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# ROOM FOR TWO IN TOBACCO CONTROL: LIMITS ON THE PREEMPTIVE SCOPE OF THE PROPOSED LEGISLATION GRANTING FDA OVERSIGHT OF TOBACCO<sup>+</sup>

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## INTRODUCTION

Congress is poised to enable the Food and Drug Administration (FDA) to regulate tobacco products, something that neither the FDA nor any other federal agency has ever been allowed to do in any significant way.<sup>1</sup> The fact that the FDA might soon have such oversight is not surprising. If there were ever an argument in support of product regulation, tobacco control is it. The handful of companies that manufacture more than ninety percent of the cigarettes sold in this country were recently adjudicated as racketeers in a case brought by the United States Department of Justice.<sup>2</sup> In her final opinion issued in August 2006, Federal District Court Judge Gladys Kessler concluded that these companies, ignoring everything but the goal of selling as many cigarettes as possible, together designed and implemented one of the most extensive disinformation campaigns in this country's

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1. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. (2007); H.R. 1108, 110th Cong. (2007). The House Bill has 222 co-sponsors. Thomas Law Library, Bill Status for H.R. 1108, <http://www.thomas.gov/cgi-bin/bdquery/z?d110:HR01108:@@P> (last visited Apr. 14, 2008). The Senate Version has 55 co-sponsors. Thomas Law Library, Bill Status for S. 625, <http://www.thomas.gov/cgi-bin/bdquery/z?d110:SN00625:@@P> (last visited Apr. 14, 2008).

2. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 26 (D.D.C. 2006); SARA GUARDINO ET AL., PUBLIC HEALTH ADVOCACY INST., *USA V. PHILIP MORRIS USA, INC., ET AL.: ANALYSIS OF JUDGE KESSLER'S FINAL OPINION AND ORDER 1* (2007).

history aimed at obfuscating the public's knowledge of tobacco-caused diseases.<sup>3</sup> This campaign, in the words of Judge Kessler, was carried out "with zeal, with deception, with a single-minded focus on [the cigarette industry's] financial success, and without regard for the human tragedy or social costs that success exacted."<sup>4</sup> Meanwhile, smoking remains the leading preventable cause of death in this country, killing 438,000 Americans every year.<sup>5</sup> For these reasons, it seems logical for the FDA to have oversight over tobacco products.

However, peel back some layers and this common sense rationale for FDA oversight becomes less apparent. The potential for FDA oversight raises some important questions, such as whether oversight gives the cigarette industry a government-issued stamp of approval that will legitimize the industry and its marketing, or whether FDA oversight is the first step towards making at least some types of tobacco use acceptable. These and other policy questions certainly warrant discussion, particularly because state public health practitioners have spent years building and refining highly effective tobacco control policies that will undoubtedly be affected.

This article discusses one part of the public health community's debate over the FDA legislation, a part which has particular relevance for the continuation of state and municipal tobacco control policies: preemption. Preemption has become a mainstay in the cigarette industry's efforts to secure favorable legal environments for it and its products.<sup>6</sup> The industry has actively supported partial smoking bans in state legislatures for years in an attempt to thwart municipalities and local governments from establishing comprehensive bans.<sup>7</sup> At the federal level, the Federal Cigarette Labeling and Advertising Act (FCLAA) preempts state law restrictions on tobacco advertising.<sup>8</sup> For example, when Massachusetts passed a law that would have limited outdoor and point-of-sale cigarette advertising, the industry successfully argued that FCLAA preempted the state law because it reserved for direct congressional oversight, to the exclusion of states, all advertising-related tobacco issues concerned with smoking and health.<sup>9</sup>

This time around, the sponsors of the proposed FDA legislation may have gotten the message. The proposed legislation pays close attention to the issue of

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3. *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 1, 28.

4. *Id.* at 28.

5. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., TARGETING TOBACCO USE 2 (2007) ("Each year, an estimated 438,000 people in the United States die prematurely from smoking or exposure to secondhand smoke . . .").

6. ROBIN HOBART, AM. MED. ASS'N, PREEMPTION: TAKING THE LOCAL OUT OF TOBACCO CONTROL 4-6 (Elva Yañez ed., 2003), available at <http://www.rwjf.org/newsroom/SLSPreemption2003.pdf>.

7. *Id.* at 4-5.

8. 15 U.S.C. § 1334(b) (2000).

9. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 532, 550-51 (2001).

preemption, describing which aspects of FDA legislation are preemptive and which are not.<sup>10</sup> This article reviews this statutory language within the context of existing tobacco control laws. Part I reviews the general scope of the FDA legislation. Part II analyzes the preemptive scope of the FDA legislation and how it affects existing tobacco control efforts. Finally, this article provides some concluding thoughts on this potential for a new direction in tobacco control.

## I. OVERVIEW OF THE PROPOSED FDA LEGISLATION

Any description of potential federal oversight of tobacco must start with the fact that there is currently no scientific evidence-driven public health regulation of tobacco at the federal level. In his book, *A Question of Intent*, Former Commissioner of the FDA, Dr. David Kessler, gives his insider's perspective and concludes that the tobacco industry's political cache allowed it to insulate its products from the typical federal oversight that governs other personal consumer products.<sup>11</sup> Even within the FDA, as Dr. Kessler and some key allies pushed the agency to assert jurisdiction over tobacco, there was opposition among his staff based on the perceived political fallout.<sup>12</sup> Eventually, Dr. Kessler and others decided to take up this Herculean challenge in the mid-1990s, only to fail years later when the United States Supreme Court concluded that the FDA lacked jurisdiction to regulate tobacco products.<sup>13</sup>

Ironically, the lethality of cigarettes provided the justification for the Court's decision. The Court found that tobacco regulation was inconsistent with the FDA's enabling legislation since the FDA would be required to conclude that tobacco products presented "a potential unreasonable risk of illness or injury" under its standard market approval process.<sup>14</sup> Further, the Court concluded that, given the "FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety[.]" and thus "could not allow [tobacco products] to be marketed."<sup>15</sup> However, this outcome was contradicted, according to the Court, by the existence of federal statutes directly

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10. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(a) (2007); H.R. 1108, 110th Cong. § 917(a) (2007).

11. See DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY*, at xii (2001) (discussing the former Commissioner's revelation that the tobacco industry had bought the support of prestigious law firms, senators, and foreign prime ministers).

12. *Id.* at 31–35.

13. *Id.* at 328–58; *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

14. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 136 (quoting 21 U.S.C. § 360c(a)(1)(C) (2000), *aff'g* 153 F.3d 155 (4th Cir. 1998), *rev'g* 966 F. Supp. 1374 (M.D.N.C. 1997)).

15. *Id.*

regulating tobacco, which showed that Congress wanted cigarettes to remain on the market.<sup>16</sup>

What, then, is the nature of the congressional actions that precluded (and continue to preclude) the FDA, or, for that matter, “any [federal] agency from exercising significant policymaking authority in the area,” according to the Court?<sup>17</sup> The statute the Court largely relied on was FCLAA.<sup>18</sup> FCLAA includes only three arguably meaningful public health requirements. First, it requires health warnings on all cigarette packages and advertisements.<sup>19</sup> The public health research literature supports the use of health warnings, but nearly unanimously concludes that the health warnings under FCLAA are ineffective.<sup>20</sup> These warnings have not been updated since 1984 and do not reflect more than two decades of research findings on the health, addiction, and marketing of cigarettes.<sup>21</sup> The research literature recommends that the warnings should be larger in size and include a rotating series of pictorials that graphically depict the health effects to the potential user and those who will be exposed to the user’s secondhand smoke.<sup>22</sup>

The second of the three public health-related provisions in FCLAA requires the disclosure of ingredients to the Secretary of Health and Human Services.<sup>23</sup> This provision is also considered ineffective by public health researchers. In general, the disclosure of product information can be a useful research tool, particularly in light of recent efforts by the tobacco industry to manufacture and market potentially reduced exposure cigarettes.<sup>24</sup> Reduced harm products seek to decrease an individual’s health risk of smoking by reducing the emission levels of certain harmful constituents.<sup>25</sup> However, FCLAA’s disclosure requirement does not

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16. *Id.* at 137–39. The Court noted that 7 U.S.C. § 1331(a) states “[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce . . .” *Id.* at 137 (alteration in original) (citation omitted).

17. *Id.* at 160.

18. *Id.* at 148–56.

19. 15 U.S.C. § 1333(a) (2000).

20. Christopher N. Banthin, *Potentially Reduced Exposure Cigarettes: The Need for a Public Health Policy*, 8 MINN. J. L. SCI. & TECH. 127, 136 (2007); see also David Hammond et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, 15 TOBACCO CONTROL, at iii19, iii24 (2006) (suggesting that cigarette labels should include more detailed information about ingredients in cigarettes to better inform the consumer).

21. See Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, § 4, 98 Stat. 2200, 2201–03 (1984) (codified at 15 U.S.C. § 1333 (2000)).

22. See Hammond et al., *supra* note 20, at iii23.

23. 15 U.S.C. § 1335a (2000) (requiring cigarette manufacturers to provide a list of cigarette ingredients to the Secretary, but this information is treated as confidential information or a trade secret).

24. See Banthin, *supra* note 20, at 143 (“Just as consumers cannot compare prices without being allowed to check price tags, policy makers cannot develop a meaningful harm reduction policy without having reasonable access to information about the current level of harm.”).

25. *Id.* at 130–32.

include brand-specific disclosures and only requires one annual disclosure without amounts of each ingredient or any brand-specific information.<sup>26</sup> Even if brand-specific information were disclosed, for the consumer, disclosure information may be relatively ineffective without any accompanying health metric with which to interpret the disclosure. But, it is important to note that current research, at least outside the doors of the tobacco industry, does not possess such a metric.<sup>27</sup>

The final health-related provision of FCLAA is the ban on cigarette advertising on television and radio,<sup>28</sup> although the marketing of cigarettes at concerts and other events, in magazines, on the Internet, and around the cash registers of seemingly every convenience store in this country appear to afford the industry plenty of opportunities to reach nearly everyone it wants to reach. Tragically, the audience includes a significant percentage of children.<sup>29</sup> Indeed, numerous state law actions have been brought based on the marketing to children through these venues.<sup>30</sup> If the ban on television and radio advertising was meant to protect children from such marketing, it appears to have failed.<sup>31</sup>

The proposed FDA legislation would supplement these congressionally mandated requirements and prohibitions with comprehensive regulatory oversight. Though the FDA's powers and responsibilities would also extend to marketing and labeling,<sup>32</sup> this article will focus here on two aspects of the proposed legislation that would affect the design of cigarettes. First, at the heart of the legislation is the ability to mandate reductions in constituent emissions and other changes in the product design or testing of cigarettes, thereby theoretically reducing the

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26. 15 U.S.C. § 1335a(a); *see also* Patricia Davidson, *Tobacco Ingredients and Smoke Constituent Reporting and Disclosure Laws: The Case for Expansion*, 77 DENV. U. L. REV. 1, 3-4 (1999) (discussing limitations to the current federal and state tobacco product disclosure laws).

27. *See* Banthin, *supra* note 20, at 132-33.

28. 15 U.S.C. § 1335 (outlawing cigarette advertisements "on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission"); *United States v. Bast*, F.2d 138, 143 (D.C. Cir. 1974) (noting that FCLAA prohibits cigarette advertising on radio and television).

29. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 562 (D.D.C. 2006) (explaining that the majority of smokers start before the age of eighteen).

30. DENNIS ECKHART, TOBACCO CONTROL LEGAL CONSORTIUM, THE TOBACCO MASTER SETTLEMENT AGREEMENT: ENFORCEMENT OF MARKETING RESTRICTIONS 5 (2004), *available at* <http://www.wmitchell.edu/tobaccolaw/resources/eckhart.pdf>.

31. The public health-related efficacy of the ban is further called into question by the fact that it blocked implementation of the "fairness doctrine," which had forced television stations that ran cigarette advertising to also air a countervailing perspective and "present a fair number of anti-smoking messages." *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582, 587-89 (D.D.C. 1971) (Wright, J., dissenting). After these anti-smoking messages began to air, "[f]or the first time in years, the statistics began to show a sustained trend toward lesser cigarette consumption." *Id.* at 587.

32. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 4 (2007); H.R. 1108, 110th Cong. § 4 (2007).

harmfulness of smoking in general.<sup>33</sup> In recent years, cigarette manufacturers have dramatically increased research and design budgets for their potentially reduced exposure cigarettes, in hopes of marketing a less risky cigarette.<sup>34</sup> Some manufacturers have already begun to introduce these products into the marketplace.<sup>35</sup> The FDA legislation establishes a regulatory framework that could mandate industry-wide use of a technological advance in cigarette design that reduces harm to smokers, developed by a particular manufacturer, if the FDA concludes that the design works.<sup>36</sup> Indeed, recent research at the University of California, San Francisco suggests that “if the government required tobacco companies to lower the nicotine levels in cigarettes, more people might be able to quit and fewer might become addicted in the first place.”<sup>37</sup> Mandating a reduction in nicotine yields would be within the regulatory gamut of the proposed FDA oversight.

Importantly, officials at the FDA would retain significant discretion in mandating emissions reduction standards and other design modifications.<sup>38</sup> An expert committee would be set up to consider all relevant scientific and public health issues.<sup>39</sup> A representative from the tobacco industry and one from tobacco leaf farmers would be on the committee, but not be allowed to participate in committee voting.<sup>40</sup> Any party challenging the proposed reduction standards would bear the burden of proving “that the proposed [reduction or modification] will not reduce or eliminate the risk of illness or injury.”<sup>41</sup> In addition, any lawsuit challenging a mandated reduction or modification would confront the deference afforded administrative rulemaking established by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, and thus deference would likely be granted to the FDA.<sup>42</sup> Finally, if the tobacco industry were to ask Congress to intervene, an override would require majorities in both houses.<sup>43</sup>

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33. S. 625, § 907(a)(3), H.R. 1108, § 907(a)(3); accord Matthew L. Myers, *Opposition in Search of a Rationale: The Case for Food and Drug Administration Regulation*, 13 TOBACCO CONTROL 441, 442 (2004) (describing the regulatory structure for implementing reduce risk technologies).

34. MARTIN STEINIK & MICHAEL SMITH, THE PATH TO A SAFER CIGARETTE: POTENTIALLY REDUCED EXPOSURE PRODUCTS (PREPS) 12–18 (2004) (on file with author).

35. Banthin, *supra* note 20, at 130–32.

36. S. 625, § 907(a); H.R. 1108, § 907(a).

37. Eric Nagourney, *Lowering Nicotine Levels May Help Cut Smoking*, N.Y. TIMES, Nov. 20, 2007, at F6.

38. S. 625, § 907(a)(4); H.R. 1108, § 907(a)(4).

39. S. 625, § 918; H.R. 1108, § 918.

40. S. 625, § 918(b)(1); H.R. 1108, § 918(b)(1).

41. S. 625, § 907(b)(1)(C); H.R. 1108, § 907(b)(1)(C).

42. 467 U.S. 837, 843–44 (1984) (giving agencies the power to formulate policy and promulgate rules when Congress has implicitly or explicitly left a gap in the enabling act).

43. See *Immigration & Naturalization Serv. v. Chadha*, 462 U.S. 919, 955 (1983) (“Congress must abide by its delegation of authority until that delegation is legislatively altered or revoked.”).

The second relevant aspect of the proposed FDA legislation is the use of a public health, outcome-based standard.<sup>44</sup> The outcome sought in this provision is not merely reducing the health risk for the individual smoker. Rather, any reductions are set “with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product[s] . . . .”<sup>45</sup> In other words, likely changes in quit rates and initiation rates must be considered. For example, a reduction in harm is counterproductive if it triggers a massive decrease in quit rates. Indeed, this possible outcome is the primary criticism of harm reduction public health programs: that the program itself may end up legitimizing harmful behavior.<sup>46</sup> The FDA standard attempts to address this concern by looking, not only at the likely health risk to the individual users, but also at the aggregate population effects of smoking prevalence.<sup>47</sup>

This public health standard would be applied across the board. For tobacco products already in the market, the FDA would have the discretion to establish a public health standard,<sup>48</sup> which presumably it would do quickly on its own initiative. Should the FDA not act, anyone may file a petition to initiate rulemaking and establishment of the standard.<sup>49</sup> In addition, the FDA is required to conduct periodic evaluation of any mandated emissions reduction.<sup>50</sup> As part of the pre-market approval process, the proposed legislation sets forth additional requirements for new reduced-exposure or modified risk products introduced by members of the tobacco industry.<sup>51</sup> More specifically, under the legislation, the FDA may only approve a modified risk tobacco product application if it determines that the product will “significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and benefit the health of the population as a whole . . . .”<sup>52</sup>

44. S. 625, § 907; H.R. 1108, § 907.

45. S. 625, § 907(a)(3); H.R. 1108, § 907(a)(3).

46. Amy Fairchild & James Colgrove, *Out of the Ashes: The Life, Death, and Rebirth of the “Safer” Cigarette in the United States*, 94 AM. J. PUB. HEALTH 192, 192 (2004). The development of needle exchange programs provides a good case study for understanding the harm reduction/harm elimination debate. Needle exchange programs, which are intended to reduce the transmittal of diseases, are criticized based on the assumption that the supply of free needles actually promotes drug use. INST. OF MED., PREVENTING HIV TRANSMISSION: THE ROLE OF STERILE NEEDLES AND BLEACH 11 (Jacques Normand et al. eds., 1995). The harm reduction advocate would respond that reducing the rates of disease occurrence associated with drug use is an important goal that can be accomplished in conjunction with other efforts to eliminate the incidence of drug use. *Id.* app. B, at 311. That some increase in drug use might occur is outweighed by the total net improvement for public health, according to the argument.

47. S. 625, § 907(a)(3); H.R. 1108, § 907(a)(3).

48. S. 625, §§ 907(a)(3), (b)(1); H.R. 1108, §§ 907(a)(3), (b)(1).

49. S. 625, § 907(b)(4); H.R. 1108, § 907(b)(4).

50. S. 625, § 907(a)(5); H.R. 1108, § 907(a)(5).

51. These products include “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.” S. 625, § 911(b)(1); H.R. 1108, § 911(b)(1).

52. S. 625, § 911(g)(1); H.R. 1108, § 911(g)(1).



The proposed legislation sets different requirements for tobacco products that *have not* been approved as modified risk products. These provisions require, *inter alia*, that the marketing and advertising of these products is carefully monitored to ensure that the “testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product”<sup>53</sup> presents any reduction in risk, unless, presumably, an independent scientific advisory committee, which would also be established under the FDA legislation, concludes that it does.<sup>54</sup> The approval is limited to five years, after which the approval “may be renewed upon a finding by the [FDA] that the requirements of [the pre-market approval process] continue to be satisfied based on the filing of a new application.”<sup>55</sup>

The balance of the proposed legislation would accomplish a litany of tobacco control objectives. It would improve cigarette health warnings by authorizing the FDA to increase the required label warning area from thirty percent to fifty percent of a package’s panel, as well as require pictorial warnings, package, and advertising inserts.<sup>56</sup> The legislation codifies the FDA rule limiting sales to minors,<sup>57</sup> and provides \$300 million per year in funding for regulation and enforcement from user fees.<sup>58</sup> Also, the legislation grants the FDA the authority to require tobacco product manufacturers to include a list of toxic smoke constituents, by brand, in cigarette advertisements.<sup>59</sup> It takes significant steps toward fighting cigarette smuggling, including American products abroad.<sup>60</sup> It allows the FDA to eliminate self-service cigarette sales, including vending machines.<sup>61</sup> It eliminates the use of brand descriptors such as “light” or “low tar,” unless the FDA approves an application for the product under the “Modified Risk Tobacco Products” section of the proposed

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53. S. 625, § 911(g)(2)(B)(iii); H.R. 1108, § 911(g)(2)(B)(iii).

54. S. 625, § 918(g); H.R. 1108, § 918(g).

55. S. 625, § 911(g)(2)(C)(i); H.R. 1108, § 911(g)(2)(C)(i). As part of the approval process, the FDA would require that “any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product . . . is limited to an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke.” S. 625, § 911(g)(2)(A)(ii); H.R. 1108, § 911(g)(2)(A)(ii).

56. S. 625, § 202; H.R. 1108, § 202.

57. When the final rule is published by the FDA it must be identical to “part 897 of the regulations promulgated . . . in the August 28, 1996, issue of the Federal Register (61 Fed. Reg., 44615–44618).” S. 625, § 102(a)(2); H.R. 1108, § 102(a)(2). Subpart B of this Federal Register issue mandates a “Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age.” Cigarettes and Smokeless Tobacco, 61 Fed. Reg. 44615, 44616 (Aug. 28, 1996).

58. S. 625, § 920(c)(4); H.R. 1108, § 920(c)(4).

59. S. 625, § 206(e)(1); H.R. 1108, § 206(e)(1).

60. S. 625, § 921; H.R. 1108, § 921.

61. Subpart B of this Federal Register issue mandates that a “retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance or mechanical device (such as a vending machine).” Cigarettes and Smokeless Tobacco, 61 Fed. Reg. 44615, 44616 (Aug. 28, 1996).

legislation.<sup>62</sup> The legislation bans candy-flavored cigarettes.<sup>63</sup> Also, it allows the FDA to require manufacturers to make public service announcements about the dangers of tobacco products.<sup>64</sup>

Although a full review is beyond the scope of this article, the proposed legislation contemplates a level of oversight that is comprehensive and far-reaching. Its enactment would be a dramatic departure from the federal government's current hands-off policy. As for tobacco control at the state level, that is the focus of the following section.

## II. THE PREEMPTIVE SCOPE OF THE PROPOSED FDA LEGISLATION ON STATE TOBACCO CONTROL EFFORTS

Where the two tiers of governance in our federalist system overlap, public health actions usually confront two possible outcomes. The best outcome is a partnership where the federal and state governments coordinate with one another and apply their resources in a unified manner to address a public health threat. This is what we should have seen when Hurricane Katrina ravaged New Orleans, but what we actually saw was the other possible outcome: a lack of coordination leading to tragedy.<sup>65</sup>

Although alarming, the tragedy following Hurricane Katrina is not without precedent. If we imagine rewinding time back to the early 1950s when United States public health scientists started to realize the full extent of cigarette-caused diseases<sup>66</sup> and then play back the last half-century at high speed, we would experience the same lack of coordination—indeed, actual federal preemption of state regulation—leading to an even greater tragedy.<sup>67</sup> During this period, millions of people became addicted to nicotine in cigarettes during childhood, smoked as adults because they could not quit, and then died prematurely from smoking—in an all-too-familiar cycle that continues today.<sup>68</sup>

In its current form, the proposed FDA legislation steers clear of creating preclusive oversight. Instead, the legislation articulates a very narrow preemptive

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62. S. 625, §§ 911(a), (b)(2)(A)(ii); H.R. 1108, §§ 911(a), (b)(2)(A)(ii).

63. S. 625, § 907(a)(1); H.R. 1108, § 907(a)(1).

64. S. 625, § 908(a); H.R. 1108, § 908(a).

65. COMM. ON HOMELAND SEC. & GOV'T AFFAIRS, HURRICANE KATRINA: A NATION STILL UNPREPARED, S. REP. NO. 109-322, at 15–17 (2d Sess. 2006).

66. Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 856 (1992).

67. *E.g.*, 15 U.S.C. § 1334(b) (2000) (“No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.”).

68. See Ctrs. for Disease Control & Prevention, *Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs—United States, 1995–1999*, 51 MORBIDITY & MORTALITY WKLY. REP. 297, 301 (2002), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5114.pdf>.

scope for itself. In this section, we examine this preemptive scope within the context of three categories. The first category is traditional state tobacco control measures, which have been implemented in one form or another in nearly every state. These traditional measures include tobacco taxes or smoking bans, for example.<sup>69</sup> The second category is tobacco litigation, and the third category is actual regulation of the product design.

### A. *Non-Preemption of Traditional State Tobacco Control Laws*

With respect to the traditional non-litigation tobacco control policies, the proposed legislation would clearly preserve the current tobacco control policies used by states and municipalities.<sup>70</sup> Tobacco control laws implement a broad array of strategies designed to reduce tobacco use. Two of the most effective strategies have been smoking bans and tobacco taxes. For over thirty years, towns and cities have been restricting smoking in governmental buildings, restaurants, and other public places.<sup>71</sup> More recently, within the last ten years, this trend has accelerated to include bars and worksites.<sup>72</sup> Smoking restrictions also have become more comprehensive as a result of mounting scientific evidence that indicates that there is no safe level of exposure, including exposure to smoke that has drifted outside of designated smoking areas in restaurants and other public places.<sup>73</sup>

Today, twenty-two states and many more cities and towns have enacted smoke-free laws that include total smoking bans in virtually all public places, including restaurants and bars.<sup>74</sup> Some states, like Massachusetts, have gone even further to prohibit smoking in all workplaces.<sup>75</sup> Evidence shows that such laws

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69. See *Am. Trucking Ass'n, Inc. v. Mich. Pub. Serv. Comm'n*, 545 U.S. 429, 434 (2005) ("Although we have long since rejected any suggestion that a state tax . . . affecting interstate commerce is immune from Commerce Clause scrutiny because it attaches only to a local or intrastate activity, we have also made clear that the Constitution neither displaces States' authority to shelter [their] people from menaces to their health and safety, nor unduly curtail[s] States' power to lay taxes for the support of state government." (alterations in original) (citations omitted)).

70. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(a)(1) (2007); H.R. 1108, 110th Cong. § 917(a)(1) (2007).

71. E.g., Melanie S. Pickett et al., *Smoke-Free Laws and Secondhand Smoke Exposure in U.S. Non-Smoking Adults, 1999–2002*, 15 TOBACCO CONTROL 302, 302, 304 (2006).

72. See AM. NONSMOKERS' RIGHTS FOUND., STATES, COMMONWEALTHS AND MUNICIPALITIES WITH 100% SMOKEFREE LAWS IN WORKPLACES, RESTAURANTS, OR BARS (2008), <http://www.no-smoke.org/pdf/100ordlist.pdf> (listing cities that have smoking bans enacted in the workplace, restaurants, and bars).

73. See *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 705–06 (D.D.C. 2006) (accepting the scientific conclusion that secondhand smoke causes lung cancer and heart disease).

74. AM. NONSMOKERS' RIGHTS FOUND., *supra* note 72; Campaign for Tobacco-Free Kids, *Smoke-Free Restaurant and Bar Laws* (2007), <http://www.tobaccofreekids.org/phillypoll/SmokeFreeMap.pdf>.

75. MASS. GEN. LAWS ANN. ch. 270, § 22(b)(1)–(2) (West Supp. 2007) ("Smoking shall be prohibited in workplaces, work spaces, common work areas, classrooms, conference and meeting rooms, offices elevators, [and] hallways . . .").

dramatically reduce the public's exposure to secondhand smoke and improve public health.<sup>76</sup> In addition, comprehensive smoking restrictions de-normalize (and dissuade) smoking, thereby reducing smoking rates in general.<sup>77</sup>

The other leading evidence-based tobacco control strategy employed by states and municipalities is to raise tobacco taxes.<sup>78</sup> States enforce tobacco taxes to target the smoker's pocket book, with the hopes that higher cigarette prices will both motivate smokers to quit and discourage adolescents from taking up the habit. Despite the addictive properties of nicotine, cigarette prices affect smoking rates.<sup>79</sup> If the cigarette prices rise, smoking rates decrease.<sup>80</sup> A ten percent increase in the cost of a pack of cigarettes will reduce smoking rates, on average, by three to five percent for adults, and by seven percent for smokers eighteen years of age and younger.<sup>81</sup>

The proposed FDA legislation clearly would preserve the ability of states to pursue these and other traditional tobacco control measures. Section 917, which governs the preservation of state and local authority, states:

Nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting *the sale, distribution, possession,*

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76. James Repace, *Respirable Particles and Carcinogens in the Air of Delaware Hospitality Venues Before and After a Smoking Ban*, 46 J. OCCUPATIONAL ENVTL. MED. 887, 903 (2004) ("Delaware's comprehensive smoking ban has significantly reduced the risk of cancer, heart disease, stroke, and respiratory disease among workers and patrons in its hospitality industry."); Richard P. Sargent et al., *Reduced Incidence of Admissions for Myocardial Infarction Associated with Public Smoking Ban: Before and After Study*, 328 BMJ 977, 978 (2004) (concluding that during the six months a smoke-free law was in effect in Helena, Montana, there was a major decline in the number of hospital admissions for acute myocardial infarction, a condition caused by secondhand smoke).

77. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T HEALTH & HUMAN SERVS., REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 375 (2000), available at [http://www.cdc.gov/tobacco/data\\_statistics/sgr/sgr\\_2000/00\\_pdfs/FullReport.pdf](http://www.cdc.gov/tobacco/data_statistics/sgr/sgr_2000/00_pdfs/FullReport.pdf).

78. *Id.* at 337–38.

79. *Id.* at 322 ("[N]umerous studies of cigarette smoking and other tobacco use . . . account for tobacco's addictive nature [and] find a strong inverse relationship between price and consumption."). The presence of an inverse relationship between smoking and the price of cigarettes, however, does not support the argument that the continuation of smoking is purely a matter of free choice. Nicotine addiction may also strongly influence behavior. *Id.* at 129.

80. *Id.* at 322 ("The demand for tobacco products is different from the demands of other consumer goods because of the addictive drug (nicotine) found in these products.").

81. *Id.* at 337; AM. MED. ASS'N, TOBACCO TAX CHALLENGE: SMOKELESS STATES NATIONAL TOBACCO POLICY INITIATIVE 2 (2003), available at <http://www.rwjf.org/newsroom/SLSTaxChallenge.pdf>.

*exposure to, access to, advertising and promotion of, or use of tobacco products* by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any *State, Tribal, or local taxation* of tobacco products.<sup>82</sup>

Under section 917, states would be free to continue to pursue smoking bans and increases in tobacco taxes, as well as other traditional tobacco control strategies such as bans on self-service displays and vending machines, increasing the minimum age sales laws, mandating reduced ignition propensity for cigarettes, and more.

In addition, section 917 along with section 203, which governs state regulation of cigarette advertising and promotion, would enhance state tobacco control authority by allowing for some advertising and promotion-related regulation.<sup>83</sup> There is little doubt that stopping cigarette advertisements that are targeted at children is an important governmental objective. Despite laws prohibiting cigarettes sales to anyone less than eighteen years of age in most states,<sup>84</sup> the vast majority of today's smokers continue to start in their mid-teens.<sup>85</sup> A substantial body of evidence points to tobacco advertising as a reason for this trend<sup>86</sup> and justifies interventions focused on these new smokers who are perhaps less addicted (and therefore more reachable) than smokers in their twenties and thirties.

This early intervention strategy was at issue in *Lorillard Tobacco Co. v. Reilly*, in which the United States Supreme Court invalidated zoning-like restrictions on tobacco advertising.<sup>87</sup> The Massachusetts Attorney General promulgated the restrictions in response to surveys that showed that tobacco advertising was clustered around areas frequented by children.<sup>88</sup> The zoning-like

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82. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(a)(1) (2007); H.R. 1108, 110th Cong. § 917(a)(1) (2007) (emphasis added).

83. S. 625, § 917(a)(2)(B); H.R. 1108 § 917(a)(2)(B) (permitting states to regulate the advertising of tobacco product use by individuals of any age); S. 625, § 203(c); H.R. 1108, § 203(c) (permitting states to impose time, place, and manner restrictions on advertising).

84. *E.g.*, MD. CODE ANN., CRIM. LAW § 10-07(b)(2) (West 2007) (prohibiting the sale of tobacco products to a minor); TENN. CODE ANN. § 39-17-1504 (West 2007) (prohibiting the sale of tobacco products to persons under the age of eighteen).

85. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 562 (D.D.C. 2006).

86. In examining the industry's racketeering conduct, Judge Kessler found that "[c]igarette marketing, which includes both advertising and promotion, is designed to play a key role in the process of recruiting young, new smokers by exposing young people to massive amounts of imagery associating positive qualities with cigarette smoking." *Id.* at 565. In addition, since 1999, several state attorneys general have brought enforcement initiatives and lawsuits to stop various cigarette manufacturers from targeting their promotional activities against youth. ECKHART, *supra* note 30, at 5–6.

87. 533 U.S. 525, 551–56 (2001).

88. *Id.* at 533; Howard K. Koh et al., *The First Decade of the Massachusetts Tobacco Control Program*, 120 PUB. HEALTH REPS. 482, 483 (2005).

component of the law prohibited outdoor advertising of tobacco products on billboards or in store-front windows around schools, playgrounds and other areas frequented by children.<sup>89</sup> Within these zones, any in-store advertisements or any part of an advertisement lower than five feet from the ground were also prohibited.<sup>90</sup> The practical effect of the in-store restriction was to remove tobacco advertising from the area around the cash register where all customers, including children, would go to pay for their items.

The tobacco industry argued, *inter alia*, that the Federal Cigarette Labeling and Advertising Act (FCLAA) expressly preempts the advertising restrictions.<sup>91</sup> The statutory language states that FCLAA preempts any “requirement or prohibition based on smoking and health . . . with respect to the advertising and promotion of . . . cigarettes . . . .”<sup>92</sup> The legislative history of FCLAA was instructive for the Court. The Court found that “Congress not only enhanced its scheme to warn the public about the hazards of smoking, but also sought to protect the public, including youth, from being inundated with images of cigarette smoking in advertising.”<sup>93</sup> To support this conclusion, the Court pointed to the ban on cigarette advertising on television and radio.<sup>94</sup> The Court held, *inter alia*, that the Massachusetts regulations restricting outdoor and point-of-sale cigarette advertising were preempted by FCLAA.<sup>95</sup>

Sections 917 and 203 of the proposed legislation would essentially reverse this decision. Section 917 states that the law will not preempt state regulation of the advertising and promotion of cigarette advertising.<sup>96</sup> Section 203 provides a similar non-preemption clause, but includes further specificity. It states that:

[T]he Federal Cigarette Labeling and Advertising Act . . . is amended . . .  
 . [so that it declares that] . . . a State or locality may enact statutes and

89. *Lorillard Tobacco Co.*, 533 U.S. at 534–35 (quoting 940 MASS. CODE REGS. 21.04(5)(a)–(b), 21.04(6) (2000)).

90. *Id.* at 535 (quoting 940 MASS. CODE REGS. 21.04(5))(a)–(b) (2000)).

91. *Lorillard Tobacco Co.*, F. Supp. 2d at 127, 133–34 (finding that Massachusetts regulations banning outdoor and ground-level tobacco advertising were not preempted by FCLAA, but that regulations regarding outdoor displays were preempted by the Act), *aff'd sub nom.* *Consol. Cigar Corp. v. Reilly*, 218 F.3d 30, 37 (1st Cir. 2000), *and rev'd* 218 F.3d 30, 53, 58 (holding that restrictions on outdoor cigarette displays did not violate federal law, including FCLAA and the First Amendment), *rev'd sub nom. Lorillard Tobacco Co.*, 533 U.S. at 551 (holding that the Massachusetts regulations governing outdoor and point-of-sale cigarette advertising were preempted by FCLAA and regulations banning outdoor advertising of smokeless tobacco or cigars within 1,000 feet of a school or playground violated the First Amendment), *and aff'd* 533 U.S. at 570 (holding that regulations requiring retailers to store tobacco products behind their counters did not violate the First Amendment).

92. 15 U.S.C. § 1334(b) (2000).

93. *Lorillard Tobacco Co.*, 533 U.S. at 547–48.

94. *Id.* at 548.

95. *Id.* at 551.

96. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(a)(2)(B) (2007); H.R. 1108, 110th Cong. § 917(a)(2)(B) (2007).

promulgate regulations, based on smoking and health, that take effect after the effective date of the [Act], imposing specific bans or restrictions on the time, place and manner, but not content, of the advertising and promotion of any cigarettes.<sup>97</sup>

This statutory language would relax the preemptive scope of FCLAA and allow Massachusetts and other states to pursue advertising restrictions designed to protect children from cigarette marketing, subject to applicable First Amendment restrictions.<sup>98</sup> Under the proposed FDA legislation, only the actual content of the advertising, including health warnings, would remain solely within the regulatory jurisdiction of the FDA.<sup>99</sup>

### B. Non-Preemption of Tobacco Litigation

The second area of tobacco control that is protected by anti-preemption language in the proposed legislation is private litigation against the manufacturers.<sup>100</sup> In addition to the traditional role of providing at least the possibility of compensating the millions of potential victims of the industry, tobacco litigation has under-girded much of tobacco control strategy primarily by creating opportunities for intervention. As the news media headlines reported on multi-million dollar jury verdicts, government officials and the public began to appreciate that the tobacco industry had played an instrumental role in creating the tobacco disease epidemic.<sup>101</sup> Starting in the late 1980s and early 1990s, the public disclosure of court pleadings and internal industry documents discovered in litigation further supported this role.<sup>102</sup> State law makers and advocates harnessed this energy into support for new and tougher tobacco control laws.<sup>103</sup> This advocacy continues to the present and is now supported by an enormous body of peer-reviewed research literature devoted to examining millions of industry documents and reporting on industry behavior.<sup>104</sup>

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97. S. 625, § 203(c); H.R. 1108, § 203(c).

98. *Lorillard Tobacco Co.*, 533 U.S. at 571 (discussing how the First Amendment constrains state efforts to limit tobacco advertising).

99. S. 625, § 203(c); H.R. 1108, § 203(c).

100. S. 625, § 917(b); H.R. 1108, § 917(b).

101. *See Millions Awarded to Three Sick Smokers; Damages Seen as Bad Sign for Tobacco*, CHI. TRIB., Apr. 8, 2000, at N3; Morton Mintz, *Jury Finds Tobacco Firm Shares Blame in Death; Liggett Told to Pay \$400,000 in Damages*, WASH. POST, June 14, 1988, at A1.

102. *E.g.*, George J. Annas, *Tobacco Litigation as Cancer Prevention: Dealing with the Devil*, 336 NEW ENG. J. MED. 304, 304 (1997); Myron Levin, *Key Smoker Death Trial Draws to Close; Jury is First to See Company Documents*, L.A. TIMES, June 1, 1988, § 1, at 4.

103. *See* AM. NONSMOKERS' RIGHTS FOUND., *supra* note 72 (surveying states and local municipalities with tobacco control laws).

104. CARL DEAL & JOANNE DOROSHOW, CTR. FOR JUSTICE AND DEMOCRACY ET AL., *THE CALA FILES: THE SECRET CAMPAIGN BY BIG TOBACCO AND OTHER MAJOR INDUSTRIES TO TAKE AWAY YOUR RIGHTS 1* (2000).

Not surprisingly, the proposed legislation seeks not to disrupt the role of litigation in tobacco control. In particular, section 917(b) states: “No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”<sup>105</sup>

The industry began facing waves of litigation starting in the early 1950s, when individuals began filing lawsuits under theories of deceit,<sup>106</sup> breach of express and implied warranty,<sup>107</sup> and negligence.<sup>108</sup> Plaintiffs later added claims of failure to warn and strict liability.<sup>109</sup> In 1994, states started filing medical reimbursement lawsuits against the industry, arguing that smoking rates, and consequently the state Medicaid expenditures incurred in treating sick and dying smokers, would have been much lower had cigarette manufacturers not obfuscated the truth about the effects of smoking on health.<sup>110</sup> Most of these lawsuits were settled in 1998 under the Master Settlement Agreement (four were settled earlier), although similar medical reimbursement-type lawsuits are being pursued in other countries.<sup>111</sup>

From September 2004 to June 2005, the tobacco industry faced one of its longest trials to date in the lawsuit brought by the United States Department of Justice, under the Racketeer Influenced and Corrupt Organizations Act (RICO).<sup>112</sup> The case involved “the exchange of millions of documents, the entry of more than 1,000 Orders, and a trial which lasted approximately nine months with 84 witnesses testifying in open court.”<sup>113</sup> Judge Kessler, in her final opinion, devotes 817 pages of her opinion to the findings of facts.<sup>114</sup> The findings detail her conclusions that the industry has devised and executed a scheme to defraud the public with regard to: the adverse health consequences of smoking;<sup>115</sup> the addictive properties of

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105. S. 625, § 917(b); H.R. 1108, § 917(b).

106. *E.g.*, *Ross v. Philip Morris & Co.*, 328 F.2d 3, 4–5 (8th Cir. 1964); *Cooper v. R.J. Reynolds Tobacco Co.*, 234 F.2d 170, 171, 174 (1st Cir. 1956).

107. *E.g.*, *Green v. Am. Tobacco Co.*, 391 F.2d 97, 99 (5th Cir. 1968), *overruled on reh'g by* 409 F.2d 1166 (5th Cir. 1969); *Pritchard v. Liggett & Myers Tobacco Co.*, 350 F.2d 479, 481 (3rd Cir. 1965).

108. *E.g.*, *Pritchard*, 350 F.2d at 481; *Lartigue v. R.J. Reynolds Tobacco Co.*, 317 F.2d 19, 22 (5th Cir. 1963).

109. *E.g.*, *Cipollone v. Liggett Group, Inc.*, 593 F. Supp. 1146, 1149 (D.N.J. 1984).

110. *E.g.*, Cliff Sherrill, Comment, *Tobacco Litigation: Medicaid Third Party Liability and Claims for Restitution*, 19 U. ARK. LITTLE ROCK L.J. 497, 501–06 (1997).

111. NAT'L ASS'N OF ATT'YS GEN., MASTER SETTLEMENT AGREEMENT § 1 (1998) [hereinafter Master Settlement Agreement], available at <http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf> (follow "Master Settlement Agreement" hyperlink); Richard A. Daynard, *Tobacco Litigation: A Mid-Course Review*, 12 CANCER CAUSES & CONTROL 383, 383–85 (2001).

112. *U.S. v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 26 (D.D.C. 2006).

113. *Id.* at 28.

114. *Id.* at 34–851.

115. *Id.* at 146–208. For decades, defendants have misleadingly “denied, distorted, and minimized the serious and harmful health consequences of smoking [cigarettes] . . .” *Id.* at 146.



nicotine;<sup>116</sup> the manipulation of nicotine and nicotine delivery;<sup>117</sup> the use of “light” and “low tar” brand indicators;<sup>118</sup> youth marketing;<sup>119</sup> environmental tobacco smoke;<sup>120</sup> and research suppression and document destruction.<sup>121</sup>

Judge Kessler ordered several equitable remedies, including the mass publication of corrective statements by the industry and prohibition on any future use of product descriptors like “light” that imply a reduction in risk.<sup>122</sup> Although Judge Kessler stated that other specific remedial action requested by the Department of Justice and a group of public health interveners “would certainly serve the public interest,” an interlocutory appellate ruling narrowing the scope of available remedies constrained her from implementing them.<sup>123</sup> Nevertheless, an ongoing appeal in this case, which has temporarily stayed all of the remedies, could potentially relax the holding reached in the interlocutory appellate ruling and allow the trial court to order the equitable remedies prohibited by the interlocutory ruling.<sup>124</sup>

The tobacco industry also continues to face the effects of a massive class action lawsuit in Florida. Originally filed in 1994 on behalf of smokers in the United States, class certification was upheld in 1996, after it was changed to include only Florida residents who had smoked.<sup>125</sup> In early 2000, after the conclusion of the liability phase of the trial, the jury found that smoking caused

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116. *Id.* at 208–308. Defendants knew about the seriousness of nicotine addiction for decades, but “they have endeavored to keep the extensive research and data they had accumulated out of the public domain and out of the hands of the public community by denying that such data existed, by refusing to disclose it, and by shutting down or censoring laboratories and research projects which were investigating the mechanisms of nicotine.” *Id.* at 307.

117. *Id.* at 308–84. Defendants have falsely “denied that they manipulated the nicotine in cigarettes so as to increase the addiction and dependence of smokers.” *Id.* at 384.

118. *Id.* at 430–561. “Defendants have known for decades that there is no clear health benefit from smoking low tar/low nicotine cigarettes as opposed to conventional full-flavor cigarettes . . . . Despite this knowledge, Defendants extensively—and successfully—marketed and promoted their low tar/light cigarettes as less harmful alternatives to full-flavor cigarettes.” *Id.* at 560.

119. *Id.* at 561–692. Defendants deliberately marketed cigarettes to youth under the age of twenty-one in order to recruit replacement smokers as a way to ensure a positive economic future for the tobacco industry. *Id.* at 561.

120. *Id.* at 692–839. The court concluded that the defendants acknowledged that environmental tobacco smoke is hazardous to nonsmokers, but publicly denied this knowledge. *Id.* at 692.

121. *Id.* at 866–67 (finding that, over the past fifty years, the defendants have suppressed, concealed, and destroyed information about smoking to prevent the public from learning about the adverse health consequences of smoking, the addictive qualities of nicotine, and to avoid litigation liability for smoking and health related claims).

122. *Id.* at 924–25, 928.

123. *Id.* at 33, 932 n.91.

124. Brief of Amici Curiae The American Medical Ass’n & Others in Support of the Plaintiff, United States & Tobacco-Free Kids Action Fund v. Philip Morris, No. 06-5267 (D.C. Cir. Nov. 26, 2007).

125. R.J. Reynolds Tobacco Co. v. Engle, 672 So. 2d 39, 42 (Fla. Dist. Ct. App. 1996); Barry Meier, *Huge Award for Smokers is Voided by Appeals Court*, N.Y. TIMES, May 22, 2003, at A20.

many diseases including cancers, lung and heart diseases; that nicotine is addictive; and that the tobacco industry defendants had committed fraud and misrepresentation, conspiracy to commit concealment, conspiracy to misrepresent, negligence, intentional infliction of emotional distress, and breach of express and implied warranties.<sup>126</sup> During the first phase of the trial, the jury found that both compensatory and punitive damages could be awarded to the plaintiffs and returned a few months later to consider the amount of damages.<sup>127</sup> In 2000, the jury found the defendant tobacco companies liable for the injuries to all three representative class members and awarded compensatory damages in the amount of \$12.7 million.<sup>128</sup> The jury then awarded the class \$145 billion, the largest punitive damages award ever issued.<sup>129</sup>

In 2006, on appeal, the Florida Supreme Court modified the compensatory damage awards and struck down the punitive damages award.<sup>130</sup> The Court held instead that the trial's first phase findings of industry liability would have *res judicata* effect for the class for a period of one year.<sup>131</sup> The members of the class may now proceed individually in what amounts to a strict liability claim where each claimant need only show that his or her injuries are among the many known cigarette-caused diseases; they may also make use of some of the jury's intentional tort findings to seek punitive damages.<sup>132</sup> Interestingly, the Supreme Judicial Court, the highest court in Massachusetts, recently ruled that an individual plaintiff could also proceed against a cigarette manufacturer on a strict liability basis where the plaintiff claimed a breach of the implied warranty of merchantability.<sup>133</sup>

The tobacco industry also faces consumer fraud class actions arising from its marketing of "light" cigarettes. These lawsuits allege that manufacturers have misled consumers by marketing "light" and "low tar" cigarettes as having less tar and nicotine than other brands, even though they knew the actual exposure levels

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126. See *Engle v. R.J. Reynolds Tobacco Co.*, No. 94-08273, 2000 WL 33534572, at \*1-5, \*16 (Fla. Cir. Ct. Nov. 6, 2000), *rev'd. sub nom. Liggett Group Inc. v. Engle*, 853 So. 2d 434 (Fla. Dist. Ct. App. 2003), *approved in part, quashed in part*, 945 So. 2d 1226 (Fla. 2006).

127. Meier, *supra* note 125 (documenting jurors' decision to award both compensatory and punitive damages at end of the first phase of trial); Rick Bragg, *Tobacco Lawsuit in Florida Yields Record Damages*, N.Y. TIMES, July 15, 2000, at A1 (documenting jurors' decision that tobacco industry to pay \$144.8 billion in punitive damages to Florida smokers during the next phase).

128. Meier, *supra* note 125.

129. *Id.*

130. *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246, 1254-56 (Fla. 2006).

131. *Id.* at 1276-77.

132. See *id.* at 1277 ("Individual plaintiffs within the class will be permitted to proceed individually with the findings set forth above given *res judicata* effect in any subsequent trial between individual class members and the defendants, provided such action is filed within one year of the mandate in this case.").

133. *Haglund v. Philip Morris Inc.*, 847 N.E.2d 315, 321-22 (Mass. 2006) (stating that under Massachusetts law, actions for breach of the implied warranty of merchantability are equivalent to strict liability).

were no different.<sup>134</sup> While most smokers and potential smokers believe that “light” cigarettes are less hazardous to their health than other brands,<sup>135</sup> consensus in the medical and public health community is that there is no difference.<sup>136</sup> Internal documents from tobacco companies show that they long believed the same thing!<sup>137</sup> Those who smoked (and continue to smoke) “light” cigarettes, reasonably believing they were being exposed to less tar or nicotine, are seeking court-ordered restitution of the money fraudulently obtained from them by the tobacco companies.<sup>138</sup> Because these claims are typically brought under state Unfair Trade and Deceptive Business Practice statutes, which allow for treble damages, plaintiffs are able to ask for three times the value of their financial losses.<sup>139</sup>

Section 917(b) of the proposed legislation would clearly preclude the potential for legal preemption of tobacco litigation. It states that nothing in the FDA legislation is to “affect any action or the liability of any person under the product liability law of any State.”<sup>140</sup> Nevertheless, in litigation, tobacco industry defendants would probably seek to exploit the fact that they are regulated by the FDA and argue to judges and juries that non-compensatory damages are not warranted. Cigarette manufacturers have similarly used the 1998 Multi-State Master Settlement Agreement (MSA) to try to immunize themselves from punitive damages and equitable remedies.<sup>141</sup> The MSA resolved lawsuits brought by forty-six states against the industry in the mid-1990s to primarily recover tobacco-related Medicaid expenditures incurred as a result of the industry misleading the public and obfuscating the health effects of their products.<sup>142</sup>

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134. *Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 33 (Ill. 2005); *Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 32–33 (Ohio 2006). See also Sherri Day, *Philip Morris is Convicted of Fraud in Marketing*, N.Y. TIMES, Mar. 22, 2003, at A6; David C. Johnston & Melanie Warner, *Tobacco Makers Lose Key Ruling on Latest Suits*, N.Y. TIMES, Sept. 26, 2006, at A1.

135. Lynn T. Kozlowski & Janine L. Pillitteri, *Beliefs About “Light” and “Ultra Light” Cigarettes and Efforts to Change Those Beliefs: An Overview of Early Efforts and Published Research*, 10 TOBACCO CONTROL (SUPP.), at i12, i13 (2001).

136. E.g., Nat’l Cancer Inst., Nat’l Insts. of Health, *Preface to SMOKING AND TOBACCO CONTROL MONOGRAPH 13, RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE*, at i, ii (Donald R. Shopland et al. eds., 2001).

137. See *supra* note 118 and accompanying text. See also Editorial, *Low-Tar Duplicity*, N.Y. TIMES, Dec. 3, 2001, at A18.

138. *Price v. Philip Morris Inc.*, No. 00-L-112, 2003 WL 22597608, at \*14 (Ill. Cir. Ct. 2003); *Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 33 (Ohio 2006).

139. E.g., *Marrone*, 850 N.E.2d at 39–40 (Grady, J., concurring and dissenting in part) (discussing the damages provision in the Ohio Consumer Sales Practice Act).

140. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(b) (2007); H.R. 1108, 110th Cong. § 917(b) (2007).

141. E.g., *Liggett Group Inc. v. Engle*, 853 So. 2d 434, 468 (Fla. Dist. Ct. App. 2003), *approved in part, quashed in part*, 945 So. 2d 1246 (Fla. 2006).

142. John M. Broder, *Cigarette Makers in a \$368 Billion Accord to Curb Lawsuits and Curtail Marketing*, N.Y. TIMES, June 21, 1997, at A1; Master Settlement Agreement, *supra* note 111, at 119–52.

The MSA was not intended to settle lawsuits brought by individuals or classes of individuals with potential claims against the tobacco industry. In early settlement talks prior to consideration of the MSA, the parties had considered a much more expansive settlement essentially designed, in part, to settle all actual and potential litigation.<sup>143</sup> The prospect of immunizing the industry in this manner became so divisive that the proposed settlement was dropped, allowing the individuals with potential claims to bring suit either individually or in the form of class actions.<sup>144</sup> Indeed, by the words of the MSA itself, these private lawsuits would appear to be protected. The MSA states “[n]either this Agreement nor any public discussions . . . with respect to this Agreement shall be . . . offered or received in evidence in any action or proceeding for any purpose other than in an action or proceeding arising under or relating to this Agreement.”<sup>145</sup> Minnesota, Florida, and Texas, which settled with the cigarette industry before the Agreement, each included effectively the same language in its agreement.<sup>146</sup>

This restriction on using the MSA in litigation, which is not related to the enforcement of the MSA, has not dissuaded the industry. In the massive tobacco class action lawsuit in Florida, *Engle v. R.J. Reynolds*, all of the leading cigarette manufacturers argued successfully before the state intermediate appellate court that the MSA prohibited the jury’s punitive damage award.<sup>147</sup> In 2000, the jury awarded approximately \$145 billion in punitive damages.<sup>148</sup> Until the jury awarded punitive damages, the trial judge had barred the industry from admitting the MSA into evidence, but on appeal, the defendants successfully argued that Florida’s version of the MSA punished them enough and that there was no need for further punishment for the harm caused to individual litigants.<sup>149</sup> The appeals court agreed,

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143. Michael Givel & Stanton A. Glantz, *The “Global Settlement” with the Tobacco Industry: 6 Years Later*, 94 AM. J. PUB. HEALTH 218, 218, 221–22 (2004).

144. *See id.* at 218.

145. *See* Master Settlement Agreement, *supra* note 111, § XVIII (f), at 106 (including a provision that protects any statements made during the negotiation of the MSA from being admitted into evidence in future litigation).

146. Settlement Agreement, Florida v. Am. Tobacco Co, Civ. Action No. 95-1466 AH, at § VI, ¶ C (Fla. Cir. Aug. 25, 1997), available at <http://stic.neu.edu/FL/flsettle.htm>; Settlement Agreement, Minnesota v. Philip Morris, Inc., Civ. Case No. CI-94-8565 (Minn. Dist. Ct. May 8, 1998), available at <http://stic.neu.edu/MN/settlement.htm>; Settlement Agreement, Texas v. Am. Tobacco Co., No. 5-96CV-91, at ¶ 22 (E.D. Tex. Jan. 16, 1998), available at <http://stic.neu.edu/Tx/Texas-settlement.htm>.

147. Liggett Group Inc. v. Engle, 853 So. 2d 434, 468–70 (Fla. Dist. Ct. App. 2003) (finding that the lower court erred in instructing the jury that the Florida Settlement Agreement (FSA) and the MSA did not constitute punishment of or deterrence to the defendants and “[t]his error precluded the defendants from presenting crucial mitigation evidence in the form of the FSA and MSA to support the argument that they had already received heavy financial obligations and binding deterrent measures for precisely the same conduct [as alleged by the plaintiffs in this case]”), *approved in part, quashed in part*, 945 So. 2d 1246 (Fla. 2006).

148. *Engle v. R.J. Reynolds Tobacco*, No. 94-08273 CA-22, 2000 WL 33534572, at \*12 (Fla. Cir. Ct. Nov. 6, 2000).

149. *Liggett Group Inc.*, 853 So. 2d at 468–70.

going so far as to state that Florida's MSA-like agreement negated any punitive damage claims.<sup>150</sup> The Florida Supreme Court later reversed this ruling but struck down the punitive damage award on other grounds.<sup>151</sup>

If the FDA legislation<sup>152</sup> were enacted, the tobacco industry would very likely make arguments similar to those in *Engle*,<sup>153</sup> as the existence of federal oversight would appear to limit the potential for malfeasance. In many lawsuits, this argument is moot. For example, in the "light" cigarette litigation, the plaintiffs are seeking to collect money spent for a product that basically does not deliver on the claim that "light" cigarettes expose smokers to less tar and nicotine.<sup>154</sup> A defendant tobacco manufacturer might argue that it has changed and stopped its wrongdoing, albeit involuntarily in the case of enhanced regulatory oversight, but this stance is irrelevant to "light" cigarette litigation. The obligation of the defendant manufacturer to, in essence, refund the money spent on "light" cigarettes remains valid. This same rationale would hold true for other consumer protection-based class actions.

Another potential argument likely to be made by the tobacco industry is that the industry will be adequately fenced in by FDA oversight and that the public therefore does not need further protection from the industry through additional court remedies. This argument appears to fall short of the mark with regard to punitive damages. This position ignores the fact that tobacco industry defendants may still engage in wrongful conduct, perhaps the same type of conduct at issue in current trials. This was the key conclusion in the federal government's successful RICO case against the industry.<sup>155</sup> Judge Kessler rejected the contention that the defendants had changed either voluntarily or because of the MSA, pointing to the flagrant misconduct that continued through the trial.<sup>156</sup> She concluded that the industry conduct would very likely continue, even within the existing tobacco control laws.<sup>157</sup>

The long-held understanding with respect to FDA oversight is that state common law tort claims create a separate and important layer of public health protection and offer a means for compensating individuals when FDA oversight

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150. *Id.*

151. *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246, 1254 (Fla. 2006) (holding that the class should be decertified because individual causation and apportionment of fault among the defendants were highly individualized and vacating the punitive damages award after finding the award excessive as a matter of law).

152. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(b) (2007); H.R. 1108, 110th Cong. § 917(b) (2007).

153. See *supra* notes 147–50 and accompanying text.

154. *Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 33 (Ohio 2006).

155. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d. 1, 848, 911–15 (D.D.C. 2006).

156. *Id.*

157. *Id.*

proves insufficient.<sup>158</sup> Although the FDA asserted in 2002 that its oversight is preemptive, the majority of courts hearing products liability cases involving drugs approved by the FDA have disagreed with this new position and allowed the cases to go forward.<sup>159</sup> The anti-preemption language in section 917(b) would help ensure that tobacco litigation would continue to exert each state's unique level of public health protection above and beyond that afforded by FDA oversight.<sup>160</sup>

Despite the intent not to alter the course of tobacco litigation, the question remains whether the FDA legislation could do more and revive the state law claims that were barred by the enactment of FCLAA. Like many other tobacco control strategies, tobacco litigation itself is constrained by preemption. Such preemption began in 1992, in *Cipollone v. Liggett Group, Inc.*<sup>161</sup> In *Cipollone*, the United States Supreme Court affirmed a lower court's ruling that FCLAA preempted failure-to-warn state claims, based on the conclusion that Congress wanted only one set of cigarette health warnings, those required by FCLAA.<sup>162</sup> Proof in state court that a manufacturer had failed to warn its customers of the dangers of smoking, according to the Court, would effectively mandate more warning requirements and, thus, must not be allowed to happen.<sup>163</sup>

Since *Cipollone*, cigarette manufacturers have used FCLAA preemption to chip away at other state law claims used in tobacco litigation. For example, in a more recent case, *Good v. Altria Group, Inc.*, the manufacturer argued that FCLAA preempted the plaintiff's claims that the marketing of light cigarettes violated the Maine Unfair Trade Practices Statute.<sup>164</sup> While the trial court agreed with this position, the United States Court of Appeals for the First Circuit did not.<sup>165</sup> The Court of Appeals found that the claim alleged "fraudulent misrepresentations in derogation of 'a more general obligation—the duty not to deceive,'" as opposed to a specific claim regarding the advertising and promotion of cigarettes, of the type that FCLAA arguably preempt.<sup>166</sup>

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158. See Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1094–99 (2007).

159. *Id.*

160. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 917(b) (2007); H.R. 1108, 110th Cong. § 917(b) (2007).

161. 505 U.S. 504 (1992).

162. See *id.* at 505, 515–17, 524–25 (1992) (finding that the 1969 amendments to FCLAA preempt state law claims challenging the adequacy of cigarette warnings on labels or in advertising), *aff'g* in part, *rev'g* in part, 893 F.2d 541 (3d Cir. 1990).

163. See *id.* at 524–25 (holding that FCLAA preempted state failure-to-warn claims that required a showing that a cigarette manufacturer's "advertising or promotions should have included additional, or more clearly stated warnings").

164. 436 F. Supp. 2d 132, 133, 144–45 (D. Me. 2006), *vacated*, 501 F.3d 29, 58–59 (1st Cir. 2007), *cert. granted* 128 S. Ct. 1119 (2008).

165. *Id.* at 153; *Good*, 501 F.3d at 58.

166. *Good*, 501 F. 3d at 42 (quoting *Cipollone*, 505 U.S. at 528–29).

A final determination will come from the United States Supreme Court, which accepted the manufacturer's petition for certiorari.<sup>167</sup> The Court's decision will have a dramatic impact on tobacco litigation. Light cigarette lawsuits have been filed under most states' unfair and deceptive trade statutes and several are awaiting trial.<sup>168</sup>

The FDA legislation could be amended to clarify the boundary for the preemption of tobacco litigation or to simply remove preemption. However, the FDA legislation, in its current form, does neither.

### *C. Preemption of Mandated Reductions in Smoke Constituent Emissions*

The final area of tobacco control in which state law measures would be affected by the proposed legislation is that of direct product regulation. As indicated in Part I of this Article, creating a framework for mandating reductions in harmful constituents in tobacco smoke is a major focus of the FDA reauthorization. Section 917(a)(2) states, in relevant part, that:

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

....

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.<sup>169</sup>

The terms included in subsection (A) above, including "adulteration," "misbranding," and so on, are all terms of art that refer to an FDA-regulated product that is not in compliance.<sup>170</sup> Although states would be allowed to ban cigarettes, the language in section 917(a)(2), discussed above, would preempt states from establishing laws that similarly mandate changes in product design. Historically speaking, this preemptive language preempts what states could do if they wanted to exercise their police power authority to mandate cigarette design

167. *Good*, 128 S. Ct. 1119 (2008).

168. *See id.*; ED SWEDA, ET AL., TOBACCO CONTROL LEGAL CONSORTIUM, LIGHT CIGARETTE LAWSUITS IN THE UNITED STATES: 2007, at 2–9 (2007), available at <http://www.tobaccolawcenter.org/resources/Lightcigarettes.pdf>.

169. S. 625, § 917(a)(2)(A)–(B); H.R. 1108, § 917(a)(2)(A)–(B).

170. *E.g.*, 21 U.S.C. §§ 351, 352 (2000) (defining "adulterated" and "misbranded" drugs and devices).

changes.<sup>171</sup> But, at least thus far, states have not sought to exercise this power, except with reference to fire safety standards.<sup>172</sup> No state limits the emission of toxic constituents in tobacco smoke. The only real glimpse of what this type of performance standard might look like comes from the recent increase in reduced ignition propensity (RIP) cigarette laws, which are expressly excluded from the preemption language.<sup>173</sup>

In June 2004, a New York state law mandating RIP standards for cigarettes went into effect.<sup>174</sup> Under this law, manufacturers are responsible for ensuring compliance by using a testing protocol from the New York Office of Fire Prevention and Control,<sup>175</sup> which essentially requires that each cigarette brand self-extinguish within a certain amount of time under controlled conditions.<sup>176</sup> Once a brand has passed, the manufacturer must provide New York officials with a written certification to that effect and place a mark on the cigarette packaging to indicate compliance.<sup>177</sup> Retesting and certification is required every three years.<sup>178</sup> Since adoption by New York, twenty-one other states have adopted RIP laws,<sup>179</sup> using the New York standard.<sup>180</sup>

States' experiences with RIP laws would appear to demonstrate one way in which states could—absent federal preemption—establish performance standards that are geared towards reducing nicotine delivery or toxic constituents in tobacco smoke. Each state could enforce a common set of performance standards using the same testing protocol. Under RIP laws, manufacturers would be free to compete with each other and adopt whatever technological means they see fit, as long as the cigarette passes the testing protocol. Even the variation in experiences and research among the participating states would perhaps inform improvements to the performance standards. Alternatively, states could adopt unique nicotine or toxic

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171. State police power would appear to include the ability to regulate or ban a product that is harmful to its citizenry. Public health protection is primarily a function of state police power. James G. Hodge, Jr., *Implementing Modern Public Health Goals Through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. HEALTH L. & POL'Y 93, 94 (1997).

172. Maine and Vermont, for example, regulate reduced ignition propensity cigarettes in fire safety statutes. 22 ME. REV. STAT. ANN. tit. 22, § 1555-E (Supp. 2007); VT. STAT. ANN. tit. 20, § 2757 (Supp. 2007).

173. S. 625, § 917(a)(2)(B); H.R. 1108, § 917(a)(2)(B).

174. N.Y. EXEC. LAW § 156-c(2)(a)(1)–(2) (McKinney 2006).

175. *Id.* § 156-c(2)(a)(2).

176. *Id.* § 156-c(2)(a)(1); accord HILLEL R. ALPERT, TOBACCO CONTROL LEGAL CONSORTIUM, REGULATING CIGARETTES FOR FIRE SAFETY 1, 2 (2007), available at <http://tclconline.org/documents/firesafecigarettes.pdf>.

177. N.Y. COMP. CODES R. & REGS. tit. 19, §§ 429.6, 429.8 (2006).

178. *Id.* § 429.6(c).

179. Coal. for Fire-Safe Cigarettes, Model Legislation, <http://www.firesafecigarettes.org> (follow “Legislative Updates” hyperlink; then follow “Adoptions” hyperlink) (last visited Mar. 17, 2008).

180. Coal. for Fire-Safe Cigarettes, *supra* note 179 (follow “Model Legislation” hyperlink) (last visited Mar. 17, 2008).



performance standards, thereby learning even more from the different approaches for reducing cigarette-caused harm.<sup>181</sup>

Whether the experience with RIP laws is predictive of what could or would occur is debatable. What we know, however, is that currently no state directly regulates cigarette product design and marketing outside the RIP context.<sup>182</sup> Concern about the preventive effects of section 917(a)(2) of the FDA legislation would only be justified under a prediction that states would take effective action along these lines and that the FDA would not.

### CONCLUSION

Like many grass roots movements, tobacco control's asymmetrical approach has worked because it does not directly challenge political dominance entrenched at the federal level. Instead, tobacco control started at the local level, building political and legal capacity until enough leverage existed to push through initiatives at the state level.<sup>183</sup> Many local communities and states involved in this effort tried different approaches and evaluated those approaches until core strategies developed: banning smoking in public places, increasing tobacco taxes, and more.<sup>184</sup> Enough momentum may now exist to push through an initiative at the federal level—FDA oversight over tobacco products. At this writing, the FDA legislation has 222 cosponsors out of 435 members in the House of Representatives,<sup>185</sup> and 55 cosponsors out of 100 members of the Senate.<sup>186</sup> On April 2, 2008, the version of the FDA legislation in the House of Representatives

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181. Under certain circumstances, the Commerce Clause may be used to block the exertion of such authority even in the absence of federal legislation. It might well form the basis of a legal challenge by tobacco interests if states were to set performance standards that vary from state to state. See Wendy E. Parmet & Christopher Banthin, *Public Health Protection and the Commerce Clause: Controlling Tobacco in the Internet Age*, 35 N.M. L. REV. 81, 83 (2005) ("Although courts traditionally assert that states have the power to protect public health, . . . the combination of recent doctrinal developments and the increasingly multi-state and even international nature of public health threats and commerce have made it more and more difficult for state public health laws to survive challenges brought under the dormant Commerce Clause.").

182. The only exception is a limited set of youth marketing restrictions found in the 1998 Master Settlement Agreement. Master Settlement Agreement, *supra* note 111, § III (a) at 14. Several states are currently prosecuting R.J. Reynolds under the Agreement for alleged misrepresentations in the marketing of one of its so-called reduced exposure cigarette brands. See Petition for Contempt & Complaint at 5, Vermont v. R.J. Reynolds Tobacco Co., No. 744 CnC & S-816-98 (Vt. Super. Ct. July 26, 2005), available at [http://www.atg.state.vt.us/upload/1125510625\\_Vermonts\\_Complaint\\_and\\_Petition.pdf](http://www.atg.state.vt.us/upload/1125510625_Vermonts_Complaint_and_Petition.pdf).

183. See *supra* notes 71–77, 102–04 and accompanying text.

184. See *supra* notes 69–81 and accompanying text.

185. See sources cited *supra* note 1.

186. *Id.*

was approved by the House Committee on Energy and Commerce.<sup>187</sup> The legislation must still go to the House of Representatives for consideration.<sup>188</sup>

Apart from the content of the legislation itself, which appears to be very effective, having a tobacco control policy at the federal level provides some important strategic advantages. First, it creates a regulatory framework to oversee the tobacco industry's efforts to re-normalize at least some types of tobacco use by claiming to reduce exposure to tobacco toxins.<sup>189</sup> Second, it affords states new opportunities for expanding their tobacco control policies.<sup>190</sup> Notably, states will be in a better legal position to prohibit cigarette advertising near schools, playgrounds and other areas where children congregate. Third, the vast resources and expertise of the FDA could make it an important partner in future tobacco control efforts, not only for local communities and states, but also for tobacco control efforts in other countries.

Nevertheless, the proposed oversight would be incapable of replacing state tobacco control policies, or of effectively drawing upon the public health practitioners and advocates who run state and local tobacco control programs. Accordingly, express anti-preemption language is essential. In its current form, the proposed FDA legislation includes such language and preserves state tobacco control policies, including tobacco litigation.<sup>191</sup> In shepherding the proposed FDA legislation through Congress, strong anti-preemption language must continue to be a priority.

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187. News Release, Comm. on Energy & Commerce, Energy and Commerce Committee Approves Landmark Tobacco Bill (Apr. 2, 2008), [http://energycommerce.house.gov/Press\\_110/110nr244.shtml](http://energycommerce.house.gov/Press_110/110nr244.shtml).

188. *Id.*

189. Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. § 911 (2007); H.R. 1108, 110th Cong. § 911 (2007).

190. *See supra* notes 83–99 and accompanying text.

191. S. 625, § 917; H.R. 1108, § 917.

