$14.2 billion in federal taxes, \$17.1 billion in state and local government excise taxes, and \$4.0 billion in sales taxes. MSA payments that year totaled \$8.5 billion. The keepers of the coffers, kept full by one product

preserving MSA cartel. PACT empowered state AGs, who also police the MSA, to enforce the law, which passed Congress without a murmur. See Prevent All Cigarette Trafficking Act of 2009 (PACT Act), Pub. L. No. 111-154, 124 Stat. 1087 (2009) (codified as amended in scattered sections of 15 and 18 U.S.C.).

246. Campaign for Tobacco-Free Kids, *supra* note 229.

247. *Id.*

248. Note that the State of New York mandates minimum cigarette prices in the state and in New York City. See *Minimum Wholesale and Retail Cigarette Prices*, Pub. 509, N.Y. ST. DEP’T OF TAX’N & FIN., (Nov. 2015), <http://www.tax.ny.gov/pdf/publications/cigarette/pub509.pdf>.

249. Alex Brill & Alan D. Viard, *A Tax on Public Health*, U.S. NEWS & WORLD REP. (May 18, 2014), <http://www.usnews.com/opinion/economic-intelligence/2014/05/08/dont-tax-e-cigarettes-like-tobacco-products>.

250. Stephen Perlberg, *Here’s Why a Pack of Cigarettes Is So Darn Expensive in New York*, BUS. INSIDER (Feb. 5, 2014), <http://www.businessinsider.com/cigarette-excise-tax-by-state-2014-2>.

251. See *Tobacco Taxes & Payments*, TRANSFORM TOBACCO, REYNOLDS AMERICAN INC., <http://www.transformtobacco.com/Pages/TaxFacts.aspx>.

used by a falling fraction of the population, are understandably nervous about the certainty of their cash flows.²⁵²

Now consider consumers. For them, tax-free e-cigarettes are all the more attractive. Not only do they offer a less health-damaging alternative to traditional cigarettes, they are also less expensive. A back-of-envelope analysis illustrates.²⁵³ Given the variation in cigarette prices, a pack-a-day smoker can spend from \$1,500 in Missouri to \$5,000 in New York City annually. On average, across the states, cigarette smokers spend \$2,250 annually. One researcher found that “[m]ost disposable e-cigarettes say they’re equivalent to about 2 packs of cigarettes and cost \$6 to \$10 apiece, meaning they’d cost about \$1,100 to \$1,800 a year.”²⁵⁴ Using the author’s larger estimate, the savings would be small in Missouri, but as much as \$3,200 a year in New York City. The savings are even larger for rechargeable e-cigarettes and cartridges. With this product, the initial cost is \$10 to \$35. Cartridges cost \$2.50 each. This translates into savings of \$1,800 annually when compared to the average cost of smoking across all states. As median household income is about \$51,000, this would mean a 3.5 percent saving in gross income.²⁵⁵

Jim Craig, an e-cigarette user in Salt Lake City, told a reporter: “Cigarettes were getting horribly expensive . . . I’ve thrown endless thousands of dollars away.”²⁵⁶ Craig was spending \$200 a month on cigarettes. He now spends \$45 a month on e-cigarettes. These immediate financial benefits do not take into account the gains from reduced health hazards, reduced social opprobrium from switching away from traditional cigarette smoking, and reduced concerns smokers may have about secondhand smoke issues.

As noted, states are looking to tax e-cigarettes. In Minnesota, e-cigarettes are taxed as tobacco products and carry a ninety-five percent tax on their wholesale cost.²⁵⁷ Lawmakers in more than a score of states are joining the hunt for revenue.²⁵⁸ Those opposing taxation point out that incentives matter. Increasing the cost of e-cigarettes will discourage those who might beneficially switch away from harmful tobacco products. Such critics are joined by small retailers and vapor shop operators who make a “we just want to stay in

252. See *Tax Facts – History*, TRANSFORM TOBACCO, REYNOLDS AMERICAN, INC., <http://www.transformtobacco.com/Pages/TaxHistory.aspx>.

253. Michael Felberbaum, *For Smokers, Can E-Cigarettes Save Money?*, COLUMBUS CEO (June 30, 2014), <http://www.columbusceo.com/content/stories/apexchange/2014/06/30/us-smart-spending-electronic-cigarettes.html>.

254. *Id.*

255. However, smokers have, on average, lower income than the national average so the savings as a share of income are greater. See Amanda Noss, *Household Income: 2012*, CENSUS BUREAU (Sept. 2013), <http://www.census.gov/prod/2013pubs/acsbr12-02.pdf>.

256. Felberbaum, *supra* note 253.

257. See *E-Cigarettes*, MINN. DEP’T OF REVENUE (July 2015), <http://www.revenue.state.mn.us/businesses/tobacco/Pages/e-Cig.aspx>.

258. Barnini Chakraborty, *States Push to Regulate, Tax Booming E-Cigarette Industry*, FOX NEWS (Mar. 18, 2014), <http://www.foxnews.com/politics/2014/03/18/states-push-to-regulate-tax-booming-e-cigarette-industry>.

business” appeal, pointing out that high taxes could drive away their customers and shut them down. A recent Washington state e-cigarette tax initiative failed. It would have defined vapor products as tobacco substitutes, making them subject to a ninety-five percent tax expected to produce \$40 million in additional revenue. While not yet taxing e-cigarettes, Utah, North Dakota, and the District of Columbia have made e-cigarettes subject to their indoor-smoking ban, arguing that e-cigarettes should be regulated like other tobacco products.²⁵⁹

Just how e-cigarettes will be taxed and regulated is a high stakes question. With e-cigarette sales volume increasing — mostly at the expense of traditional cigarettes — the MSA-burdened tobacco companies are conflicted. They may desire to hold down the price of e-cigarettes for themselves, but they also may wish to put a price squeeze on their e-cigarette competitors. After all, the large tobacco companies will be selling e-cigarettes and would benefit from low prices. At the same time, the dominant firms might welcome having all e-cigarette sellers participate in the MSA to prevent having to face an even heavier MSA burden alone. Keeping excise taxes lower would mean larger e-cigarette revenues, which could supplement the MSA kitty.

Reynolds’s lobbying efforts illustrate the point. When North Carolina’s legislature was debating a bill to tax and regulate e-cigarettes, Reynolds lobbied in favor of the bill.²⁶⁰ In a February 2013 meeting in Washington, D.C., Reynolds met with various nonprofit groups and e-cigarette advocates. According to reports on the meeting, Reynolds announced a strategy to avoid the most severe regulatory restrictions. The company instructed their lobbyist to support taxing e-cigarettes across the states, but at a lower level than traditional cigarettes.²⁶¹ Reynolds argued that placing a tax on e-cigarettes would cause them to be viewed as a legitimate product; in other words, the product would become politically valuable and thus an asset to be used in forging future political agreements.

Greg Conley, then the legislative director for Consumer Advocates for Smoke-Free Alternatives Association (now president of the American Vaping Association) participated in the D.C. meeting with Reynolds. Conley indicated that “[w]hen Reynolds enters the market with e-cigarettes, they already have established relationships” that will give them a distribution advantage over their small e-cigarette competitors.²⁶² This advantage can be significant. Reynolds’ Vuse achieved substantial market share within weeks of its introduction into

259. *Id.*

260. Matthew Bandyk, *Tobacco Stubs out E-Cigarette Competitors*, DAILY CALLER (Apr. 6, 2013), <http://dailycaller.com/2012/04/06/big-tobacco-stubs-oput-e-cigarette-competitors>.

261. *Id.*

262. *Id.* Conley discussed Reynolds’s strategy further in Gregory Conley, *Big Tobacco’s War on Vaping*, NAT’L REV. ONLINE (Jan. 16, 2015, 4:00 AM), <http://www.nationalreview.com/article/396466/big-tobaccos-war-vaping-gregory-conley>.

select markets.²⁶³ The imposition of additional regulatory requirements on e-cigarette manufacturers is likely to further enhance the competitive strength of the Big 2.

In sum, as we look across the e-cigarette regulatory landscape, we see Bootleggers and Baptists jumping on the issue from different perspectives and interests. Among those easy to identify are state politician Bootleggers and televangelists who appear to be concerned about tobacco bond revenues but speak like Baptists when they cloak their revenue needs in a public interest appeal. They act as if they are concerned about lost MSA revenues that will occur as consumers switch from traditional cigarettes to e-cigarettes, and have every incentive to do so. The result could be greater state budget difficulties as tobacco revenues fall. Predictably, these same Bootleggers are looking for ways to classify e-cigarettes that do not contain tobacco as tobacco products so they can be taxed like cigarettes. Nearby are holders of tobacco bonds who are seeing degraded bond ratings and lost market value. The directors of the state agencies that issued those bonds are worried, too. Even though, in most cases, they bear no recourse liability, they know that a default on the tobacco bonds they issued could put an ugly credit rating bruise on future state bond issues. Then, there are some Bootleggers, like Reynolds, that have seen the handwriting on the wall. They are acting as though they hope to reduce dramatically the fortunes of e-cigarette producers by supporting favorable forms of Baptist-preferred regulation and taxation. Reynolds is harmonizing in the back row of the Baptist choir.

Conclusion

Cigarette makers, through the MSA and federal regulation, live in a highly taxed, regulated, and cartelized industry. Their cozy cartel has not been contested by new competition for years. But now they face competition from upstart e-cigarette companies, as the primary market for e-cigarettes is current cigarette smokers. Incumbents do not relish change, though there is no doubt that Big Tobacco is well positioned to move into e-cigarettes, as they have been doing, and are likely to do just fine in that market. But the story is more complicated than that. This is not just a matter of existing firms adapting to new technology or facing the prospect of withering away. Instead, the story is about influencing the next set of regulatory constraints to be faced by future industry players.

The Bootleggers and Baptists of the e-cigarette story look beyond competition between traditional cigarettes and e-cigarettes — they seek to influence the future regulatory environment within which e-cigarette producers will operate. The Baptists are public and private health advocates who are opposed to cigarettes and have expressed similar hostility to e-cigarettes. It is a

263. See *supra* note 138 and accompanying text.

somewhat fractured group, as a dissenting but distinct minority of health advocates believes that, properly regulated, e-cigarettes provide a realistic way to reduce dependence on traditional cigarettes and thereby reduce the primary health hazards posed by smoking cigarettes. As is often the case, the Baptists provide political cover for the Bootleggers who have real money on the line, not just high ideals about what is supposed to be good for people.

Bootleggers who wear Baptist clothing are the NRT makers, such as Nicorette's producer GSK, who are favored by federal health law. They are concerned that the sale of their products could take a direct hit as former smokers switch from such products to e-cigarettes. They have no interest in welcoming e-cigarette makers into the NRT club.

The traditional cigarette industry cartel and the key parties who benefit from the current structure are threatened by the rapid emergence of outside e-cigarette firms. The major tobacco companies are responding to the upstarts with e-cigarette products of their own. Their marketing and distribution expertise empower them to counter the threat from the initial e-cigarette innovators, particularly if regulatory measures increase the costs of entry into the market and create barriers for smaller, less-capitalized firms with less developed marketing and distribution networks. But while the cigarette companies can respond and gain e-cigarette revenues by doing so, the revenue they produce for MSA payments is reduced each time a traditional cigarette smoker switches to an e-cigarette. This creates another group of potential Bootleggers—states and bondholders.

States are facing declining tax revenue from traditional cigarettes and, similarly disturbing, are facing the possibility of default on tobacco bonds. States do not relish tarnished fiscal reputations and bondholders have no interest in suffering losses. The declining revenue problem caused by the decline in traditional cigarette sales threatens politically important parties who are highly organized. The addition of the states and the tobacco bondholders operating in the shadow of the MSA enriches the Bootlegger/Baptist model and illuminates the e-cigarette struggle far better than has been the case for past tobacco industry struggles. For example, past regulatory episodes involved public health advocates who favored a reduction in advertising and marketing strategies that targeted younger smokers. These advocates were accommodated by cigarette producers who wanted to reduce advertising expenditures and limit the entry of new competition. Regulatory successes brought some satisfaction to both groups and often set the stage for the next regulatory battle. This struggle ended when the attorneys general negotiated the MSA. This yielded what was thought to be the ultimate regulatory cartel. The rise of e-cigarettes threatens the cartel and arouses a three-pronged response from health advocates, Big Tobacco, and state governments and their tobacco bond holders. Because of this rich reaction and the size of the stakes, the status quo cannot survive. A new regulatory environment will evolve, turning threats into opportunities for some and creating a new institutional environment for others.

The question is whether this new regulatory environment will enhance public welfare, or merely serve the interests of Bootleggers.

There is an obvious irony here. To the extent that e-cigarettes provide a less hazardous alternative to consumers who seek to break their smoking habit, Bootlegger/Baptist induced regulations that limit e-cigarette competition and evolution bring with them a social cost measured in lost opportunities to improve human health. Given that nearly 500,000 people in the United States die from smoking-related illnesses each year, the cost could be significant.²⁶⁴

Going further, regulatory actions that limit e-cigarette marketability chill development of yet-to-be-tested smoking alternatives that might also threaten the market share of traditional tobacco and smoking cessation products. As Dr. David Abrams recently warned in the *Journal of the American Medical Association*: the adoption of “overly restrictive” regulations of e-cigarettes could “support the established tobacco industry” and have the perverse effect of “perpetuat[ing] the sales of conventional cigarettes well into the next century rather than speed their obsolescence.”²⁶⁵

Vested interests always oppose innovations that threaten the status quo. Maintaining the status quo through regulatory restrictions, however, is not always in the public interest, and in this case might come at the expense of public health.

264. *Tobacco-Related Mortality*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 6, 2014), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality.

265. See Abrams, *supra* note 115, at 136; see also Saitta, et al., *supra* note 114, at 57 (“[E]-cigarettes are not a gateway to smoking but a gateway from smoking, and heavy regulation by restricting access to e-cigarettes would just encourage continuing use of much healthier tobacco smoking.”).