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Potentially Reduced Exposure Cigarettes: The Need for a Public Health Policy

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I. INTRODUCTION

On July 26, 2005, Vermont Attorney General, William Sorrell, announced that his office had filed a lawsuit against R.J. Reynolds Tobacco Company for using false and misleading advertising in the promotion of Eclipse cigarettes.[1] R.J. Reynolds claimed that smoking Eclipse cigarettes may be less harmful than smoking traditional cigarettes.[2] Several years earlier, in late 2000, Eclipse cigarettes were the subject of a Massachusetts Department of Public Health investigation that found virtually no difference between the smoke emitted by Eclipse cigarettes and that of several other conventional cigarette brands.[3] Indeed, Eclipse smoke contained even higher levels of certain toxic constituents, according to the study.[4] The findings attracted the attention of a group of state attorneys

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1. *See* Press Release, Vermont Attorney General William Sorrell, Attorney General William H. Sorrell Sues R.J. Reynolds For Consumer Fraud and Violation of Tobacco Master Settlement Agreement (July 26, 2005), *available at* http://www.atg.state.vt.us/display.php?pubsec=4&curdoc=970.

2. *See* R.J. Reynolds, *How Eclipse Works*, http://www.eclipse.rjrt.com/ECL/story3.jsp (last visited Jan. 26, 2007).

3. *See* Letter from Howard Koh, Commissioner, Massachusetts Department of Public Health, to Robert Pitofsky, Chairman, Federal Trade Commission (Oct. 3, 2000), *available at* http://www.tobaccofreekids.org/reports/eclipse/maletter.pdf.

4. *See id*.

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general who asked R.J. Reynolds for the scientific data supporting its claims.[5] Their conclusion: R.J. Reynolds had no "competent and reliable scientific evidence to substantiate such representations."[6]

R.J. Reynolds is not the only cigarette manufacturer claiming to have risk-reduction technology. Nearly the entire domestic cigarette industry is radically, and in a public fashion, shifting much of its business in this direction.[7] Industry research and development in this area climbed 40% from 1999 to 2004.[8] Sales are expected to account for 3% of U.S. industry sales volume in cigarettes, or $1 billion in sales, by 2009.[9] By 2015, financial analysts expect sales to exceed $20 billion and comprise 44% of the current U.S. industry sales volume.[10] Other companies are following this trend by introducing "less risky" tobacco products, such as Exalt™ and Revel® tobacco chew packets,[11] Ariva® tobacco lozenges, and Stonewall Hard Snuff®.[12] Collectively, these so-called "reduced risk" tobacco products are referred to as Potentially Reduced Exposure Products (PREPs).[13] This article focuses on the cigarette category of PREPs.

The tobacco industry may be counting on its multi-billion dollar investment in PREPs not only to produce a potentially less risky tobacco product, but more importantly to build

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5. *See* Tom Precious, *Cigarette Claiming Reduced Risks to Health is Probed by Spitzer*, BUFF. NEWS, Jan. 13, 2004, at A8.

6. 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.

7. *See* Martin Steinik & Michael Smith, The Path to a Safer Cigarette, J P Morgan Global Equity Research (July 26, 2004) (on file with author).

8. *See id*.

9. *See id*.

10. *See id*.

11. *See* Revel®, http://www.revel.com (last visited Jan. 26, 2006); *see also* Press Release, Swedish Match, Swedish Match Announces Test Market of Exalt™ – an Alternative for Smokers (April 27, 2001), *available at* http://nweb.waymaker.se/bitonline/2001/04/27/20010427BIT00770/bit0001.pdf.

12. *See* Press Release, Star Scientific, Inc., Star Scientific Statement on Ariva® and Stonewall Hard Snuff®, Tobacco Products for the Twenty-First Century (May 4, 2006), *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=105863&p=irol-newsArticle&ID=852475&highlight.

13. *See* A. B. Breland et al., *Acute effects of Advance™: a Potential Exposure Product for Smokers*, 11 TOBACCO CONTROL 376, 376-378 (2002).

capacity for the idea that at least some types of tobacco use are deemed acceptable. Tobacco use is the single most preventable cause of death in the United States, killing 400,000 Americans every year.[14] Tobacco-related mortality is higher than that caused by alcohol, AIDS, automobile collisions, illegal drugs, murders, and suicides combined.[15] Millions more suffer adverse health effects from smoking and exposure to secondhand smoke.[16]

This article examines the cigarette industry's interest in harm reduction, and ultimately recommends the need for a responsive legal policy. Part II examines some of the new PREP cigarettes as well as the research and technology that led to their development. Part III discusses the manner in which the cigarette industry behaved in the absence of product regulation of cigarettes. Part IV takes a closer look at the Eclipse cigarette lawsuit and potential problems that may be beyond the reach of such legal remedies. Part V recommends regulatory policies for PREPs and cites examples of recent legislative proposals in this area.

II. HARM REDUCTION CLAIMS AND TECHNOLOGY

Tobacco smoke might best be described as a toxic brew that contains acetone, ammonia, arsenic, benzene, cadmium, carbon monoxide, formaldehyde, hydrogen cyanide, lead, toluene and more. [17] Each puff of smoke contains more than fifty known or probable carcinogens.[18] Consequently, the U.S. Environmental Protection Agency classifies tobacco smoke as a Group A carcinogen.[19] The 2004 U.S. Surgeon General's Report concluded that smoking causes diseases in nearly every organ of

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14. *See* Ctrs. for Disease Control and Prevention, *Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs – United States, 1995-1999*, 51 MORBIDITY & MORTALITY WKLY. REP. 297, 300 (2002), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5114.pdf.

15. *See* Eric Lindblom & Katie McMahon, *Toll of Tobacco in the United States of America*, CAMPAIGN FOR TOBACCO-FREE KIDS, Jan. 4, 2007, *available at* http://www.tobaccofreekids.org/research/factsheets/pdf/0072.pdf.

16. *See* FRANK A. SLOAN ET AL., THE PRICE OF SMOKING 197-244 (MIT Press 2004).

17. *See* U.S. DEPT. OF HEALTH AND HUMAN SERVS., 1986 SURGEON GENERAL REPORT: THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING 225-52 (1986), *available at* http://www.cdc.gov/tobacco/sgr/sgr_1986/index.htm.

18. *See id*.

19. *See* U.S. ENVTL. PROT. AGENCY, EPA/600/6-90/006F, RESPIRATORY HEALTH EFFECTS OF PASSIVE SMOKING: LUNG CANCER AND OTHER DISORDERS 5-63 to -68 (1993).

the body,[20] and the 2006 U.S. Surgeon General's Report stated that there is no known safe level of smoking or exposure to secondhand smoke.[21]

PREP technology allegedly works by reducing the emission of carcinogens in cigarette smoke.[22] One proposed way to do this is to avoid combustion, which creates some of the carcinogens found in tobacco smoke.[23] R.J. Reynolds uses this method in its Eclipse cigarettes. Eclipse creates a smoke-like vapor by heating tobacco without burning it in a process analogous to cooking a meal in an oven at a temperature that will not burn it.[24] Using a match or lighter, the smoker ignites a miniature heating element embedded in the tip of each Eclipse cigarette.[25] The smoker draws on Eclipse just like a conventional cigarette and the heating element super heats air before it is drawn through the tobacco and into the smoker's lungs.[26] The heating element and tobacco are wrapped in paper and aluminum foil.[27] There is no filter.[28]

Accord cigarettes, produced by Philip Morris, similarly involve heating tobacco, but the smoker inserts the Accord cigarette into a small, battery-powered heating device about the size of a small mobile phone.[29] When the smoker draws on the cigarette, the heating device automatically delivers a specific amount of tobacco vapor into the smoker's lungs.[30] A screen on the device shows the smoker how many puffs remain in the cigarette.[31]

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20. *See* Press Release, U.S. Dep't of Health and Human Servs., New Surgeon General's Report Expands List of Diseases Caused by Smoking (May 27, 2004), *available at* http://www.hhs.gov/news/press/2004pres/20040527a.html.

21. *See* Press Release, U.S. Dep't of Health and Human Servs., New Surgeon General's Report Focuses on the Effects of Secondhand Smoke (June 27, 2006), *available at* http://www.hhs.gov/news/press/2006pres/20060627.html.

22. *See* J. Slade et al., *Eclipse: Does It Live Up to its Health Claims?*, 11 TOBACCO CONTROL ii64, ii64-ii70 (2002).

23. *See id*.

24. R.J. Reynolds, *supra* note 2.

25. *See id*.

26. *See id*.

27. *See id*.

28. *See id*.

29. *See* Lexi Krock, *Anatomy of a Cigarette*, NOVA ONLINE, http://www.pbs.org/wgbh/nova/cigarette/anatomy.html (updated Oct. 21, 2006).

30. *See id*.

31. *See id*.

Another technique for reducing carcinogenic emissions from cigarettes is to change the tobacco curing process,[32] which can be altered to reduce a group of carcinogens called tobacco specific nitrosamines (TSNAs).[33] For example, using direct-fire burners in tobacco barns during the curing process causes high levels of TSNAs.[34] Eliminating direct-fire burners may reduce levels of TSNAs.[35] Brown and Williamson claims that its Advance™ cigarette has "less of the toxins" in part because of such a patented curing process that inhibits the formation of TSNAs.[36]

Chemical additives are also used in the attempt to reduce carcinogenic emissions from cigarettes. Omni cigarettes, produced by Vector Tobacco, use palladium, a rare metal, as a burning catalyst to reduce levels of polycyclic aromatic hydrocarbons (PAHs) as well as TSNAs.[37] PAHs are a potent group of carcinogens that form during the combustion process.[38] Palladium increases the efficiency of combustion when a cigarette is lit and smoked, which leads to a more complete burning of the tobacco and theoretically reduces the emissions of certain carcinogens like PAHs and TSNAs.[39]

It is also possible for manufacturers to genetically modify tobacco, a process which Vector Tobacco uses in making its reduced-nicotine cigarette called Quest®.[40] Quest® comes in three varieties: "Low Nicotine," "Extra Low Nicotine," and "Nicotine-Free."[41] Users are invited to move in steps to

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32. *See* N. Gray & P. Boyle, *The Case of the Disappearing Nitrosamines: A Potentially Global Phenomenon*, 13 TOBACCO CONTROL 13, 13 (2004).

33. *See id*.

34. *See id*.

35. *See id*.

36. *See* A. B. Breland et al., *Tobacco Specific Nitrosamines and Potential Reduced Exposure Products for Smokers: A Preliminary Evaluation of Advance™*, 12 TOBACCO CONTROL 317, 317 (2003).

37. *See* JEFF FOWLES, NOVEL TOBACCO PRODUCTS: HEALTH RISK IMPLICATIONS AND INTERNATIONAL CONCERNS 13 (2001), *available at* http://www.ndp.govt.nz/publications/noveltobaccoproductsreport.pdf.

38. *See* DOROTHY HATSUKAMI & STEPHEN HECHT, HOPE OR HAZARD? WHAT RESEARCH TELLS US ABOUT "POTENTIALLY REDUCED-EXPOSURE" TOBACCO PRODUCTS 6 (2005), *available at* http://www.rwjf.org/files/research/Hope%20or%20Hazard.pdf.

39. *See id*.

40. *See* J. Dunsby & L. Bero, *A Nicotine Delivery Device Without the Nicotine? Tobacco Industry Development of Low Nicotine Cigarettes*, 13 TOBACCO CONTROL 362, 367 (2004).

41. Welcome to the World of Quest!, http://www.questcigs.com (last visited Jan. 25, 2007).

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"nicotine-free smoking."[42] In the late 1980s, Philip Morris briefly offered a nicotine-free cigarette called Next by adapting the method used to remove caffeine from coffee to remove nicotine from tobacco.[43]

One of the most highly watched PREP brands is expected to be based on Philip Morris' very popular flagship brand Marlboro, and will be called Marlboro Ultra Smooth. [44] The product was recently test marketed in three cities.[45] Marlboro Ultra Smooth uses highly activated carbon in its filter.[46] The activated carbon captures some carcinogenic constituents as the smoke is drawn through the filter.[47] The technology has been shown to reduce emissions of butadiene, acetaldehyde, acrolein, benzene, acrylonitrile and other carcinogens in cigarette smoke.[48]

Despite the tobacco industry's research and development, at this point, there are no reliable predictions or assessments of the risks involved in using these products or whether they are less harmful than traditional cigarettes.[49] At the outset, it is important to understand that the measurement of levels of constituents in smoke is not an accurate gauge of actual exposure levels.[50] The design and composition of each cigarette brand affects the manner in which smokers smoke, and therefore, their exposure levels. [51] Differences in how a smoker holds a cigarette, the frequency and depth of each puff of smoke, the length of time each puff of smoke is held in the lungs, and many other factors must all be accounted for in order to

42. *See id*.

43. *See* Dunsby & Bero, *supra* note 40, at 363-64.

44. *See* Press Release, Altria Group, Inc., Remarks by David R. Beran Executive Vice President Finance, Planning and Information Philip Morris USA Inc.: Prudential Back-to-School Conference (Sept. 7, 2005), *available at* http://www.altria.com/media/press_release/03_02_pr_2005_09_07_02.asp#.

45. *See id*.

46. Murray Laugesen & Jefferson Fowles, *Marlboro Ultrasmooth: a Potential Reduced Exposure Cigarette?*, 15 TOBACCO CONTROL 430, 430-31 (2006).

47. *See id*.

48. *See id*.

49. *See* COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, INST. OF MEDICINE, CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION vii-ix (Kathleen Stratton et al., eds. 2001); *see also* Dorothy K. Hatsukami et al., *Methods to Assess Potential Reduced Exposure Products*, 7 NICOTINE & TOBACCO RESEARCH 827, 827 (2005).

50. *See* COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, INST. OF MEDICINE, *supra* note 49, at 210.

51. *See id*.

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determine actual exposure levels.[52]

Even if evaluators could account for differences in smoking behavior and identify the actual exposure levels by brand, further research would be needed to predict comprehensively changes in health effects from smoking.[53] Current technology is unable to accurately map the relationship between exposure to tobacco smoke and the tobacco-related diseases at levels necessary to detect whether reduction in exposure would correspond to a meaningful reduction in harmful effects.[54] For certain carcinogens a 50% reduction in exposure might yield an immense health benefit, yet for others it might have no effect at all.

A promising approach for assessing the health effects of PREP technology, according to Hatsukami and colleagues, is the use of biomarkers.[55] Biomarkers are measurable conditions in the body that correlate to one or more aspects of the course of a disease.[56] Examples of a measurable condition might include chemical levels, measures of tissue inflammation, or changes in tissue structure.[57] Hatsukami and colleagues identified several biomarkers linked to diseases common in smokers and looked at the feasibility of measuring each of these biomarkers.[58] They measured differences in the biomarkers among smokers and nonsmokers, looked at changes in biomarkers after smoking cessation and reduced smoking, and looked at the response of biomarkers to different doses of tobacco smoke.[59] Although Hatsukami and colleagues concluded that "no existing biomarkers have been demonstrated to be predictive of tobacco-related disease," they feel further research may yield effective protocols for evaluating PREPs.[60]

It should come as no surprise that manufacturers have the ability to change the design and composition of cigarettes so that

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52. *See id*.

53. *See* Dorothy K. Hatsukami et al., *Harm Reduction Approaches to Reducing Tobacco-Related Mortality*, 25 ANN. REV. PUB. HEALTH 377, 381 (2004).

54. *See* COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, INST. OF MEDICINE, *supra* note 49 at 9–11.

55. *See* Dorothy K. Hatsukami et al., *Biomarkers to Assess the Utility of Potential Reduced Exposure Tobacco Products*, 8 NICOTINE & TOBACCO RES. 169, 169 (2006).

56. *See id*.

57. *See id*. at 169–80.

58. *Id*.

59. *See id*. at 169–70.

60. *Id*. at 169.

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they emit fewer carcinogens or are less addictive. Cigarettes are highly engineered products—not simply tobacco wrapped in paper. Some design features that affect the function of a cigarette include paper porosity, tobacco rod length and density, tobacco rod girth, ventilation holes, filter size and length, filter composition, tobacco leaf type, genetic modification of tobacco leaves, tobacco leaf preparation, and other ingredients. The critical question is whether manufacturers are willing to change cigarette design and composition in a manner that meaningfully reduces the impact of tobacco on the public's health.

III. THE ABSENCE OF REGULATORY OVERSIGHT

Currently, cigarette manufacturers can legally produce different brands of cigarettes that pose different harmful effects to the health of smokers. The health risk and lethality of cigarettes is completely unregulated.[61] Indeed, federal law actually presumes that all cigarette brands are equally harmful. Congress mandates that the same health warnings appear on all cigarette packages and advertisements.[62] The only disclosure requirement applicable to manufacturers is an annual disclosure listing the ingredients, which does not require the amount of each ingredient or contain any brand specific information.[63]

Undoubtedly this is an unusually weak level of oversight for a product that contributes to the death of more than 400,000 Americans every year.[64] Yet in 2000 a closely divided U.S. Supreme Court, in *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, concluded that this is exactly what

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61. *See* Matthew L. Meyers, *Opposition in Search of a Rationale: the Case for Food and Drug Administration Regulation*, 13 TOBACCO CONTROL 441 (2004).

62. *See* 15 U.S.C. § 1333(a) (2000). The current federally mandated provide no information on PREP brands, let alone warn against overestimating the benefits of PREPs. *See* Comprehensive Smoking Education Act of Oct. 12, 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984). The health warnings have not been updated since 1984, more than a decade before manufacturers first introduced PREP brands. *Id*.

63. *See* Patricia Davidson, *Tobacco Ingredients and Smoke Constituent Reporting and Disclosure Laws: The Case for Expansion*, 77 DENV. U.L. REV. 1, 3 (1999).

64. Ctrs. for Disease Control and Prevention, *Cigarette Smoking-Attributable Morbidity – United States, 2000*, 52 MORBIDITY & MORTALITY WKLY. REP. 842, 842 (2003), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5235.pdf.

Congress intended.[65] The case began after the Food and Drug Administration (FDA) determined that its authority included the ability to regulate cigarettes and smokeless tobacco.[66] The FDA based its authority on findings that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices."[67] The FDA immediately promulgated regulations restricting sales and advertising aimed at children[68] and foreshadowed the possibility of actual product regulation under its market-approval process.[69] The leading cigarette manufacturers responded by challenging the assertion of this authority.[70]

The Court found that the FDA's assertion contradicted congressional pronouncements regarding the oversight of tobacco.[71] The Federal Cigarette Labeling and Advertising Act and other federal statutes provided the Court with ample evidence that Congress, though willing to establish health warnings and the like, did not contemplate that tobacco products would be regulated as drugs or medical devices.[72] Furthermore, the Court found that the structure of the FDA's enabling legislation, the Food, Drug and Cosmetic Act, was inconsistent with regulating tobacco products as drugs or medical devices 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 and ban their sale.[73]

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65. *See* Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 (2000).

66. *See* Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619 (Aug. 28, 1996); *see also* Analysis Regarding Food and Drug Administration's Jurisdiction Over Nicotine Containing-Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453 (Aug. 11, 1995).

67. *See* Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. at 44,632-33; Analysis Regarding Food and Drug Administration's Jurisdiction Over Nicotine Containing-Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. at 41,453.

68. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996).

69. *See id*. at 44,412.

70. *See Brown & Williamson*, 529 U.S. 120.

71. *See id*. at 142.

72. *See id*. at 137–139.

73. *See id*. at 136 (quoting 21 U.S.C. § 360c(a)(1)(C) (2000)).

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The review of tobacco-related federal legislation also showed that Congress had carved out very unique treatment for tobacco manufacturers. Justice O'Connor stated, "Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area."[74]

Congress regulates tobacco directly, giving only marginal oversight responsibility to federal agencies. The Federal Trade Commission enforces the health warning requirements, but is not authorized to change the health warnings[75] even though they have not been updated since 1984[76] and are widely considered to be inadequate.[77] The Secretary of Health and Human Services obtains one aggregate list of cigarette ingredients from each manufacturer, but cannot require anything more specific.[78] The list does not identify the amount of each ingredient, the ingredients contained in a particular brand, or even the specific ingredients used by a manufacturer.[79] Additionally, tobacco products were specifically excluded from the authority of the Consumer Products Safety Commission and the authority of the U.S. Environmental Protection Agency under the Toxic Substance Control Act.[80]

The tobacco industry has similarly avoided product regulation by states. Around the same time the FDA-asserted authority was struck down, Massachusetts enacted the strictest cigarette-ingredients disclosure law in the country.[81] The

74. *Id*. at 159–60.

75. *See* 15 U.S.C. § 1333 (2000) (prescribing a narrow and exhaustive list of mandatory warnings while granting authority to the Federal Trade Commission only to ensure that cigarette manufacturers comply with the warning requirements).

76. *See* Comprehensive Smoking Education Act of October 12, 1984, Pub. L. No. 98–474, 98 Stat. 2200 (1984).

77. *See, e.g.*, D. 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 iii19, iii19 (2006).

78. *See* 15 U.S.C. § 1335a(a) (2000).

79. *See id*.

80. *See* 15 U.S.C. § 2052(a)(1)(B) (2000); 15 U.S.C. § 1261(f)(2)(2000).

81. *See* MASS. GEN. LAWS. ch. 94, § 307B (2006). The only other states to require cigarette manufacturers to disclose information about their products are Minnesota and Texas, but these disclosure laws have been criticized as being inadequate. *See* Davidson, *supra* note 63, at 17–28.

disclosure law required submission of an annual report identifying "any added constituent other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco, to be listed in descending order according to weight, measure or numerical count" for each brand of cigarette, snuff, or chewing tobacco sold in Massachusetts.[82] The law was intended to provide the Massachusetts Department of Public Health with information to aid in studying the health effects of each brand of cigarette.

The leading cigarette manufacturers brought a suit challenging the disclosure law and deftly pitted the value of trade secrets against the importance of protecting the public's health.[83] The court faulted Massachusetts for failing to "identify any background principles of state law that successfully obviate [the manufacturers'] property interest in their trade secrets,"[84] but ignored the bedrock principle that the state's "police power" includes the power and responsibility of protecting the public's health.[85] The court concluded that the trade secret was a property interest deserving protection under a regulatory takings analysis[86] and that the Massachusetts law amounted to an unconstitutional taking without just compensation.[87]

The immunity from regulatory oversight undoubtedly stems from the vast financial resources of the cigarette manufacturers that have earned them an unparalleled influence on the political process.[88] Yet, even more important than the question of how

82. *See* § 307B of the Massachusetts General Laws.

83. *See* Philip Morris, Inc. v. Reilly, 312 F.3d 24, 26 (2002).

84. *Id.* at 33.

85. *See* 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).

86. *See Philip Morris*, 312 F.3d at 45–47.

87. *See id.*

88. Former FDA Commission David Kessler recalls that those in the agency opposed to regulation argued that tobacco was just too powerful to bait. *See* DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 34-35 (2001). Since 1997, the year after the FDA asserted its authority to regulate tobacco, "tobacco interests have given more than $30.9 million in political donations to federal candidates, national parties and non-party political action committees." *See* TOBACCO FREE KIDS ACTION FUND & COMMON CAUSE, CAMPAIGN CONTRIBUTIONS BY TOBACCO INTERESTS ANNUAL REPORT: SEPTEMBER 2005 1 (2005), *available at* http://tobaccofreeaction.org/contributions/september2005/september2005.pdf. In 2004, the tobacco industry spent an additional $23 million on lobbyists, or $173,000 each day that Congress was in session that year. *Id.* at 2. The threat of legal challenges in the courts adds to the difficulty of shepherding tobacco control bills through the legislative process, particularly at the state level. *See*

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the tobacco industry has escaped product regulation is the impact of the lack of tobacco regulation. With the nature of its products hidden from scrutiny, the tobacco industry has engineered and implemented design changes with devastating effects on the public's health. Chief among such changes was the radical increase in the addictiveness of cigarettes. In 1972, Philip Morris researcher William Dunn famously recommended, "[t]he cigarette should be conceived not as a product but as a package. The product is nicotine . . . [t]hink of the cigarette pack as a storage container for a day's supply of nicotine. Think of the cigarette as a dispenser for a unit dose of nicotine."[89] Adopting this perspective, the cigarette manufacturers transformed the cigarette from shredded tobacco leaf rolled in paper into a delivery device for nicotine.[90]

Nicotine mimics a neurotransmitter in the body and triggers the release of artificially high levels of various hormones that alter the smoker's mood and mental performance.[91] Over time, once brain cells adapt to the regular presence of nicotine and the brain can function at normal levels in its presence, the smoker develops a tolerance and becomes dependent on nicotine in order to function normally and escape withdrawal symptoms.[92] By raising the pH of cigarette smoke through the addition of ammonia compounds and manipulating smoke particulate size to achieve the fastest possible absorption deep in the lungs, tobacco manufacturers have enhanced this effect.[93] These and other changes maximized the rate and amount of the delivery and absorption of nicotine but did so at the expense of the public's health.[94] The increase in delivery and absorption of

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Wendy Parmet & Christopher Banthin, *Public Health Protection and the Commerce Clause: Controlling Tobacco in the Internet Age*, 35 N.M. L. REV. 81, 83 (2005).

89. *See* WILLIAM L. DUNN, MOTIVES AND INCENTIVES IN CIGARETTE SMOKING 4 (n.d.), *available at* http://tobaccodocuments.org/landman/2024273959-3975.html (last visited Jan. 26, 2007).

90. *See* PETER BOYLE ET AL., TOBACCO SCIENCE, POLICY AND PUBLIC HEALTH, chs. 6–9 (Oxford Univ. Press 2004); *see also* United States v. Philip Morris USA, Inc., No. 99-2496(GK), 2006 WL 2380648 at * 47 (D.D.C. Aug. 17, 2006) (stating "Defendants Have Falsely Denied That They Can and Do Control the Level of Nicotine Delivered In Order to Create and Sustain Addiction").

91. *See id*.

92. *See id*.

93. *See id*.

94. *See id*.

nicotine was accompanied by an increase in exposure to carcinogenic smoke constituents.[95] Increases in addictiveness also triggered an increase in the average number of cigarettes smoked per day by each smoker, as well as an increase in the percentage of the population that smoked.[96]

Another example of industry conduct in the absence of product oversight is the advent of "light" cigarette brands. By the late 1960s, scientific studies showed that tar and nicotine correlated with a significantly increased risk of developing numerous diseases, particularly lung cancer.[97] Cigarette manufacturers viewed these findings as a threat to their profitability[98] and responded by marketing and selling "light" cigarettes. Manufacturers also developed an industry testing protocol for nicotine and tar levels.[99] They called it the "FTC method"—though the Federal Trade Commission neither mandated nor approved the testing method—and cigarette makers prominently posted the test results on their packaging and advertising for each brand.[100] "Light" cigarette brands displayed relatively low tar and nicotine measurements based on this method.[101]

However, while touted by manufacturers for lower tar and nicotine levels, "light" cigarette brands actually exposed smokers to nearly the same amounts of tar and nicotine as other cigarette brands.[102] The "FTC method" failed (and continues to fail) to account for the effect that a cigarette brand's design has on smoking behavior. After each puff of smoke, the brain registers how much nicotine it received and unconsciously increases or decreases the effort expended to get the amount of nicotine that the brain desires from the next puff.[103] Cigarette manufacturers

95. *See id*.

96. *See id*.

97. *See* R. W. Pollay & R. Dewhirst, *The Dark Side of Marketing Seemingly "Light" Cigarettes: Successful Images and Failed Fact*, 11 TOBACCO CONTROL i18, i18 (2002).

98. *See id*.

99. *See* Lynn T. Kozlowski et al., *Cigarette Design*, *in* SMOKING AND TOBACCO CONTROL MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE 13 (2001).

100. *See id*.

101. *See id*.

102. *See id*. at 18–32.

103. *See* Neal L. Benowitz, *Compensatory Smoking of Low-Yield Cigarettes*, *in* SMOKING AND TOBACCO CONTROL MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND

knew that smokers of "light" cigarettes would take in much more tar and nicotine than smokers were led to believe.[104] Some manufacturers even placed vents near the filters that were designed to add fresh air to smoke during testing, but that were covered by the smoker's fingers when smoked under normal conditions.[105]

The impact of "light" cigarettes on the public's health is enormous. The "light" cigarette and other similar innovations touted by cigarette manufacturers as health improvements have not reduced the health risk associated with smoking.[106] Yet, people continue to believe that "light" cigarettes are less risky than other cigarette brands; a misperception that is at least partly attributable to the hundreds of millions of marketing dollars spent promoting "light" cigarettes.[107]

IV. THE "VERMONT LAWSUIT"

The Vermont Attorney General's lawsuit against R.J. Reynolds is the result of a coordinated effort among several states, including active support by California, Connecticut, the District of Columbia, Idaho, Illinois, Iowa, Maine, New York, and Tennessee.[108] The Vermont lawsuit is being brought under the 1998 Multi-state Master Settlement Agreement (MSA).[109] The MSA settled lawsuits brought by the states to recover

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NICOTINE 41 (Donald R. Shopland ed., 2001).

104. *See* Richard W. Pollay & Timothy Dewhirst, *Marketing Cigarettes with Low Machine-Measured Yields*, *in* SMOKING AND TOBACCO CONTROL MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE 230-31 (Donald R. Shopland ed. 2001).

105. *See* L. T. Kozlowski & R. J. O'Connor, *Cigarette Filter Ventilation Is a Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents*, 11 TOBACCO CONTROL i40, i40 (2002).

106. *See* Michael J. Thun & David M. Burns, *Health Impact of "Reduced Yield" Cigarettes: A Critical Assessment of the Epidemiological Evidence*, 10 TOBACCO CONTROL i4, i9 (2002).

107. *See* 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 il2, il2 (2001). *See generally* Saul Shiffman et al., *Smokers' Belief about "Light" and "Ultra Light" Cigarettes*, 10 TOBACCO CONTROL il7 (2001); Saul Shiffman et al., *Effect of Health Messages about "Light" and "Ultra Light" Cigarettes on Beliefs and Quitting Intent*, 10 TOBACCO CONTROL i24 (2001).

108. *See* Press Release, Vermont Attorney General William Sorrell, *supra* note 1.

109. *See* Petition for Contempt & Complaint, *supra* note 6. The lawsuit also alleges violation of Vermont's Unlawful and Unfair Practices Law. *Id.*

smoking-related Medicaid and other public healthcare costs caused by the cigarette manufacturers' wrongdoing.[110] In these cases, states alleged that smoking rates, and consequently the Medicaid and related expenditures they incurred in treating sick and dying smokers, would have been much lower if cigarette manufacturers had been honest with the public about the dangers caused by smoking and not committed other wrongful acts orchestrated to keep smoking rates as high as possible.[111] The lawsuits successfully forced the manufacturers to shoulder at least some of these medical costs.[112]

The MSA also established some marketing restrictions. The National Association of Attorneys General (NAAG) supervises state enforcement of the MSA.[113] NAAG established the Tobacco Enforcement Committee, which is composed of several attorneys who coordinate and oversee industry compliance and the Enforcement Working Group, which primarily assists and advises the Enforcement Committee.[114] The Tobacco Project, also established by NAAG, coordinates and supports enforcement efforts and serves as a clearinghouse of information.[115] The marketing restrictions and ongoing enforcement efforts have led to some important changes in tobacco marketing and have kept tobacco-related issues on the radar screens of state officials charged with regulating advertising in magazines, free samples, advertising at sporting events, and other promotional activities. All of the domestic cigarette manufacturers have been implicated in at least one enforcement action; R.J. Reynolds has been responsible for a disproportionately large share.[116]

The Vermont lawsuit alleges that R.J. Reynolds' advertising for Eclipse cigarettes violates section III(r) of the MSA, which prohibits cigarette manufacturers from making "any material

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110. *See* Michele Bloch, Richard Daynard & Ruth Roemer, *A Year of Living Dangerously: The Tobacco Control Community Meets the Global Settlement*, 113 PUB. HEALTH REPS. 488, 490–91 (1998).

111. *See id*. at 490.

112. *See* Richard A. Daynard et al., Commentary, *Implications for Tobacco Control of the Multistate Tobacco Settlement*, 91 AM. J. OF PUB. HEALTH 1967, 1968 (2001).

113. *See* DENNIS ECKHART, TOBACCO CONTROL LEAGUE CONSORTIUM, THE TOBACCO MASTER SETTLEMENT AGREEMENT: ENFORCEMENT OF MARKETING RESTRICTIONS 1 (2004), *available at* http://www.wmitchell.edu/tobaccolaw/resources/eckhart.pdf.

114. *See id*. at 3.

115. *See id*.

116. *See id*.

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misrepresentation of fact regarding the health consequences of using any tobacco product, including any tobacco additives, filters, paper or other ingredients."[117] The complaint filed by the state of Vermont identifies several alleged misrepresentations made by R.J. Reynolds in Eclipse cigarette advertising:

> Discover the difference. A cigarette that may present less risk of cancer, bronchitis, and possibly emphysema.
>
> A cigarette that responds to concerns about certain smoking-related illnesses. Including cancer.
>
> A better way to smoke. The best choice for smokers who worry about their health is to quit. Eclipse is the next best choice.
>
> Extensive scientific studies show that compared to other cigarettes: Eclipse may present less risk of cancer, and Eclipse produces less inflammation in the respiratory system, which suggests lower risk of chronic bronchitis and possibly even emphysema.
>
> Because Eclipse primarily heats rather than burns tobacco, its smoke chemistry is fundamentally different, and the toxicity of its smoke is dramatically reduced compared to other cigarettes. For example, studies with smokers who switched to Eclipse from their usual brand show that Eclipse produced:
>
> - 17-57% less lung inflammation (after two months in smokers of 2 packs or more/day)
>
> - 70% lower smoking-related mutagenicity (DNA changes).
>
> Because [Eclipse] primarily heats tobacco rather than burning it, testing shows that the smoke is very different from that of other cigarettes. The results of many of these tests have, in fact, been presented at scientific meetings or published in scientific journals.
>
> Extensive analysis of Eclipse shows that [it] contains far less of many of the compounds that have been linked to the risk of cancer and associated with certain other smoking-related illnesses.[118]

The complaint alleges that these claims are no more than unproven marketing ploys meant to exploit smokers' health concerns.[119] R.J. Reynolds is accused of lacking any "competent and reliable scientific evidence to substantiate such representations."[120]

The exact form and breadth of the injunctive relief sought by the Vermont Attorney General will become apparent as litigation proceeds. Currently, the complaint asks that R.J Reynolds be prohibited from representing in any fashion that its products reduce the risk of disease, that its products are safer

117. *See* Petition for Contempt & Complaint, *supra* note 6, at 1.
118. *Id*. at 3–5.
119. *See id*. at 4–5.
120. *Id*. at 5.

than other cigarettes or provide a safe alternative to quitting, or that the smoke is safer, without first possessing "competent and reliable scientific information."[121] The court may look favorably upon a request by the Vermont Attorney General for detailed research and surveillance protocols to be put in place. Courts are reluctant to limit the application of state Unfair and Deceptive Practices laws, upon which the MSA is premised, preferring instead to preserve flexibility to address unforeseen or complex abusive business schemes. [122]

Nevertheless, enforcement under the MSA, even when diligently pursued, may be inadequate to prevent PREPs from posing a public-health risk. As an initial matter, the MSA fails to require the disclosure of information for determining the health effects of product design and ingredients.[123] A manufacturer may secretly alter the addictiveness of cigarettes, use even deadlier toxic ingredients to create new cigarette flavors, or make other changes that make smoking even more dangerous, in perfect secrecy. Just as a consumer 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.

Within the context of marketing oversight, an area which the MSA purports to provide oversight, there are also reasons for concern. For the Eclipse-type advertising identified in the Vermont lawsuit, the MSA provides an effective form of oversight. R.J. Reynolds appears to have recommended switching to Eclipse cigarettes for specific health-related reasons without determining whether Eclipse provides any advantages over traditional cigarettes in the face of contradictory research by the Massachusetts Department of Public Health. However, in the future, state attorneys general are likely to confront more subtle health claims than those used to promote Eclipse cigarettes. Such advertisement might take the form of a discussion of how some new technology works and how it affects smoke chemistry, and do so without saying anything explicit about decreasing risks associated with smoking. The manufacturers could even post a disclaimer on the packaging or

121. *See id*.

122. *See* JONATHAN SHELDON & CAROLYN L. CARTER, UNFAIR AND DECEPTIVE ACTS AND PRACTICES §1.1 (6th ed. 2004).

123. NAT'L ASS'N OF ATTORNEYS GEN., MASTER SETTLEMENT AGREEMENT (n.d.), *available at* http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724_1032468605_cigmsa.pdf (last visited Jan. 26, 2007).

product website, such as the following: "[c]urrent technology is insufficient to determine whether Move cigarettes are actually less harmful. Therefore, you should not assume there is any health benefit in switching to Move. Quitting is always the best option for your health."

This type of advertising can be misleading to smokers struggling with addiction-induced dissociation.[124] Addiction to nicotine can cause smokers to grasp whatever evidence or suggestion rationalizes continued smoking, while at the same time dissociating themselves from health recommendations or warnings.[125]

Responding to the misleading effects of these subtle types of advertising under authority granted by the MSA would involve substantial resources and time. Unlike rulings by administrative agencies to which courts afford substantial discretion,[126] MSA enforcement involves meeting the high evidentiary standards imposed by courts in the litigation process. The case-by-case approach of evaluating abuses like the hypothetical Move cigarette advertisement could quickly overwhelm the limited budgets of enforcement officials. Moreover, after an issue has been litigated, the manufacturer need only make slight wording changes to start the entire process over again.

Another potentially abusive practice related to PREPs involves the targeting of individuals who might quit or never start smoking if they were not otherwise persuaded to use a "less harmful" type of cigarette. States invest hundreds of millions of dollars into cessation programs via Medicaid coverage of cessation aids.[127] A manufacturer could easily target its PREP advertising at current and future recipients of these cessation services in an effort to reduce quit rates and keep that demographic smoking. In fact, in a survey designed to determine the impact of Eclipse marketing, respondents who

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124. *See* Richard D. Hurt & Channing R. Robertson, *Prying Open the Door to the Tobacco Industry's Secrets about Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173, 1174 (1998).

125. *See id*.

126. *See, e.g.*, Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837 (1984).

127. *See* ERIC LINDBLOM, CAMPAIGN FOR TOBACCO-FREE KIDS, A BROKEN PROMISE TO OUR CHILDREN: THE 1998 STATE TOBACCO SETTLEMENT SEVEN YEARS LATER i-iv (2005), *available at* http://www.tobaccofreekids.org/reports/settlements/2006/fullreport.pdf.

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were contemplating quitting demonstrated the greatest interest in trying Eclipse cigarettes and after exposure to Eclipse advertising, showed a reduced interest in quitting.[128] The MSA says nothing about targeting smokers who would otherwise quit.

The most troubling aspect of relying solely on the MSA for oversight of PREPs is that tobacco manufacturers can establish harm-reduction policies without actually having to meet any predetermined goals. Manufacturers decide the extent to which their cigarette brands incorporate PREP technology. Manufacturers can even define what constitutes a "less harmful" cigarette by focusing on reducing certain carcinogens, but not other harmful aspects of smoking. For example, R.J. Reynolds admits that Eclipse cigarettes do nothing to reduce the risk from cardiovascular disease, which causes 50% of smoking-related deaths.[129] Also, manufacturers largely ignore the addictiveness of cigarettes, as well as the carcinogenic properties of nicotine.[130] It would even be possible for manufacturers to increase the lethality or addictiveness of traditional cigarettes just to make PREPs appear less harmful or addictive.[131] There is ultimately little reason—apart from the threat of regulatory oversight or other liability—to believe manufacturers would want to reduce emissions in a manner that might compromise aroma, taste, addictiveness and sales.

Even if one assumes that market forces could force manufacturers to produce a substantially less-risky cigarette in the absence of mandated performance standards,[132] the harm

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128. *See* Saul Shiffman et al., *Smoker and Ex-Smoker Reactions to Cigarettes Claiming Reduced Risk*, 13 TOBACCO CONTROL 78, 78 (2004).

129. *See* Joan Stephenson, *A "Safer" Cigarette? Prove It, Says Critics*, 283 J. AM. MED. ASS'N 2507, 2508 (2000).

130. *See* Jack Henningfield et al., *Reducing Tobacco Addiction Through Tobacco Product Regulation*, 13 TOBACCO CONTROL 132, 132 (2004).

131. *See, e.g.*, Gregory N. Connolly, et al., Harvard School of Public Health, Trends in Smoke Nicotine Yield and Relationship to Design Characteristics Among Popular U.S. Cigarette Brands, 1997-2005 (2007), *available at* http://www.hsph.harvard.edu/nicotine/trends.pdf.

132. Smokers and potential smokers generally rely on manufacturers for information about cigarettes. *See* Michael Cummings et al., *Are Smokers Adequately Informed about the Health Risks of Smoking and Medicinal Nicotine?*, 6 NICOTINE & TOBACCO RES. 333, 339 (2004). The perception of risk by individuals can be shaped mostly by a manufacturers' advertising, perhaps because most people mistakenly believe that a government agency has approved such claims. *See* William Hamilton et al., *Smokers' Responses to Advertisements for Regular and Light Cigarettes and Potentially Reduced-Exposure Tobacco Products*, 6 NICOTINE & TOBACCO RES. 353, 360 (2004). Or, manufacturers' promotional efforts simply drown out countervailing views. *See* FED. TRADE COMM'N, CIGARETTE REPORT FOR 2002 1 (2004), *available at*

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caused by tobacco might actually increase in the aggregate. Critics of the use of harm reduction policies, as contrasted with the use of harm elimination policies, argue that it sends the wrong message and can perpetuate or even increase the risky behavior in question.[133] In the case of tobacco, such as light cigarette brands, PREPs could attract smokers and potential smokers who might otherwise quit or never start smoking. Although the harm to individual smokers may be lower, the reduction may be accompanied by an increase in smoking rates, which could lead to an aggregate increase in harm because more people would be smoking.[134] Without the protections afforded by evidenced-based performance standards, universal application of these standards, and monitoring to counterbalance aggregate increases in smoking and disease rates, the introduction of PREP cigarettes could end up doing more harm than good.

V. LOOKING TO THE FUTURE

A responsive policy capable of addressing concerns raised by PREP cigarettes could be established by states. The protection and regulation of public health has traditionally been considered a core part of inherent state police powers.[135] This role is illustrated by the aggressive stance many states have adopted regarding tobacco control and prevention. For example, states have banned smoking in public places, taxed tobacco products, established youth access laws, and have created cessation programs.[136]

Having an accurate listing of brand-specific constituent yields would save time and expense for states attorneys general who are monitoring PREP cigarette advertising under the MSA and for public health scientists who are trying to create disease prediction models. Additionally, with comprehensive disclosure

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http://www.ftc.gov/reports/cigarette/041022cigaretterpt.pdf.

133. *See* 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).

134. *See id*.

135. *See* Hodge, *supra* note 85.

136. *See generally* Dileep. G. Bal et al., *The California Tobacco Control Program*, *in* TOBACCO AND HEALTH 341–45 (Karen Slama ed., 1995) (noting the role of legislation regarding public smoking bans and media campaigns in promulgating an anti-smoking message in California); *see also* Parmet & Banthin, *supra* note 88, at 88-90 (discussing states' use of tobacco taxes to dissuade smoking).

also comes the ability to mandate the manner in which constituent yields are measured and the requirement that manufacturers to take a documented stance on each of its brands. Misleading advertisements and marketing would become harder to sustain, and thus less likely to occur, in the face of ongoing verification by regulators.[137]

A model for the establishment of harm reduction goals at the state level can be found in the successful implementation of reduced ignition propensity laws. Such laws are aimed at reducing fires caused by unattended cigarettes, which is one of the leading causes of fires in homes.[138] Connolly and colleagues examined the implementation of New York's reduced ignition propensity law and found that manufacturers were able to meet performance goals, which in turn, led to a dramatic reduction in ignition propensity of cigarettes compared to traditional brands.[139] Similar laws have been passed in Vermont, California, and Canada.[140]

Of course the FDA could establish a responsive policy. Indeed, legislation has been filed for the reauthorization of FDA jurisdiction over tobacco products. In May 2004, Senators Mike DeWine and Edward Kennedy introduced Senate Bill 2461 to provide the FDA with oversight over tobacco products and marketing.[141] The FDA reauthorization legislation would require manufacturers to obtain approval before marketing a PREP cigarette.[142] The application process would require the submission of product and marketing information in a process that is largely open for public comment, including annual post-market surveillances, and must be renewed every five years.[143] The FDA would approve applications only if the applicant demonstrated that the actual manner in which consumers use

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137. *See* Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 YALE L. J. 785, 812 (2001).

138. JOHN R. HALL, JR., NATIONAL FIRE PROTECTION ASSOCIATION, THE SMOKING-MATERIAL FIRE PROBLEM 10 (2006).

139. *See* G. N. Connolly et al., *Effects of the New York State Cigarette Fire Safety Standard on Ignition Propensity, Smoke Constituents, and the Consumer Market*, 14 TOBACCO CONTROL 321, 321-27 (2005).

140. VT. STAT. ANN. tit. 20, § 2757 (2006); CAL. HEALTH & SAFETY CODE § 14952 (2006); Cigarette Ignition Propensity Regulations (Tobacco) Act SOR/2005-178, 139 C. Gaz. 1505 (2005).

141. Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004) ("To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.").

142. *See id*. at § 911.

143. *See id*.

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the product "significantly reduce[s] harm and the risk of tobacco-related disease to individual tobacco users" and "benefit[s] the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[144] Importantly, the FDA would also have authority to set performance standards for reductions in carcinogenic emissions and nicotine, and to limit marketing for PREP cigarettes based on their aggregate effects on smoking rates.[145]

Cigarette manufacturers know that they can shape smokers' perceptions of risk, perhaps because most people mistakenly believe that a government agency has approved such claims,[146] or perhaps because cigarette manufacturers' promotional budgets simply drown out countervailing views.[147] In its lawsuit against R.J. Reynolds, Vermont attempted to draw a line in the sand that PREP cigarettes shall not be marketed in a manner that caused smokers to overestimate the actual harm reduction value of these products. And in the absence of scientific proof, there is not actual harm reduction value.

With the introduction of PREP cigarettes in the absence of ingredient disclosure requirements, an investigation by an FDA-like review or other typical oversight of health claims, the public's health is once again at risk as a result of tobacco. According to Judge Gladys Kessler who for seven years presided over the Federal Governments Racketeer Influenced and Corrupt Organizations case, the Defendants' misled smokers and potential smokers into believing that light cigarettes were less harmful to keep them smoking.[148] Today, decades after the initial introduction of light cigarettes, the Defendants' continue to misled smokers and potential smokers into believing that light cigarettes are safer than other cigarette brands, according to Judge Kessler.[149]

144. *See id*.
145. *See id*.
146. *See* Hamilton et al., *supra* note 132.
147. *See* FED. TRADE. COMM'N, *supra* note 132.
148. *See* U.S. v. Philip Morris USA, Inc., No. 99-2496 (GK) 2006 WL 2380648 to 2006 WL 23089681, at *177–78 (D. D.C. Aug. 17, 2006).
149. *See id*. at *204–06.