

SMOKING ABROAD AND SMOKELESS AT HOME: HOLDING THE TOBACCO INDUSTRY ACCOUNTABLE IN A NEW ERA

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INTRODUCTION

Over four decades ago, the U.S. Surgeon General issued a landmark report stating that cigarette smoking causes cancer and other deadly diseases and “substantially contributes . . . to the overall death rate” in this country.¹ Since the 1964 Report, the U.S. government has issued several other reports documenting the mounting scientific evidence that conclusively established the causal connections between smoking and many lethal and debilitating diseases, and millions of Americans have died from smoking and smoking-related illnesses.² Largely as a result of numerous documents uncovered in litigation against the industry and some key whistleblower accounts, the insidious practices of the tobacco industry have become clear. Since at least a decade before the 1964 Report was issued, tobacco companies have been engaging in a concerted effort to suppress and counter information about the health impacts and the addictiveness of smoking, and about the industry’s own manufacturing and marketing practices, which included the deliberate targeting of children and adolescents

1. PUB. HEALTH SERV., U.S. DEP’T OF HEALTH, EDUC. AND WELFARE, PUBL’N NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 31, 37–38 (1964), available at http://profiles.nlm.nih.gov/NN/B/B/M/Q/_/nnbbmq.pdf [hereinafter 1964 SURGEON GENERAL REPORT ON SMOKING AND HEALTH]. More specifically, the Surgeon General’s 1964 report determined that existing studies established a causal link between cigarette smoking and lung cancer, laryngeal cancer, and chronic bronchitis. See *id.* at 37–38. The report further concluded that there was an association between cigarette smoking and other cancers, emphysema, and heart disease. See *id.* at 37–39.

2. In a 1986 report, the Surgeon General noted that “[t]he data reviewed in 17 previous U.S. Public Health Service reports on the health consequences of smoking have conclusively established cigarette smoking as the largest single preventable cause of premature death and disability in the United States.” PUB. HEALTH SERV., U.S. DEP’T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING: A REPORT OF THE SURGEON GENERAL vii (1986), available at http://profiles.nlm.nih.gov/NN/B/C/P/M/_/nnbcpm.pdf. The Surgeon General’s most recent report on the health consequences of smoking stated that cigarette smoking remains “the single greatest cause of avoidable morbidity and mortality in the United States,” “causing approximately 440,000 deaths each year and costing approximately \$157 billion in annual health-related economic losses.” PUB. HEALTH SERV., U.S. DEP’T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL 3, 9 (2004), available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm [hereinafter 2004 SURGEON GENERAL REPORT ON THE HEALTH CONSEQUENCES OF SMOKING].

and the manipulation of the design and nicotine content of cigarettes to increase their addictiveness.³

In this article, I argue that these activities amount to a dual-pronged strategy that I call a “disinformation plus path-dependence” strategy. As used by the tobacco industry, this strategy consists of (1) the pervasive dissemination of disinformation to encourage nonrational decisionmaking about tobacco product use, and (2) the subsequent deprivation of free choice on the part of those who become addicted to the products, even if the disinformation problem is corrected.

The industry’s implementation of its “disinformation plus path-dependence” strategy to sell cigarettes has played a key role in allowing tobacco companies to remain largely unregulated in this country⁴ until very recently. Over four decades after the 1964 Report and over two decades after the industry’s deceptive practices in manufacturing and marketing cigarettes became widely known, legislation was finally enacted to provide the Food and Drug Administration (FDA) with authority to regulate tobacco products. Until this legislation—the Family Smoking Prevention and Tobacco Control Act (TCA)⁵—was enacted in June of 2009, the federal regulation that existed focused only on providing the public and government with information about the health consequences of tobacco product use. Given the nature of the tobacco industry’s disinformation campaign and the fact that the industry has coupled this campaign with the manufacture and

3. See, e.g., WILLIAM HALTOM & MICHAEL McCANN, *DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS* 237–39 (2004); Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 *STAN. L. & POL’Y REV.* 76–80 (1997); *infra* Part I.B.

4. Additionally, tobacco companies have kept a stream of millions of dollars flowing into the campaign coffers of federal and state politicians. See, e.g., Ctr. for Responsive Politics, *Tobacco: Long-term Contribution Trends*, <http://www.opensecrets.org/industries/indus.asp?Ind=A02&cycle=2006> (last visited Dec. 22, 2009) (aggregating data from reports submitted to the Federal Election Commission for the election cycles over the period from 1990 to 2010, finding that the tobacco companies contributed \$46,246,278 to Republican congressional candidates, and \$16,385,286 to Democratic congressional candidates); TOBACCO FREE KIDS ACTION FUND & COMMON CAUSE, *CAMPAIGN CONTRIBUTIONS BY TOBACCO INTERESTS ANNUAL REPORT: SEPTEMBER 2007* 16 (2007), available at http://tobaccofreeaction.org/contributions/Report_2007_09/Contributions_2007_09.pdf (reporting that tobacco companies have spent over \$170 million on lobbying Congress members since 1999); NAT’L INST. ON MONEY IN STATE POLITICS, *TOUGH TIMES FOR TOBACCO: TOBACCO BANS, TAX INCREASES PASS, DESPITE BIG TOBACCO CAMPAIGN DONATIONS 2* (2007), available at <http://www.followthemoney.org/press/Reports/200710221.pdf> (reporting that “[t]obacco manufacturers and retailers gave \$96 million to state level candidates, committees and ballot measures in the 2005 and 2006 election cycles”).

5. Pub. L. No. 111-31, §§ 101–06, 123 Stat. 1776, 1783–1842 (2009) (to be codified at 21 U.S.C. §§ 387a–387u and scattered sections of 15 U.S.C.).

marketing of highly addictive products, this form of information provision regulation was entirely inadequate.

A number of non-federal regulatory measures, including state and local indoor smoking bans, state tort suits, and the Master Settlement Agreement, which imposes significant marketing restrictions on cigarette manufacturers, eventually had considerable success in diminishing the industry's ability to maintain its "disinformation plus path-dependence" strategy with respect to cigarette sales in this country. However, tobacco manufacturers have responded by exploiting two openings for a successful disinformation campaign: smokeless tobacco products⁶ and the global cigarette market.⁷ The industry thus threatens the continuation of its "disinformation plus path-dependence" strategy. Although the TCA represents an important step toward meaningful regulation of the manufacture and marketing of tobacco products, it appears likely that it will not provide an effective counter to these most recent manifestations of the industry's strategy.

In Part I of this article, I trace the U.S. experience of the tobacco epidemic from a legal perspective: the so-called "tobacco wars." In particular, I explain how the tobacco industry has remained virtually free of regulatory oversight, largely as a result of its disinformation campaign; describe the industry's "disinformation plus path-dependence" strategy; and argue that, until the recent enactment of the TCA, the federal regulation of the industry, which was focused on the provision of information about the health impacts of tobacco product use, was an inadequate response to that strategy.

In Part II, I turn to the relatively recent surge in various state and local means of regulation, and explain how these non-federal measures ultimately reached the critical mass that made the industry's "disinformation plus path-dependence" strategy much less viable as a means of maintaining a cigarette consumer base in the United States.

In Part III, I explain what appear to be the industry's two principal responses to declining U.S. cigarette sales: a domestic "smokeless" manifestation of its "disinformation plus path-dependence" strategy and a transnational "smoking" manifestation of the strategy.

6. David Vladeck alerted me to this development and its public health significance.

7. Recently, the largest U.S. tobacco company created an international spin-off to market cigarettes in other countries. *See* Altria, Philip Morris International Spin-off: Investor Information, http://www.altria.com/investors/2_2_1_pmispinoff.asp (last visited Dec. 22, 2009) (announcing that Altria—the parent company of Philip Morris USA and International—and its "Board of Directors voted on January 30, 2008, to authorize the spin off of 100% of the shares of Philip Morris International" and that the distribution was made on March 28, 2008).

Finally, in Part IV, I describe the landmark nature of the TCA and explain how it is to a significant extent based on the three principal lessons learned through this country's decades-long experience with the industry's "disinformation plus path-dependence" strategy: that the strategy is highly effective and can cause harm on a massive scale, but can be combated. I will argue, however, that given both that the industry has already adapted to increased regulation in response to the confluence of non-federal regulatory measures that preceded the Act, and that the industry has the ability to continue to adapt its malleable strategy to ongoing regulatory pressure, the Act does not go far enough.

I.

THE HISTORIC UNDER-REGULATION OF THE TOBACCO INDUSTRY AND ITS "DISINFORMATION PLUS PATH-DEPENDENCE" STRATEGY

In the 1964 Report, the Surgeon General announced the U.S. Public Health Service's determination that "[c]igarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action" by the federal government.⁸ In subsequent reports, the Surgeon General made increasingly stronger calls for federal regulation as it became apparent that the country was experiencing a massive public health crisis caused by tobacco use.⁹ Nevertheless, tobacco companies remained virtually unregulated throughout most of their history of manufacturing and marketing their products in this country.

8. 1964 SURGEON GENERAL REPORT ON SMOKING AND HEALTH, *supra* note 1, at 33.

9. See, e.g., PUB. HEALTH SERV., U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—THE CHANGING CIGARETTE: A REPORT OF THE SURGEON GENERAL vii (1981), available at http://profiles.nlm.nih.gov/NN/B/B/S/N/_/nnbbsn.pdf ("In the regulatory area, this Report suggests the need to increase the public's access to information about the product it buys. Advertisements and packages alike should display yield figures more prominently, including measures of carbon monoxide and possibly other hazardous ingredients."); *id.* at 201 (citing previous recommendations by heads of the health department that Congress pass legislation that would "require 'tar' and nicotine levels on packages and advertisements, with provision for adding to the label any ingredients subsequently identified as hazardous" (in 1966) and "legislation authorizing the regulation of cigarettes by formulation of maximum permissible levels of hazardous ingredients" (in 1974 and 1975)).

A. *The Development of Regulation Focused on the Provision of Information Regarding the Health Impacts of Tobacco Products*

Shortly after the issuance of the 1964 Report on cigarette smoking and health, the Federal Trade Commission (FTC) responded to the Surgeon General's call for remedial action by promulgating a rule that would have required cigarette manufacturers to disclose that "cigarette smoking is dangerous to health and may cause death from cancer and other diseases" in all cigarette advertising and on all cigarette packaging.¹⁰ To market cigarettes without such a disclosure, the FTC determined, would be "an unfair or deceptive act or practice" in violation of the Federal Trade Commission Act.¹¹

However, tobacco companies responded quickly and convinced Congress to suspend the FTC's rule and to instead enact legislation

10. Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8325 (July 2, 1964). In explaining the basis and purpose of the rule, the FTC noted that it had been monitoring unfair and deceptive advertising of cigarettes since the 1930s, but that recently it had become increasingly concerned "with fulfilling its statutory responsibilities in the area of cigarette merchandising" in light of the accumulation of evidence indicating that cigarette smoking posed "very grave hazards to life and health." *Id.* at 8325. Consequently, the FTC stated, it "was prepared . . . to act upon" the Surgeon General's call for remedial action. *Id.* at 8326.

11. *Id.* In explaining this determination, the FTC stated:

It is a deceptive act or practice for an advertiser to make representations concerning the satisfactions to be derived from using so hazardous a product as cigarettes without, at the same time, disclosing the dangers to health involved in its use.

. . . .

This principle is applicable *a fortiori* to cigarette advertising that not only stresses the satisfactions of smoking, but makes a positive attempt to allay the consuming public's fears or anxiety with respect to the dangers of smoking by representing or implying that smoking the advertised brand is or may be harmless or less harmful than smoking other brands.

Id. at 8356. The FTC noted further that "[i]t is all the more imperative to hold cigarette manufacturers to the duty of fair and non-deceptive marketing in view of the evident attractiveness of cigarette smoking to children and teenagers, and the fact that it is habit-forming." *Id.* at 8355. The sorts of cigarette advertisement that concerned the FTC were recently on display at the New York Public Library in an exhibit entitled "Not a Cough in a Carload: Images Used by Tobacco Companies to Hide the Hazards of Smoking." See Stuart Elliott, *When Doctors, and Even Santa, Endorsed Tobacco*, N.Y. TIMES, Oct. 7, 2008, at B3. The exhibit contains hundreds of print and television advertisements from the 1920s to early 1950s featuring endorsements from physicians, members of Congress, Santa Claus, professional athletes, actors, and cartoon characters. See *id.* The exhibit is available online at <http://tobacco.stanford.edu> (last visited Dec. 22, 2009).

that required health warnings only on product packaging.¹² This law—the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA)¹³—weakened the required warning statement by mandating only a statement that “cigarette smoking *may* be hazardous to your health” and required no reference to the risk of death from smoking-related diseases.¹⁴ Furthermore, the 1965 FCLAA provided that companies could not be required to include any statements “relating to smoking and health” on product packaging other than that required by the Act¹⁵ and could not be required to include *any* warnings in cigarette advertising until the Act’s preemption provision regarding the regulation of cigarette advertising terminated in four years.¹⁶

Since 1965, the federal government has subjected tobacco companies to greater—but still quite limited—marketing regulation. In 1969, Congress amended the FCLAA to strengthen the warning requirements for cigarette packaging,¹⁷ reinstate the FTC’s authority to issue the rule requiring disclosure of the health risks of smoking in cigarette advertising,¹⁸ and ban broadcast advertising of cigarettes.¹⁹

12. See Elizabeth Brenner Drew, *The Quiet Victory of the Cigarette Lobby: How It Found the Best Filter Yet—Congress*, ATLANTIC MONTHLY, Sept. 1965, at 76. In her article criticizing the bill shortly after its passage, Drew wrote:

[T]he bill is not, as its sponsors suggested, an example of congressional initiative to protect public health; it is an unabashed act to protect private industry from government regulation. Behind the façade of a requirement for printing a warning on cigarette packages (which is not expected to deter smoking much), Congress tied the hands of the Federal Trade Commission by forbidding it to proceed with its own plans to apply much more stringent regulations.

Id.; see also Ronald Bayer & James Colgrove, *Children and Bystanders First, in UNFILTERED: CONFLICTS OVER TOBACCO POLICY AND PUBLIC HEALTH* 8, 10 (2004) (noting that the legislation “was widely viewed as a victory for the tobacco industry”).

13. Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965).

14. See *id.* § 4, 79 Stat. at 283 (emphasis added). In contrast, the FTC rule had required the disclosure that “cigarette smoking *is* dangerous to health and may cause death from cancer and other diseases.” See 29 Fed. Reg. at 8235 (emphasis added).

15. Federal Cigarette Labeling and Advertising Act of 1965, § 5(a), 79 Stat. at 283.

16. See *id.* §§ 5(b), 10, 79 Stat. at 283, 284 (“The provisions of this Act which affect the regulation of advertising shall terminate on July 1, 1969, but such termination shall not be construed as limiting, expanding, or otherwise affecting the jurisdiction or authority which the Federal Trade Commission or any other Federal agency had prior to the date of enactment of this Act.”).

17. See Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 4, 84 Stat. 87, 88 (1970) (requiring on cigarette packaging the statement “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health”).

18. See *id.* §§ 5(b), 7, 84 Stat. at 88, 89 (providing that “[n]o requirement or prohibition based on smoking and health shall be imposed under *State* law with respect to advertising or promotion of any cigarettes” and mandating that the FTC could not act

The FTC issued what was in effect the equivalent of the advertising rule the following year in an order based on the agency's determination that the six major U.S. tobacco companies had systematically represented in their cigarette advertisements that smoking is "desirable" without making "clear and conspicuous disclosures that cigarette smoking is dangerous to health."²⁰ Such representations were, the

on the rule until after July 1, 1971, and that the rule could not take "effect until six months after the [FTC] has notified the Congress of the text of such rule, in order that Congress may act if it so desires") (emphasis added); *see also* *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 515 (1992) (explaining that, "[a]lthough the [1969] Act also directed the FTC not to 'take any action before July 1, 1971, with respect to its pending trade regulation rule proceeding relating to cigarette advertising,' the narrowing of the pre-emption provision to prohibit only restrictions 'imposed under State law' cleared the way for the FTC to extend the warning-label requirement to print advertisements for cigarettes").

19. *See* Public Health Cigarette Smoking Act of 1969, *supra* note 17, § 6, 84 Stat. at 89 (prohibiting the advertising of cigarettes "on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission" after January 1, 1971). It bears mention that the tobacco industry supported a congressional ban on broadcast advertising after the Federal Communications Commission (FCC) determined that, given the health dangers of cigarette smoking, the "Fairness Doctrine" and the general obligation of those licensed to broadcast over the public airwaves to serve the public interest, broadcasters who aired cigarette ads were required to provide free air time for anti-smoking messages. *See* Bayer & Colgrove, *supra* note 12, at 11–12. After the ban took effect, anti-smoking ads disappeared from the airwaves along with smoking ads, and the industry was able to shift all its advertising expenditures to print media, where it would be free of the FCC's jurisdiction (and thus not subject to the Fairness Doctrine). *See id.* at 12–13 (noting that in the year following the broadcast advertising ban, tobacco companies increased newspaper advertising expenditures by 400% and magazine advertising expenditures by 50%).

20. Complaint at 6, *Lorillard*, 80 F.T.C. 455, 457 (1972). The six major cigarette manufacturers against which the FTC brought the complaint were Lorillard, Philip Morris, American Brands, Brown & Williamson, R.J. Reynolds (RJR), and Liggett & Myers. *See id.* Although there have since been corporate restructurings and name changes, this handful of corporate actors has continued to dominate the U.S. cigarette market. *See* Bayer & Colgrove, *supra* note 12, at 9. In 1990, a company named Commonwealth Brands bought six cigarette brands from Brown & Williamson and marketed them as discount cigarettes. *See* Hoovers Company Profile, Commonwealth Brands, Inc., http://www.hoovers.com/commonwealth-brands/—ID__104160—/free-co-profile.xhtml (last visited Dec. 22, 2009). Brown & Williamson, the U.S. subsidiary of British American Tobacco (BAT), merged with American Brands after BAT acquired it in 1994. *See* BAT, Our History, Recent Past: 1969–Now, http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO52ADJ8?opendocument&SKN=3 (last visited Dec. 22, 2009); Glen Collins, *Legal Setback for F.T.C. in Bid to Block Tobacco Merger*, N.Y. TIMES, Nov. 17, 1994, at D4; Brown & Williamson Tobacco Corporation, Company History, <http://www.fundinguniverse.com/company-histories/Brown-amp;-Williamson-Tobacco-Corporation-Company-History.html> (last visited Dec. 22, 2009). A decade later, in August of 2004, RJR and Brown & Williamson merged to form Reynolds American, Inc. *See* Press Release, BAT, RJR, B&W Complete Transaction: Reynolds American Inc. Established (Aug. 2, 2004), available at http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO

agency concluded, deceptive acts and unfair practices in violation of the Federal Trade Commission Act because the companies thereby intentionally misled the public regarding the dangers of smoking.²¹ In this decision, the FTC required that the companies include in their advertising the new warning statement required on cigarette packaging under the recent amendment to the FCLAA.²² A decade later, Congress codified the FTC's order by again amending the FCLAA to extend the health-warning requirements to cigarette advertising.²³ Congress also amended the Act's warning provisions, requiring rotation of the four now familiar, more specific warning statements (such as "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Diseases, Emphysema, and May Complicate Pregnancy").²⁴

Shortly after amending the FCLAA for the second time, Congress enacted separate legislation addressing, for the first time, smokeless tobacco products. Like the FCLAA, this statute—the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act)²⁵—establishes health disclosure require-

6PTC5Q?opendocument&SKN=2&TMP=1. Philip Morris changed the name of its parent company to Altria at the beginning of 2003, but its domestic and international tobacco companies retain the name (Philip Morris USA and Philip Morris International). See Assoc. Press, *Philip Morris Changes Name to Altria*, USA TODAY, Jan. 27, 2003, available at http://www.usatoday.com/money/industries/food/2003-01-27-altria_x.htm. As a result of these changes, there are now five major cigarette manufacturers in the United States. The FTC lists the manufacturers and their parent companies in the introduction to its most recent report to Congress on cigarette sales, advertising, and promotion. See FTC, CIGARETTE REPORT FOR 2004 AND 2005 I (2007), available at <http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf> [hereinafter FTC CIGARETTE REPORT 2004 & 2005].

21. See Complaint at 6–12, *Lorillard*, 80 F.T.C. 455, 457–58 (1972).

22. See Order, *Lorillard*, 80 F.T.C. 455, 460 (1972) (requiring that all non-broadcast advertisements contain the statement prescribed for product packaging in the Public Health Cigarette Smoking Act of 1969; namely: "The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health").

23. See Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 4, 98 Stat. 2200, 2200–03 (1984) (codified as amended at 15 U.S.C. § 1331–1341 as the Federal Cigarette Labeling and Advertising Act).

24. 15 U.S.C. § 1333(a). The other three statements, each also preceded by "SURGEON GENERAL'S WARNING:" are: "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.;" "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.;" and "Cigarette Smoke Contains Carbon Monoxide." *Id.* These statements replaced the single, more general statement required by the Public Health Cigarette Smoking Act of 1969, which is quoted *supra*, note 17.

25. Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401–4408 (2006).

ments for smokeless tobacco packaging and advertising, and bans broadcast advertising of smokeless tobacco products.²⁶

The federal government's separate and much later focus on smokeless tobacco products was undoubtedly a result of two aspects of the U.S. tobacco landscape as it existed when the Surgeon General published the first report on the health consequences of *cigarette* smoking in 1964: the U.S. market for smokeless tobacco was very small, and there was a dearth of information about the health impacts of smokeless tobacco use. Six of the seven tobacco companies that dominated the market at that time produced only cigarettes and other "smoking" products.²⁷ There was only one major tobacco company that produced smokeless products at the time—U.S. Tobacco—and it, in turn, did not produce smoking products.²⁸ In fact, it was not until over two decades after the initial report on smoking that the Surgeon General issued the first governmental report focusing on smokeless tobacco.²⁹ This report, issued in 1986, recognized that the use of smokeless products was on the rise³⁰ and warned of the health threats

26. See *id.* § 4402(a), (f). The Act requires rotation of three warnings: "THIS PRODUCT MAY CAUSE MOUTH CANCER," "THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS," and "THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES." *Id.* § 4402(a).

27. See *supra*, note 20 (listing the six major U.S. cigarette manufacturers that continue to dominate the U.S. market, albeit in different corporate forms as a result of mergers, acquisitions, and name changes).

28. See *Regulation of Tobacco Products (Part 1): Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 103d Cong., at 598 (Mar. 25 & Apr. 14, 1994) [hereinafter *Waxman Hearings on Regulation of Tobacco Products, Part 1*] (statement of Joseph Taddeo, President, U.S. Tobacco Company) ("U.S. Tobacco is a leading manufacturer and producer of smokeless tobacco products, including moist snuff. U.S. Tobacco does not manufacture cigarettes.").

29. See PUB. HEALTH SERV., U.S. DEP'T OF HEALTH AND HUMAN SERVS., *THE HEALTH CONSEQUENCES OF USING SMOKELESS TOBACCO* v (1986) [hereinafter *SURGEON GENERAL'S 1986 REPORT ON SMOKELESS TOBACCO*] ("Almost 30 years after the Public Health Service's first statement on the health effects of cigarette smoking, it is now possible to issue the first comprehensive, indepth [sic] review of the relationship between smokeless tobacco use and health."). Some of the previous reports briefly mentioned smokeless products and indicated that they were potentially dangerous to health, but none gave the products serious attention until the 1986 report. See, e.g., PUB. HEALTH SERV., U.S. DEP'T OF HEALTH, EDUC., AND WELFARE, *SMOKING AND HEALTH: A REPORT OF THE SURGEON GENERAL 13-38 to 13-41* (1979) ("The combination of the low prevalence of snuff use and tobacco chewing and the low incidence of oral cancer in the U.S. makes it difficult to accumulate the large number of subjects necessary for an adequate epidemiologic study.").

30. See *SURGEON GENERAL'S 1986 REPORT ON SMOKELESS TOBACCO*, *supra* note 29, at v ("[S]mokeless tobacco products, particularly chewing tobacco and snuff, have recently emerged as popular products for the first time since the turn of the century. National estimates indicate that at least 12 million Americans used some form of

that they posed, including oral cancer, gum recession, and cardiovascular disease.³¹ In light of these findings, the Surgeon General cautioned the American public that “the oral use of smokeless tobacco represents a significant health risk” and consequently “is not a safe substitute for smoking cigarettes.”³²

While tobacco companies have thus been subject to some marketing regulation since the 1960s, their manufacturing processes historically have been almost entirely unregulated. Unlike most consumer product industries whose manufacturing processes are governed by regulatory regimes such as that established by the Consumer Product Safety Act,³³ tobacco companies have not been required to adhere to any standards in manufacturing their products. In fact, tobacco products and guns are the only products exempted from the Consumer Product Safety Act that are not subject to manufacturing regulation by other, product-specific statutes.³⁴ The FCLAA and the Smokeless Tobacco Act required merely that tobacco companies submit “a list of the ingredients added to tobacco in the manufacture of” their products to the Department of Health and Human Services (HHS).³⁵ The HHS had no authority to require anything further of tobacco companies based on the ingredient lists; indeed, the companies submitted the lists anonymously and without identifying the particular product brand containing the ingredients.³⁶ In short, tobacco companies have essen-

smokeless tobacco during 1985 with use increasing especially among male adolescents and young male adults.”).

31. *See id.* at vii–viii, xxiii–xxvi.

32. *Id.* at vii.

33. 15 U.S.C. §§ 2051–2085 (2006).

34. *See id.* § 2052(a)(5)(B) (exempting tobacco products); *id.* § 2052(a)(5)(F) (exempting “any article” subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986,” which imposes a tax on pistols, revolvers, firearms, shells, and cartridges, 21 U.S.C. § 4181, “or any component of any such article”). Regarding the absence of regulation of the gun industry, see Wendy Wagner, *When All Else Fails: Regulating Risky Products through Tort Litigation*, 95 *GEO. L.J.* 693, 722 (2007) (noting that “guns may be one of the few products in the United States whose design is not overseen by federal regulators,” and that such exemptions are “spread” across many statutes and therefore are very difficult to reform).

35. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1335a(a) (2006); Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4403(a) (2006).

36. *See* Federal Cigarette Labeling and Advertising Act § 1335a(a); Comprehensive Smokeless Tobacco Health Education Act of 1986 § 4403(a). Instead, both statutes directed the HHS to use the ingredient information it received to periodically report to Congress on the health impacts of the ingredients. *See* Federal Cigarette Labeling and Advertising Act § 1335a(b)(1); Comprehensive Smokeless Tobacco Health Education Act of 1986 § 4403(b)(1). In addition to these reporting duties, the HHS was required to “establish and carry out a program to inform the public of any dangers to human health” from cigarette smoking, Federal Cigarette Labeling and

tially been permitted to manufacture their products entirely behind closed doors.

The tobacco industry remained largely unregulated even though, after the 1964 Report, the Surgeon General's reports on the health consequences of smoking documented with alarm the increasing evidence of the myriad harms that smoking caused to the health not only of smokers, but also of non-smokers exposed to what came to be known as "secondhand smoke."³⁷ Furthermore, it became clear that the limited information provision regulation that was in place was failing to control the cigarette epidemic. Notwithstanding the increasing prevalence of information about the health threats presented by smoking, cigarette sales continually rose for about two decades after the 1964 Report,³⁸ and cigarette smoking became—and remains—the

Advertising Act § 1341(a), and from the use of smokeless tobacco, Comprehensive Smokeless Tobacco Health Education Act of 1986, § 4401(a).

37. As the Surgeon General explained in the first report analyzing the evidence on the health implications of so-called "involuntary smoking," the report was the first since 1964 that recognized that "disease risk due to the inhalation of tobacco smoke is not limited to the individual who is smoking, but can extend to those who inhale tobacco smoke emitted into the air." PUB. HEALTH SERV., U.S. DEP'T OF HEALTH AND HUMAN SERVS., *THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING, A REPORT OF THE SURGEON GENERAL IX* (1986), available at http://profiles.nlm.nih.gov/NN/B/C/P/M/_/nnbcpm.pdf. In particular, the Surgeon General determined that the available scientific evidence established, *inter alia*, that "[i]nvoluntary smoking is a cause of disease, including lung cancer, in healthy nonsmokers." *Id.* at 7.

Notably, these revelations about the health dangers of secondhand smoke and the Environmental Protection Agency's subsequent moves toward regulating it as an indoor air pollutant led the tobacco companies to form an alliance with chemical companies and other industry actors to launch the so-called "sound science" movement, the effects of which have been incredibly far-reaching. See Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Industries and Activities*, 52 U. KAN. L. REV. 897, 906–08 (2004) [hereinafter McGarity, *Our Science Is Sound Science and Their Science Is Junk Science*]; Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155, 199–210, 224 (2003); *cf. infra* notes 73–78 and accompanying text (discussing the tobacco industry's public relations campaign to manufacture doubt about health risks of smoking, which included the establishment of ostensibly independent research councils).

Further, recent findings have led to increasing concern among public health experts about so-called "third-hand smoke." See Roni Caryn Rabin, *A New Cigarette Hazard: 'Third-Hand Smoke'*, N.Y. TIMES, Jan. 2, 2009, available at <http://www.nytimes.com/2009/01/03/health/research/03smoke.html>. Specifically, these new studies suggest that children's health is still significantly endangered from exposure to the toxins in cigarette smoke even if their parents go outside to smoke, because a significant amount of noxious residue remains in smokers' hair and on their skin and clothing. See *id.*

38. See FTC CIGARETTE REPORT 2004 & 2005, *supra* note 20, at tbl.1.

leading cause of preventable death and disease in the United States.³⁹ In the late 1980s and early 1990s, the reasons for this increase in cigarette use were finally laid bare. Largely as a result of documents uncovered in state tort litigation and some key whistleblower accounts, it became clear that the tobacco industry had consistently been implementing what I call a “disinformation plus path-dependence” strategy that was highly successful in ensuring the continued use of its products even in the face of information such as that contained in the required warning statements.

In the mid-1950s, as the scientific evidence of the health risks of smoking on which the 1964 Report was based began to accumulate, the industry swiftly put into place a highly sophisticated and complex disinformation campaign by which tobacco companies have systematically countered and diluted the federally mandated warnings. They did this not only with outright denials of the health consequences of their products, but also—and primarily—with more subtle messages conveyed through the promotion of cigarettes with sophisticated advertising techniques, and through the packaging and design of the products themselves.⁴⁰ Furthermore, although the deleterious consequences of cigarette smoking were known, the highly addictive nature of tobacco products was still not widely recognized, at least by scientific experts outside of the industry.⁴¹ Rather, up until the mid-1980s, when the FCLAA was amended for the second time and the Smokeless Tobacco Act was first enacted, the Surgeon General reports had not changed the 1964 Report’s conclusion that “[t]he tobacco habit should be characterized as an *habituation* rather than an *addiction*.”⁴²

39. See *supra* note 2 and accompanying text. As the Surgeon General noted in the most recent report on the health impacts of smoking, this is the case “[d]espite the many prior reports on the topic and the high level of public knowledge in the United States of the adverse effects of smoking in general.” 2004 SURGEON GENERAL REPORT ON THE HEALTH CONSEQUENCES OF SMOKING, *supra* note 2, at 9.

40. See Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1470–83 (1999) [hereinafter *Some Evidence of Market Manipulation*].

41. As discussed *infra* notes 46–51 and accompanying text, the industry was aware of the addictive nature of tobacco products but kept this knowledge from the public.

42. 1964 SURGEON GENERAL REPORT ON SMOKING AND HEALTH, *supra* note 1, at 354. This characterization of tobacco dependence, the report explains, is “in conformity with accepted World Health Organization definitions, since once established there is little tendency to increase the dose; psychic but not physical dependence is developed; and the detrimental effects are primarily on the individual rather than society.” *Id.* at 354.

B. The “Disinformation Plus Path-Dependence” Strategy

These two relatively late developments in public knowledge—one relating to the industry’s practices and the other to the addictive nature of tobacco products—unveiled the two-pronged strategy that the industry had been using to achieve its extraordinary success in cigarette sales, even in an atmosphere in which information on the harmful health impacts of smoking was widespread. I describe this strategy as one of “disinformation plus path-dependence”, as it consists of (1) the pervasive dissemination of disinformation to encourage nonrational decisionmaking about tobacco product use, and (2) the subsequent deprivation of free choice on the part of those who become addicted to the products, even if the disinformation problem is corrected.

Beginning with the revelation of the “path-dependence” prong of the strategy, in the wake of the 1964 Surgeon General’s Report, a scientific consensus that nicotine was highly addictive rapidly emerged. The Surgeon General finally recognized this in the 1988 Report on Nicotine Addiction, essentially retracting the 1964 Report’s conclusion that smoking was not properly classified as addictive: “It is now clear,” the report declared, that “cigarettes and other forms of tobacco are addicting and actions of nicotine provide the pharmacologic basis of tobacco addiction.”⁴³ The addictive nature of tobacco products, the report further noted, parallels that of illegal drugs such as cocaine and heroin.⁴⁴ The 600-plus page report goes on to discuss the public health implications of this determination at length, which all flow from the recognition of the urgent need to begin addressing nicotine as the extremely addictive drug that it is.⁴⁵

43. PUB. HEALTH SERV., U.S. DEP’T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, A REPORT OF THE SURGEON GENERAL 11 (1988), available at http://profiles.nlm.nih.gov/NN/B/B/Z/D/_/nnbbzd.pdf [hereinafter SURGEON GENERAL REPORT ON NICOTINE ADDICTION]. The report points out that the habituation/addiction distinction on which the 1964 Report based its findings was no longer considered valid, as the World Health Organization had determined that it was based on a misunderstanding of the mechanisms and consequences of drug use. See *id.* Nevertheless, the report further notes that tobacco products are addictive “even by th[is] earlier distinction in nomenclature.” *Id.*

44. See *id.* at vi (“This Report shows conclusively that cigarettes and other forms of tobacco are addicting in the same sense as are drugs such as heroin and cocaine.”); see also, e.g., *id.* at 281–82, 284–85 (explaining in more detail the various measures of dependence and noting similarities between nicotine and drugs such as heroin and cocaine).

45. Most importantly, the report determined that (1) ubiquitous health warnings notwithstanding, many tobacco users would need treatment in order to quit, and (2) as most tobacco users started as adolescents, nicotine addiction needed to be integrated

Around the same time, it became apparent that the addictiveness of tobacco products was purposeful, rather than merely a previously unrecognized characteristic of tobacco. That is, the industry had from the beginning made the addictive quality of its products a key part of its business strategy (the “path-dependence” prong). Moreover, it became clear that the industry’s strategy was also to suppress and counter this and other information about the nature of its products through an extremely sophisticated public disinformation campaign.

In the late 1980s and early 1990s, documents produced in litigation against the industry and a few key whistleblower accounts revealed that the industry had well understood the harmful health impacts and the addictive nature of cigarettes long before the larger scientific community did, and that the tobacco companies had not only suppressed that information, but had also actively countered it through deceptive marketing. The companies understood the addictiveness of their products so well, in fact, that they deliberately manipulated their products to increase nicotine delivery and, thus, addictiveness.⁴⁶

These sources revealed that tobacco companies had been secretly studying nicotine addiction since at least the 1960s.⁴⁷ Indeed, researchers working for Philip Morris were the first to successfully design a research method for assessing the addictive properties of nicotine as delivered to the body by the use of tobacco products.⁴⁸ Their

into drug educational programs to inform children early on and repeatedly about the addictive nature as well as dangers of tobacco use. *See id.* at v–vi.

46. *See, e.g.,* ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* 339 (2007) (noting that the documents demonstrated that “tobacco companies had known the addictive properties of nicotine for decades,” and that, “[d]espite their campaign to discredit the [Surgeon General’s] report [on nicotine addiction], the companies had been deeply involved in studying the scientific and behavioral effects of nicotine since at least the 1960s”).

47. *See id.*

48. *See Regulation of Tobacco Products (Part 2): Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 103rd Cong. 5–7 (Apr. 28, May 17 & 26, 1994) [hereinafter *Waxman Hearings on Regulation of Tobacco Products, Part 2*] (statement of Dr. Victor John DeNoble). In one of the 1994 hearings on tobacco products held by Representative Waxman as chair of the House Subcommittee on Health and the Environment, Dr. Victor DeNoble, who was the lead scientist conducting this research for Philip Morris in the early 1980s, testified about this and other studies on the addictive properties of nicotine conducted at the Philip Morris Research Center and about the company’s reactions to its scientists’ findings. *See id.* As Dr. Jack Henningfield, a chief scientist at the National Institute on Drug Addiction, explained to a *New York Times* reporter covering the hearings, at the time Dr. DeNoble was doing this research, “there was no study that had done a good job of establishing a ‘rat model’ for addiction to nicotine. . . . A major reason for the problem was that the method of giving nicotine to rats in previous studies was unlike the ways humans receive doses of nicotine in cigarettes—in short, powerful

study determining that nicotine was addictive, as recognized by the editors of the scientific journal that accepted the paper on the study for publication in the early 1980s, was tremendously significant, as it occurred several years before the Surgeon General issued the Report on Nicotine Addiction.⁴⁹ However, their paper was never published; Philip Morris compelled the authors to withdraw it.⁵⁰ The larger scientific community and the public were thus denied the benefit of this vital information. Had it been published, the Surgeon General's report undoubtedly would have been issued much earlier.⁵¹

Industry documents, insider accounts, and patents filed by tobacco companies made clear not only that tobacco officials understood that nicotine was addictive and that this quality was the key to maintaining demand for their products, but also that they had developed manufacturing technologies and marketing strategies designed to exploit this quality.⁵² On the manufacturing front, the industry had developed the capability to manipulate nicotine levels of tobacco products and to make the amounts of nicotine in cigarettes appear lower in the FTC's testing than the amounts that smokers would in fact consume.⁵³ In 1994, David Kessler, then commissioner of the FDA, testified before Representative Henry Waxman's Subcommittee on Health and the Environment on the extent of the tobacco industry's knowledge about nicotine and how it used that knowledge in manufac-

bursts." Philip J. Hiltz, *Philip Morris Blocked '83 Paper Showing Tobacco Is Addictive, Panel Finds*, N.Y. TIMES, Apr. 1, 1994, at A21.

49. See *Waxman Hearings on Regulation of Tobacco Products, Part 2*, *supra* note 48, at 6; Hiltz, *supra* note 48.

50. See *Waxman Hearings on Regulation of Tobacco Products, Part 2*, *supra* note 48, at 6; Hiltz, *supra* note 48. Dr. DeNoble also testified that Philip Morris officials prohibited him from presenting the paper at a 1983 meeting of the American Psychological Association. He lost his job shortly thereafter, when Philip Morris, "without prior discussion or prior warning," "abruptly closed" the behavioral pharmacology laboratory that he had established to conduct the nicotine research. *Waxman Hearings on Regulation of Tobacco Products, Part 2*, *supra* note 48, at 5-6.

51. According to Dr. Henningfield, the company's suppression of the paper "set the field back by six years at least." Hiltz, *supra* note 48.

52. See *Waxman Hearings on Regulation of Tobacco Products, Part 1*, *supra* note 48, at 29.

53. See, e.g., *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1107 (D.C. Cir. 2009) (noting that, in the criminal trial that resulted from the U.S. government's prosecution of the major cigarette manufacturers, "[e]vidence showed that Defendants undertook extensive research into the physiological impact of nicotine, how it operates within the human body, and how the physical and chemical design parameters of cigarettes influence the delivery of nicotine to smokers," and that "[a]s a result of this research, they recognized and internally acknowledged that smoking and nicotine are addictive and they engineered their products around creating and sustaining this addiction"); see *infra* notes 56-60 and accompanying text (discussing the industry's manipulation of cigarette designs to evade detection by the FTC's testing method).

turing its products. In summarizing the agency's preliminary conclusions, Kessler stated: "The public may think of cigarettes as no more than blended tobacco rolled in paper. But they are more than that. Some of today's cigarettes may in fact qualify as high technology nicotine delivery systems. . . ."54

Kessler went on to explain that, in the several decades since the tobacco industry's secret research revealed the addictive nature of nicotine, tobacco companies had patented numerous processes and technologies for manipulating nicotine levels in their products. For example, the industry developed methods for increasing nicotine levels by adding it to cigarette paper and filters.⁵⁵ Furthermore, tobacco companies increased nicotine content and otherwise manipulated cigarettes in ways that would evade detection by the "smoking" machine that the FTC used to measure nicotine levels.⁵⁶ More specifically, the FTC machine's nicotine measurements were rendered inaccurate by cigarette designs such as the placement of ventilation holes that smokers tended to cover with their fingers but remained open when the machine "smoked," and the placement of tobacco where it would not be "smoked" by the machine but would be consumed by actual smokers.⁵⁷

That the design of cigarettes rendered the FTC's means of measuring nicotine levels inaccurately low did not mean, however, that the industry was unaware of how much nicotine smokers actually ingested. To the contrary, the industry took great pains to ascertain accurately the addictiveness of its products. In the mid-1960s, Philip Morris developed a "Human Smoker Simulator" that, unlike the FTC's machine, permitted the company to precisely mimic the way

54. See *Waxman Hearings on Regulation of Tobacco Products, Part 1, supra* note 28, at 29.

55. See *id.* at 30. As Kessler explained to the subcommittee, although the patents "do not tell us what processes are currently in use," they do indicate "the industry's capabilities and research and they provide insight into what industry may be attempting to achieve with its products." *Id.* Former industry scientists provided the press and the FDA with accounts of manufacturing practices that made clear that the industry was in fact using various technologies to manipulate nicotine levels to maintain addictive levels. For example, Jeffrey Wigand, a biochemist who was a high-ranking research scientist at Brown & Williamson in the late 1990s, told the FDA and, eventually, the press, that the company had used ammonia and the blending of different types of tobacco to increase the nicotine content of their products. See BRANDT, *supra* note 46, at 376-78; see also *id.* at 358-61 (describing the 1994 ABC broadcast reporting on the account of the industry's production processes provided by one of the first whistleblowers, a former employer of R.J. Reynolds).

56. See *Waxman Hearings on Regulation of Tobacco Products, Part 1, supra* note 28, at 62-63.

57. See *id.*

smokers actually smoked a particular cigarette, and thus to measure correctly the amount of nicotine consumed.⁵⁸ The company concealed both this successful method of measurement and the true nicotine levels of cigarettes from the FTC, thereby deceiving the agency and the public about the content of its products.⁵⁹ As a result, the industry completely turned on its head the FTC's purpose in conducting the nicotine tests, which was to provide consumers with standardized information on the relative nicotine content of various brands.⁶⁰

The disinformation prong of the industry's strategy involved not only the suppression of information about the nature of its products, but also massive advertising and public relations campaigns designed to glamorize tobacco product use and to manufacture doubt about the dangers of cigarettes. As Jon Hanson and Douglas Kysar have detailed in their work on market manipulation by consumer product industries, in addition to "a careful orchestration and eventual suppression of internal research into the health issues raised by cigarettes," the major tobacco companies devised a highly successful means of manipulating consumer preferences with disinformation.⁶¹ Specifically, as they explain, the tobacco industry's approach consisted of a combination of (1) a marketing campaign that involved path-breaking uses of imagery, product placement, and packaging design to make cigarettes appear highly desirable notwithstanding the

58. See *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 464–65 (D.D.C. 2006), *aff'd in part, vacated in part* 566 F.3d 1095 (D.C. Cir. 2009). This and myriad other aspects of Philip Morris's and the other major cigarette manufacturers' deception of the FTC and the public are extensively documented in the findings and conclusions of law set forth by federal district court Judge Gladys Kessler in her opinion holding that the companies repeatedly violated and continue to violate the Racketeer Influenced and Corrupt Organizations Act (RICO) by engaging in a decades-long conspiracy to defraud consumers about the health consequences and addictiveness of cigarette smoking. See *Philip Morris USA*, 449 F. Supp. 2d at 852. Significantly, *all* of the district court's findings and legal conclusions, as well the bulk of the court's order granting the United States injunctive relief against the companies, were recently upheld by the D.C. Circuit Court of Appeals. See 566 F.3d at 1105, 1150.

59. See *Philip Morris USA*, 449 F. Supp. 2d at 464–65.

60. As discussed *infra*, note 82, it was not until 2000 that the FTC stopped making the results of its nicotine testing public in response to the knowledge, long possessed by the industry, that the FTC's machine indicated that smokers were consuming less nicotine than they in fact did.

61. *Some Evidence of Market Manipulation*, *supra* note 40, at 1470. For a more complete explication of their theory of market manipulation by consumer product industries and recommended policy responses, see generally, Jon D. Hanson & Douglas O. Kysar, *Taking Behavioralism Seriously: The Problem of Market Manipulation*, 74 N.Y.U. L. REV. 630 (1999) [hereinafter *The Problem of Market Manipulation*], and Jon D. Hanson & Douglas O. Kysar, *Taking Behavioralism Seriously: A Response to Market Manipulation*, 6 ROGER WILLIAMS U. L. REV. 259 (2000).

widespread availability of the health dangers of smoking,⁶² and (2) a public relations campaign designed to encourage public acceptance of these marketing messages by appearing to be separate from the industry's profit-seeking interests, and thereby serving as an ostensibly objective scientific counter to the federal government's information about the health consequences of smoking.⁶³ Both these campaigns were calculated to exploit the tendency of individuals to behave in what Hanson and Kysar term "nonrational" ways in their decision-making about using many commercially marketed products, including tobacco products.⁶⁴ As they explain in the specific context of tobacco industry marketing:

[T]he presence of powerful and ubiquitous cognitive biases among individual consumers creates an opportunity to manipulate perceptions and preferences that no profit-maximizing tobacco manufacturer can ignore. Over the past century, tobacco firms' marketing, promotional, and public relations efforts have capitalized on that possibility of manipulation. In the process, they have devised and tested countless manipulative strategies to lower consumer risk perceptions and elevate product demand.⁶⁵

For example, the industry's marketing campaign included what the industry itself deemed various types of "health image" or "health reassurance" cigarettes—the sorts of product marketing that would now qualify as "modified risk" under the new tobacco-control legislation.⁶⁶ As Hanson and Kysar point out, "these products," such as filter-tipped and "light" cigarettes, "were the result of industry advances

62. See Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 40, at 1470–83.

63. See *id.* at 1470, 1483–94.

64. See Jon D. Hanson & Douglas O. Kysar, *The Joint Failure of Economic Theory and Legal Regulation*, in *SMOKING: RISK, PERCEPTION, & POLICY* 229 (Paul Slovic ed., 2001) [hereinafter *The Joint Failure of Economic Theory and Legal Regulation*].

65. *Id.* at 230; *cf.* Hanson & Kysar, *The Problem of Market Manipulation*, *supra* note 61, at 633, 635, 640 (explaining the social science "evidence that human decisionmaking processes are prone to nonrational, yet systematic, tendencies," and that, "[on]ce one accepts that individuals systematically behave in nonrational ways, it follows from an economic perspective that others will exploit those tendencies for gain;" and arguing that, as a result, "the rational actor model, upon which the law and economics project depends, is significantly flawed"). Hanson and Kysar's explication of the exploitation of cognitive consumer biases by the tobacco industry makes clear that this exploitation has been key to the success of the industry's "disinformation plus path-dependence" strategy. Although the complexities of all their analyses and arguments regarding this phenomenon are beyond the scope of this article, they are an extremely important contribution to the debate about legal regulation of consumer product industries.

66. See *infra* notes 172–76 and accompanying text.

in marketing, rather than technological expertise.”⁶⁷ They were designed to “create the *perception* of a safer product, irrespective of whether the product was actually safer.”⁶⁸ In fact, as the industry has known since at least the mid-1960s, when it developed an accurate method of measuring nicotine consumption, the “health reassurance” cigarettes were not safer than “regular” cigarettes.⁶⁹ In fact, some also presented even greater health risks; for example, an early and popular filtered cigarette employed asbestos as a filtering agent and was lauded as a healthier alternative to regular cigarettes.⁷⁰

In addition to product design, a principal part of the industry’s marketing campaign was to permeate American culture with imagery of cigarette smoking as “desirable, socially acceptable, safe, healthy, and prevalent.”⁷¹ This message was primarily directed at children and adolescents, who are, of course, the most likely to use—and consequently get addicted to—such products notwithstanding warnings about dangerous health consequences.⁷²

The industry combined and buttressed this “up-front” marketing campaign with a major public relations campaign designed “to foster and perpetuate ‘controversy’ over whether cigarettes cause diseases and . . . whether they are addictive.”⁷³ Beginning in the 1950s, as medical evidence began to mount that cigarette smoking presented a

67. *Some Evidence of Market Manipulation*, *supra* note 40, at 1473.

68. *Id.* at 1474.

69. See, for example, *id.*, which notes that not only was there little evidence to support the industry’s assertions regarding the safety of so-called “health reassurance” cigarettes, but that smokers who switched to these cigarettes from the regular variety tended to engage in “nicotine regulation” that effectively eliminated any possible health benefit. It appears that the tobacco industry was well aware of these details when it developed its supposed “reduced risk” products. *Id.* at 1474–75.

70. See, e.g., *Some Evidence of Market Manipulation*, *supra* note 40, at 1474.

71. *Id.* at 1480; see also *id.* at 1479–83 (“The industry’s strategy for [recruiting new smokers] is pervasive, relentless advertising. Cigarettes are among the most promoted consumer products in the United States. . . . Tobacco imagery—product brand names, logos, and advertising messages—is ubiquitous.”).

72. See, e.g., BRANDT, *supra* note 46, at 386–91 (discussing the industry’s targeting of children in advertising and detailing R.J. Reynold’s Joe Camel campaign); *Some Evidence of Market Manipulation*, *supra* note 40, at 1479–83 (“After cigarette manufacturers survived the health revelations of the 1950s and 1960s . . . [t]he paramount goal of the industry changed from maintaining the existent smoking population to recruiting new smokers, especially *young* new smokers.”). As highlighted in the Surgeon General’s 1988 Report on Nicotine Addiction, “this addiction almost always begins during childhood or adolescence.” SURGEON GENERAL REPORT ON NICOTINE ADDICTION, *supra* note 43, at vi. “Many children and adolescents who are experimenting with cigarettes and other forms of tobacco state that they do not intend to use tobacco in later years. They are unaware of, or underestimate, the strength of tobacco addiction.” *Id.*

73. *Some Evidence of Market Manipulation*, *supra* note 40, at 1483–84.

significant health threat, the major cigarette manufacturers quickly responded by hiring a major public relations firm.⁷⁴ This firm—Hill & Knowlton—played a primary role in designing the industry’s public relations response to the scientific studies linking cigarette smoking to deadly diseases.⁷⁵ Although not explicitly framed as advertising, this response was nonetheless part of the industry’s marketing program, albeit a “less traditional marketing maneuver[].”⁷⁶ More specifically, the industry formed ostensibly independent “research councils” of scientists purportedly dedicated to informing the public about the health impacts of smoking.⁷⁷ Internal documents uncovered in litigation revealed, however, that the work of the industry research councils was “self-consciously designed to promote favorable research, suppress negative research where possible, and attack negative research when it could not be suppressed.”⁷⁸

74. *See id.* at 1484–85.

75. *See id.* at 1485–87.

76. *Id.* at 1483.

77. *See id.* at 1485–92. At the beginning of 1954, the industry “announced the formation of the [Tobacco Industry Research Council (TIRC)] in a full-page advertisement entitled ‘A Frank Statement to Cigarette Smokers,’” which ran in hundreds of newspapers across the country. *Id.* at 1486. This “Statement” described the TIRC as being headed by “a scientist of unimpeachable integrity and national repute,” and as having “an Advisory Board of scientists disinterested in the cigarette industry.” *Id.* The industry continued to project its research councils as independent for decades. In its annual reports from 1972 to 1991, for example, the Council for Tobacco Research (CTR) “stated that its Scientific Advisory Board funded peer-reviewed research projects, ‘judging them solely on the basis of scientific merit and relevance.’” *Id.* at 1489.

Compare, for example, McGarity, *Our Science Is Sound Science and Their Science Is Junk Science*, *supra* note 37, at 906–08, which summarizes a memorandum from the public relations firm Burson-Marsteller to Philip Morris proposing a strategy (that the industry implemented) for countering the Environmental Protection Agency’s report on the dangers of secondhand smoke. Specifically, the memorandum urged the “assembling of a corps of scientists to attack the EPA report and belittle the risks posed by (secondhand smoke).” *Id.* at 907. This was necessary, according to the public relations firm, because “[t]hus far, the industry’s scientific effort had ‘been conducted under industry aegis, and the results—from a public relations perspective—have been less than successful.’” *Id.* Thus, “it was ‘[a]bsolutely critical’ that the industry ‘call upon the scientific experts’ already in the industry’s stable ‘for public service’ and ‘to expand their number along a variety of fronts’” *Id.*

78. *Some Evidence of Market Manipulation*, *supra* note 40, at 1488. As Hanson and Kysar note, “Perhaps the most succinct statement of these objectives comes from a [Brown & Williamson] memorandum . . . : ‘Doubt is our product since it is the best means of competing with the ‘body of fact’ that exists in the mind of the general public. It is also the means of establishing a controversy.’” *Id.*; *see also id.* at 1492–1502 (detailing the documentary evidence of the industry’s manufacturing of doubt about the health consequences of smoking and the addictive qualities of nicotine). Indeed, company documents produced in litigation revealed that, almost two decades before the Surgeon General’s 1964 Report on smoking and health, the indus-

A disinformation campaign, such as that of the tobacco industry, that is deliberately designed to exploit nonrational consumer risk perceptions, is particularly effective when the product is highly addictive—i.e., when coupled with “path-dependence.” In fact, the industry’s “disinformation plus path-dependence” strategy was so successful that cigarette smoking became a defining feature of American culture: notwithstanding the widespread availability of information about the harmful health consequences of smoking, millions of Americans have died from and continue to suffer from smoking and smoking-related illnesses.⁷⁹ It was not until the mid-1990s, when documents produced in litigation revealed the industry as one that had been implementing such a strategy, that it became clear why the principal federal regulation that was in place until recently—requiring the “Surgeon General” warning labels (none of which, notably, warned of the addictive nature of the products)⁸⁰—was grossly inadequate.

C. Federal Attempts to Respond to the “Disinformation Plus Path-Dependence” Strategy

An information provision approach to federal regulation is ineffectual as a tool for protecting the public from an industry willing to increase the addictiveness of products it knows are deadly while publicly and deceptively disavowing both the products’ addictive nature and their harmful health consequences.⁸¹ Such an approach makes

try had been conducting secret research on the health effects of tobacco products. *See* BRANDT, *supra* note 46, at 330–31. In summarizing the evidence produced in the trial of one of the key cases against the industry—*Cipollone v. Liggett Group, Inc.*—Brandt notes that the plaintiff demonstrated that, instead of “tak[ing] action to modify [its] product” in response to this research indicating the health dangers of smoking, the tobacco industry “publicly denied these risks through a sophisticated public relations program and an aggressive lobbying crusade, even while it confirmed the carcinogenic properties of tobacco smoke in its own laboratories.” *Id.* at 331.

79. Indeed, as Kessler noted in the 1994 congressional hearings on tobacco products: “Remarkably, we see that nicotine exerts its grip even on patients for whom the dangers of smoking could not be starker. After surgery for lung cancer, almost half of the smokers resume smoking. Even when a smoker has his or her larynx removed, 40 percent try smoking again.” *Waxman Hearings on Regulation of Tobacco Products, Part 1*, *supra* note 28, at 28.

80. In the 1988 Report on Nicotine Addiction, the Surgeon General recommended that a warning about the addictiveness of tobacco products be added to the rotation required by the FCLAA and Smokeless Tobacco Act, *see* SURGEON GENERAL REPORT ON NICOTINE ADDICTION, *supra* note 43, at vi, but Congress did not amend the acts to include such a warning until it enacted the TCA, *see infra* note 197.

81. As late as 1994, decades after the Surgeon General’s first report on the health impacts of smoking and six years after the Report on Nicotine Addiction, each of the top officials of the seven leading U.S. tobacco companies stood before Congress and testified, under oath, that they did not believe that cigarettes cause cancer or other

sense only on the assumption that the danger of tobacco products is entirely captured by the fact of their deleterious health consequences: various cancers, respiratory and cardiovascular diseases, and so on. Although one might argue that this assumption was justified based on the information available when the Surgeon General made it in the 1964 Report and for two decades or so thereafter, the assumption was completely belied once the addictive nature of nicotine and the industry's systematic misconduct became public knowledge in the late 1980s and early 1990s—i.e., once the industry's strategy was revealed as one of “disinformation plus path-dependence.”

In light of these developments in public knowledge about the nature of tobacco products and of the industry that designed and marketed them, many governmental officials recognized the urgent need for much greater regulation of the tobacco industry, regulation beyond the traditional information provision approach.⁸² Shortly after Representative Waxman's 1994 hearings on tobacco products, the FDA is-

diseases or that nicotine is addictive. *See Waxman Hearings on Regulation of Tobacco Products, Part 1, supra* note 28, at 160, 620–21 (denials that cigarettes cause cancer), 628 (denial that nicotine is addictive), 742 (denial that smokeless tobacco causes oral cancer).

More specifically regarding whether nicotine is addictive, the top executives of Philip Morris, Lorillard, Liggett, Brown & Williamson, and American Tobacco testified that they “believe[d] that nicotine is not addictive.” *Id.* at 628. R.J. Reynold's CEO stated: “[C]igarettes and nicotine clearly do not meet the classic definition of addiction.” *Id.* And the president of U.S. Tobacco (the leading manufacturer of smokeless-tobacco products) told the subcommittee, “I don't believe that nicotine or our products are addictive.” *Id.*

Industry officials also made numerous denials of the health dangers of their products at the hearing. A representative of the Tobacco Institute (the trade association for all the major cigarette companies), for example, testified that, “Yes, I deny that [cigarette ingredients] cause cancer and are not safe.” *Id.* at 160. He further stated that EPA's classification of nicotine as a Class I carcinogen “was a gross mistake.” *Id.*

82. As more information became available about the addictive properties of nicotine and the sophisticated design of cigarettes, the FTC came to realize that fully addressing the tobacco problem was beyond its expertise. The agency thus has repeatedly appealed to Congress to delegate authority over cigarette testing to one of the agencies with scientific and public health expertise. *See FTC, Prepared Statement Before the Senate Committee on Commerce, Science, and Transportation* 11 (Nov. 13, 2007), available at <http://www.ftc.gov/os/testimony/P064508tobacco.pdf> (noting that the agency had made the same request two times before, in 1999 and 2003). In its most recent communication to Congress about the issue in November of 2007, the FTC explained its concerns about the capacity of the current testing method—the “smoking” machine—to accurately measure nicotine levels and its resulting decision in 2000 to stop issuing reports documenting the test results rather than risk misleading the public about the amounts of nicotine in various brands. *See id.* at 5–10. According to the agency, it had become clear that the scientific expertise necessary to protect the public health from tobacco products was beyond the purview of the FTC. *See id.* at 11.

sued a proposed rule regulating all tobacco products as drug delivery devices.⁸³ In light of the industry's knowledge and practices relating to nicotine, the FDA determined that tobacco products fell within the statutory definition that triggered its regulatory authority: "Based on the evidence now before the agency, cigarettes and smokeless tobacco products are drug delivery systems *whose purpose* is to deliver nicotine to the body in a manner in which it can be most readily absorbed by the consumer."⁸⁴ The FDA rule subjected the industry to much greater marketing regulation than mere information provision. Specifically, the rule aimed to prevent tobacco companies from marketing to children and adolescents⁸⁵ by, *inter alia*, prohibiting the giving out of free samples of tobacco products, promotion of tobacco product brands on non-tobacco items (such as clothing and accessories), brand name sponsorship of sport and musical events, and by restricting advertising to black text on white background in publications with significant underage readership.⁸⁶

The rule thus represented a significant development in the conceptualization of the tobacco epidemic by governmental authorities. No longer did the government characterize the epidemic as one caused by harmful products that also happen to be pleasurable, habit-forming,

83. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents; Proposed Rule, 60 Fed. Reg. 41,314 (proposed Aug. 11, 1995) [hereinafter Proposed FDA Rule]. The rule was made final after minor changes the following year. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule, 61 Fed. Reg. 44,396 (Aug. 28, 1996) [hereinafter Final FDA Rule]. As the FDA stated in explaining its assertion of regulatory authority over tobacco products, after "conduct[ing] an extensive investigation and comprehensive legal analysis," the agency had determined "that the nicotine in cigarettes and smokeless tobacco products is a drug within the meaning of the [Federal Food, Drug, and Cosmetic Act] because it is intended to affect the structure or function of the body and it achieves its intended effects through chemical action within the human body." Proposed FDA Rule, 60 Fed. Reg. at 41,346. Because of the intent element in the statutory definition on which the FDA's authority is based, revelations about the industry's knowledge and practices relating to the nicotine in tobacco products were a necessary condition of the FDA's assertion of authority; the addictiveness of nicotine was not alone sufficient. As then-FDA Commissioner David Kessler testified in Representative Waxman's 1994 hearings, before this information was uncovered, "[t]he assumption ha[d] been that the nicotine in cigarettes is present solely because it is a natural and unavoidable component of tobacco." *Waxman Hearings on Regulation of Tobacco Products, Part 1, supra* note 28, at 28. But, he continued, in light of the recently uncovered information about the industry's practices, "that assumption needs to be reexamined": "The amount of nicotine in a cigarette may be there by design." *Id.*

84. Proposed FDA Rule, 60 Fed. Reg. at 41,346 (emphasis added).

85. Final FDA Rule, 61 Fed. Reg. at 44,397-98.

86. *Id.* at 44,617-18.

or even merely naturally addictive. Rather, the epidemic was caused by harmful products that were purposefully and deceptively designed to be extremely addictive. In short, with this FDA rule, the government began to catch up with the tobacco industry and to counter the “disinformation plus path-dependence” strategy.

The potential borne by the FDA’s rule for curbing the tobacco epidemic was unfortunately never realized: the industry mounted a successful judicial challenge to the regulation, derailing the federal government’s attempt to begin providing public health protections that would meaningfully respond to the industry’s strategy. In 2000, the U.S. Supreme Court held in *FDA v. Brown & Williamson Tobacco Corp.*⁸⁷ that Congress had not given the FDA authority to regulate tobacco, and therefore struck down the FDA’s rule.⁸⁸ As a result, the Supreme Court’s decision required that Congress enact specific legislation authorizing the FDA to regulate tobacco before the FDA could take action.⁸⁹ The Court therefore put the tobacco regulatory ball back into Congress’s court, where the industry has continued to wield tremendous influence.⁹⁰

Over a decade after the Court’s decision in *Brown & Williamson*, the principal federal control applicable to tobacco products remained the federal legislation requiring disclosure of information on the health implications of tobacco product use.⁹¹ Though a number of bills granting the FDA authority to regulate tobacco were introduced in

87. 529 U.S. 120 (2000).

88. *Id.* at 160–61. The FDA subsequently revoked its rule. *See, e.g.*, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Revocation, 63 Fed. Reg. 17,135 (Mar. 31, 2000).

89. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 161.

90. *See supra* note 4.

91. For a brief period after the FDA issued the rule and before the Supreme Court issued its decision invalidating the rule, it seemed likely that Congress would pass legislation giving the FDA limited authority to regulate tobacco. At this time, the industry was facing increasingly formidable lawsuits and a public relations disaster as documents detailing its long-standing misconduct mounted through the discovery process. *See BRANDT, supra* note 46, at 412–21. In April of 1997, the industry began secret settlement negotiations with state attorneys general who had brought cases to recover state healthcare costs incurred in treating people with smoking-related diseases. *See id.* at 420. Ultimately, the companies agreed to support legislation giving the FDA authority to regulate tobacco. *See id.* at 422; DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* 360–61 (2001); Joe Nocera, *If It’s Good for Philip Morris, Can It Also Be Good for Public Health?*, N.Y. TIMES, June 18, 2006 (Magazine), at 46, 50. But when protests from many in the public-health community led to the removal of the settlement provision immunizing the industry from lawsuits, the industry withdrew its support, and the tobacco legislation never materialized. *See BRANDT, supra* note 46, at 427–29; KESSLER, *supra*, at 361; Nocera, *supra*, at 50.

Congress in the wake of the Court's decision, these efforts to enact legislation ultimately failed.⁹² Thus, until the recent enactment of the TCA, the tobacco industry remained largely unregulated at the federal level.

II.

THE ROLE OF STATE AND LOCAL REGULATION IN COUNTERING THE INDUSTRY'S USE OF ITS "DISINFORMATION PLUS PATH-DEPENDENCE" STRATEGY TO SELL CIGARETTES IN THE UNITED STATES

Over the course of the last few decades before the TCA was enacted, state and localities did succeed in implementing some significant tobacco-control measures that went beyond the provision of information about the health dangers of smoking. Initially, documents produced in litigation brought against the industry in state court by private plaintiffs and state attorneys general brought to light much of the companies' longstanding misconduct.⁹³ In the wake of the resulting widespread awareness of the nature of the industry's practices, indoor smoking bans have swept across the country, despite strong industry opposition.⁹⁴ These bans—extending to offices, restaurants, and even quintessential "smoking" environments such as bars and casinos—would not have been possible without the dramatic reversal that has occurred in societal perceptions about the acceptability of smoking and the nature of the industry, a reversal undoubtedly driven in large part by the revelations of the industry's systematic public de-

92. See P. A. McDaniel & R. E. Malone, *Understanding Philip Morris's Pursuit of U.S. Government Regulation of Tobacco*, 14 *TOBACCO CONTROL* 194–96 (2005) ("After the Supreme Court decision (in *Brown & Williamson*), Congressional efforts to pass some form of legislation granting FDA authority over tobacco multiplied: at least eight bills were introduced between 2000 and 2001."); *id.* at 197 tbl.1 (comparing provisions of two bills introduced in 2001 and one introduced in 2004 and again in 2005).

93. See, e.g., *Some Evidence of Market Manipulation*, *supra* note 40, at 1468 (noting that the state litigation against the industry "and resultant policymaking initiatives have uncovered enormous amounts of documentation and data regarding the once secret details of industry conduct").

94. See, e.g., *NAT'L INST. ON MONEY IN STATE POLITICS*, *supra* note 4, at 2 ("Laws restricting public smoking passed in 13 states in 2007."); cf. Marc Santora, *Cigarette Tax Arrives Amid Grumbling and Vows*, *N.Y. TIMES*, June 4, 2008, at B3 (reporting on New York's new \$1.25 tax on packs of cigarettes, which "ma[d]e the combined tax in New York City the nation's highest and push[ed] the price of a pack of cigarettes above \$8 in most places"); Kevin Sack, *States Look to Tobacco Tax for Budget Holes*, *N.Y. TIMES*, Apr. 21, 2008, available at <http://www.nytimes.com/2008/04/21/us/21tobacco.html> ("Since 2002, 43 states and the District of Columbia have enacted 76 distinct tobacco tax increases"). For a map depicting the current status of indoor smoking bans in the United States, see <http://www.no-smoke.org/pdf/100Map.pdf>.

ception uncovered in the state lawsuits.⁹⁵ These bans have, in turn, further increased the stigma associated with smoking.⁹⁶ As a result, although intended to protect non-smokers from exposure to cigarette smoke, these bans have also served—albeit crudely—as a counter to the deceptive marketing tactics designed to exploit nonrational decisionmaking tendencies, a counter that health information provision requirements cannot provide. True, awareness of the industry’s conduct and the increased stigma associated with smoking are of limited use to smokers, whose ability to freely choose whether to use tobacco products is severely curtailed by their addiction. Such awareness and stigma, do, however, reduce the likelihood that other adults will start smoking.

The state litigation against the tobacco industry has further aided the battle against smoking by diminishing the industry’s ability to maintain its strategy vis-à-vis cigarette sales. The Master Settlement Agreement (MSA) that concluded the litigation restricts the industry’s ability to market to children and adolescents.⁹⁷ Because the MSA is between the major cigarette manufacturers and forty-six states, the District of Columbia, and five other U.S. jurisdictions, the agreement created a nearly nationwide set of restrictions on the industry’s marketing toward children, including, for example, the banning of cartoons and of advertising on billboards.⁹⁸ For example, thirty-eight

95. Atlantic City recently joined a number of other states in banning smoking from the gambling floors of all its casinos, which had been exempted from the statewide ban on smoking in public buildings. See Assoc. Press, *Atlantic City Tightens Curb on Smoking*, N.Y. TIMES, Apr. 24, 2008, at B3. A dealer at one of the city’s casinos told a reporter that she believed the ban would have minimal impact on business: “Think back just a few years ago,” she noted. “You could smoke in malls, you could smoke in restaurants, you could even smoke in hospitals. . . . Now you can’t, and it’s become the norm. People are used to it.” *Id.*; cf. Eric M. Weiss, *D.C. Smoking Ban Approved*, WASH. POST, Jan. 5, 2006, at A1 (citing a Harvard School of Public Health study finding “little or no change in bar and restaurant patronage or tax collections after that [Massachusetts’s smoking] ban was put in place in July 2004”). Under pressure from casino executives, however, the Atlantic City Council subsequently suspended the total ban for one year; during this time, only 75% of the floor space must be smoke-free. See, e.g., Editorial, *Gambling With Lives*, N.Y. TIMES, Nov. 18, 2008, at A26.

96. Cf., e.g., Santora, *supra* note 94 (“Fear of a dreaded disease has been part of the bargain [of cigarette smoking] for years. Shame came slower, as smokers were cast from offices, restaurants and even bars.”).

97. Master Settlement Agreement, Nov. 23, 1998, secs. III(a)-(1), available at http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724_1032468605_cigmsa.pdf.

98. See C. STEPHEN REDHEAD, CONG. RESEARCH SERV., CODE NO. RL30058, TOBACCO MASTER SETTLEMENT AGREEMENT (1998): OVERVIEW, IMPLEMENTATION BY STATES, AND CONGRESSIONAL ISSUES 1, 12 (1999), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30058.pdf> [hereinafter Redhead,

state attorneys general recently invoked the youth-marketing restrictions of the MSA in launching an investigation into Reynolds American's marketing of cigarettes in a large array of flavors such as "Twista Lime" and "Mocha Taboo."⁹⁹ In response, the company reached an agreement with the states under which it is obligated "to stop identifying cigarettes with candy, fruit, desserts or alcoholic beverage names, imagery or ads."¹⁰⁰

This confluence of increased public awareness of the industry's deceptive business strategies as a result of the state litigation, of marketing restrictions imposed by the MSA, and of the numerous indoor smoking bans across the nation, appears to have been bad for cigarette business in the United States. In 2005, cigarette sales dropped to a fifty-five-year low, the culmination of a sharp decline that began in the late 1990s.¹⁰¹ In fact, by that year, cigarette sales had fallen by more than twenty-one percent since the execution of the MSA in 1998.¹⁰² In the FTC's most recent report on cigarette sales and the major companies' advertising and promotion expenditures, the agency found "that the total number of cigarettes sold or given away decreased by 4.2 billion cigarettes (1.1 percent) from 2003 to 2004, and then by 8.8 billion (2.4 percent) from 2004 to 2005."¹⁰³

Tobacco MSA]; Master Settlement Agreement, *supra* note 97, secs. III(a)–(l). The MSA also requires dissolution of the industry's research councils and prohibits agreements between companies to suppress health-related research. See Master Settlement Agreement, *supra* note 97, secs. III(o), (q).

99. See Assoc. Press, Michael Gormley, *Reynolds Agrees to Quit Selling Flavored Cigarettes in U.S.*, USA TODAY, Oct. 11, 2006.

100. *Id.*

101. See CBS & Associated Press, *U.S. Cigarette Sales Hit 55-Year Low*, Mar. 9, 2006, CBS NEWS, available at <http://www.cbsnews.com/stories/2006/03/09/business/main1384910.shtml>

102. See *id.* ("Cigarette sales declined 4.2 percent last year (2005) from 2004, one of the largest one-year percentage decreases since 1999."); Gregory N. Connolly & Hillel R. Alpert, *Trends in the Use of Cigarettes and Other Tobacco Products*, 229 J. AM. MED. ASSOC. 2629 (2008) ("Cigarette sales declined 18% from 21.1 billion packs in 2000 to 17.4 billion packs in 2007.").

103. FTC CIGARETTE REPORT 2004 & 2005, *supra* note 20, at 1. The report contains a table documenting cigarette sales since 1967 (the year the agency issued its first cigarette report) that shows an overall steady decline in cigarette sales reported by manufacturers and in the U.S. Department of Agriculture's estimates of cigarette consumption since 1983. See *id.* at 12–13 tbls.1 & 1A. This trend was maintained even though the FTC began including cigarettes given away (i.e., in addition to cigarettes sold) in 2001. See *id.* at 13 tbl.1A.

III.

THE TOBACCO INDUSTRY'S MOST RECENT
MANIFESTATIONS OF ITS "DISINFORMATION
PLUS PATH-DEPENDENCE" STRATEGY

Despite the spread of information concerning the grave health hazards of smoking, there continues to be a gap in public awareness about the health implications of smokeless tobacco and the industry's conduct with respect to smokeless products. There is a similar gap in public awareness as to cigarettes in other parts of the world, particularly in developing countries. It appears that, faced with declining domestic cigarette sales, the industry perceives these two gaps as opportunities again to implement its "disinformation plus path-dependence" strategy.

A. *The "Smokeless" Domestic Manifestation*

Importantly, the societal knowledge and associated stigma—with respect to both tobacco product use and the industry—have largely focused on cigarettes, and not on smokeless tobacco products. This makes sense given that cigarette sales have dominated the tobacco market since tobacco product manufacturing became a mass industry in the United States in the wake of World War I.¹⁰⁴ Because the health impacts of smokeless tobacco products were neither as widely publicized nor, given the much higher number of smokers than smokeless tobacco users, as widely felt, the one major producer of smokeless products—U.S. Tobacco—has not been subject to the same degree of public scrutiny as the six major cigarette producers.¹⁰⁵

104. See BRANDT, *supra* note 46, at 24 (describing the 19th century agricultural developments and curing processes that were "critical to the ultimate triumph of the cigarette as a commodity of mass consumption"); *id.* at 53 (explaining that "World War I would mark a critical watershed in establishing the cigarette as a dominant product of modern consumer culture").

105. Representative Waxman did, however, devote considerable time to U.S. Tobacco's practices and to smokeless products in his 1994 tobacco hearings, and the evidence presented made clear that U.S. Tobacco had adopted similar manufacturing and marketing practices as the cigarette companies. See, *Health Effects of Smokeless Tobacco: Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 103rd Cong. 2 (Nov. 29, 1994) (stating that the testimony presented at the hearing revealed "that chemical analyses of smokeless tobacco show clear evidence of nicotine manipulation"); *id.* at 1–2 (noting that "[a]llegations of nicotine manipulation in smokeless tobacco first came to the subcommittee's attention on March 25, when Dr. (David) Kessler presented information that smokeless tobacco products with lower amounts of nicotine are marketed as starter products for new users and that advertising is used then to encourage users to graduate to products with higher nicotine levels"); see also FDA, *Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery*

In the last few years, however, the structure of the tobacco market in this country has undergone a rather striking change: the disappearance of the smoking/smokeless market division that has heretofore separated the major cigarette manufacturers from the one major smokeless manufacturer. In 2006, the country's first and second largest cigarette manufacturers—Philip Morris and Reynolds American,¹⁰⁶ respectively—entered the smokeless market,¹⁰⁷ and Reynolds American bought Conwood, the second largest smokeless tobacco manufacturer in the country.¹⁰⁸ Toward the end of 2008, Altria—the parent company of Philip Morris—effectively completed the obliteration of the smoking/smokeless market divide by buying U.S. Tobacco.¹⁰⁹

Importantly, these two top cigarette manufacturers appear to be positioning themselves not only to capture the traditional U.S. smokeless product market—loose tobacco, primarily in the form of moist snuff—but also to expand that market by introducing a “spit-free” product under the companies’ most popular cigarette brand names.¹¹⁰ In contrast to traditional loose smokeless tobacco like snuff “dip” and loose-leaf “chew,” this new product, known as “snus,” eliminates the need to spit because the tobacco is packed in small pouches that resemble tea bags.¹¹¹ In 2006, Reynolds American began test marketing its Camel Snus; the following year, Philip Morris launched its Marlboro Snus.¹¹² According to Philip Morris, it designed Marlboro Snus

Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619–45,318 (proposed Aug. 28, 1996) (documenting the industry's manipulation of the nicotine content of smokeless-tobacco products).

106. Reynolds American was formed in 2004 as a result of a merger between R.J. Reynolds and Brown & Williamson. See *supra* note 20.

107. See Vanessa O'Connell, *Marlboro Brand Goes Smokeless*, WALL ST. J., June 9, 2007, at A3; Tim Whitmire, *Reynolds Makes Big Move Into Smokeless Tobacco*, SALEM NEWS, June 11, 2006, available at http://www.salem-news.com/articles/june112006/smokeless_ashtrays_61106.php.

108. See Reynolds American, *Reynolds American Fact Sheet*, at <http://files.shareholder.com/downloads/RAI/698068624x0x278558/d3bee8ad-b2bb-47f6-9a2a-df9f1bee8182/FactSheet.pdf>, at 10 (last visited Dec. 22, 2009). Conwood makes moist snuff brands such as Kodiak and Grizzly. See Conwood Sales Co., <http://www.cwdlp.com/moistPremium.htm> (last visited Dec. 22, 2009); Conwood Sales Co., <http://www.cwdlp.com/moistPriceValue.htm> (last visited Dec. 22, 2009).

109. See Bloomberg News, *Altria to Buy UST, a Snuff Maker, for \$10.3 Billion*, N.Y. TIMES, Sept. 9, 2008, at C2.

110. See O'Connell, *Marlboro Brand Goes Smokeless*, *supra* note 107; Whitmire, *supra* note 107.

111. See Mark Landler & Andrew Martin, *Smokeless from Sweden*, N.Y. TIMES, Oct. 3, 2007, at C1.

112. See O'Connell, *Marlboro Brand Goes Smokeless*, *supra* note 107; Whitmire, *supra* note 107. Apparently inspired by Reynolds American, which marketed its first snus product using its Camel name, Philip Morris attached the Marlboro name to its

for “adult smokers interested in smokeless tobacco alternatives to cigarettes.”¹¹³ Before being bought by Altria, U.S. Tobacco had also made forays into the emerging new market for smokeless products by introducing spit-free pouch products.¹¹⁴

The companies’ strategies for marketing snus indicate that the contemplated “smoker” market for smokeless products includes not only, or even primarily, smokers who want to stop smoking, but rather (1) smokers desiring a “bridge” source of nicotine in the office, on airplanes, and other places where smoking is now prohibited, and (2) new potential tobacco consumers who are now less likely to begin using cigarettes given the associated stigma and widespread awareness of the industry’s conduct with respect to cigarette marketing and manufacturing.¹¹⁵ Traditional “spit” smokeless products have never been nearly as popular as cigarettes in this country, particularly among women.¹¹⁶ Although the decline in cigarette sales has been accompanied by an increase in sales of moist snuff,¹¹⁷ it is unlikely that tradi-

snus product in 2007 after an unsuccessful test run of such a product under the new name “Toboka” the previous year. See Barnaby J. Feder, *Philip Morris Tries Smokeless Tobacco Product*, N.Y. TIMES, June 9, 2007, at C3. Lorillard, the third largest U.S. cigarette manufacturer, has also recently taken steps to develop smokeless products. In 2006, the company entered into an agreement with the U.S. subsidiary of Swedish Match, Sweden’s leading snus manufacturer, “to jointly develop and market a select line of smokeless products in the United States.” See Press Release, Lorillard Tobacco Company, *Lorillard Tobacco Company Enters into Joint Venture to Develop a Select Line of Smokeless Tobacco Products* (Oct. 25, 2006), available at <http://www.lorillard.com/index.php?id=96>.

113. Philip Morris U.S.A. Company, Marlboro Snus Fact Sheet, http://www.philipmorrisusa.com/en/cms/Products/Smokeless_Tobacco/Marlboro_Snus/default.aspx (last visited Dec. 22, 2009).

114. See Letter from Daniel C. Schwartz, Partner, Bryan Cave LLP, to Donald S. Clark, Secretary, Federal Trade Commission (July 21, 2003), available at <http://www.ftc.gov/os/comments/smokelesscomments/revel.pdf> (informing the FTC about and soliciting its comments on U.S. Tobacco’s planned advertisement for the smokeless tobacco pouch product Revel, which stated, *inter alia*, “No Secondhand Smoke. Another Reason to Switch to Revel,” and “It’s truly discreet, with no smoke, no odor, and no spitting.”); see also Wendy Koch, *As Cigarette Sales Dip, New Products Raise Concerns*, USA TODAY, Aug. 6, 2007, at A1 (“The challenge is getting a smoker ‘to create a new behavior.’” (quoting Dan Butler, president of U.S. Tobacco Company)).

115. See Micah L. Berman, *Tobacco Litigation Without the Smoke? Cigarette Companies in the Smokeless Tobacco Industry*, 11 J. HEALTH CARE L. & POL’Y 7, 13–17 (concluding that the marketing strategies of Philip Morris, Reynolds American, and U.S. Tobacco indicate that “the tobacco companies are not marketing smokeless tobacco as a product that will help current smokers quit,” but rather “are trying to increase their customer base for tobacco products while at the same time suggesting that current smokers may be able to use smokeless tobacco and cigarettes”).

116. See SURGEON GENERAL’S 1986 REPORT ON SMOKELESS TOBACCO, *supra* note 29, at xx, xxii.

117. See FTC, SMOKELESS TOBACCO REPORT FOR THE YEARS 2002–2005 24 tbl.4D (2007) [hereinafter FTC SMOKELESS TOBACCO REPORT] (reporting that the volume of

tional smokeless products will ever be as widely used as cigarettes were. In light of this, as an executive of Reynolds American stated, the introduction of the spit-free smokeless products is the industry's "effort to create a different tobacco category in the United States."¹¹⁸

Even more recently, the industry has introduced yet another smokeless tobacco "product category"—one that, disturbingly, appears highly likely to be even more attractive than snus to the young and to those less inclined to start using tobacco products: tobacco "candy." In January of 2009, Reynolds American began test marketing various types of finely ground flavored tobacco held together with food-grade binding agents that dissolve quickly in the mouth.¹¹⁹ The three so-called "dissolvables" that the company introduced include "Tic-Tac" like pellets branded as Camel Orbs, toothpick-size sticks branded as Camel Sticks, and translucent strips branded as Camel Strips (resembling Listerine breath-freshening strips).¹²⁰

Thus far, the tobacco companies' marketing strategies for making the new category of product attractive to this apparent target population suggest that the industry is seeking to exploit the smoking/smokeless dichotomy embodied in the public's mindset. The new smokeless marketing emphasizes certain differences between the two types of product—specifically, the undesirable characteristics of cigarettes that smokeless products do not have, or purportedly have to a lesser degree. The most obvious difference—and the one that the companies make explicit claims about in their advertisements—is that smokeless products are smoke-free, and may consequently be consumed unfet-

moist snuff sold (by pounds) has more than doubled from 1986 to 2005, and that dollar sales and advertising and promotional expenditures were both over five times higher in 2005 than 1986). In contrast, the volumes of all the other types of smokeless-tobacco product—i.e., loose-leaf chewing tobacco, plug/twist chewing tobacco, and dry snuff—have fallen over the same time period. *See id.* at 21–23 tbls. 4A, 4B, & 4C. In its summary of the data it collected, the FTC stated that "moist snuff consistently generated more revenue than any other type of smokeless tobacco," accounting for "85.2% of smokeless tobacco sales" in 2005, and "continued to receive the greatest advertising and promotional support." *Id.* at 10.

118. Koch, *supra* note 114.

119. Esme E. Deprez, *Will Cigarette Maker Reynolds Try Kicking the Habit?*, BUS. WEEK ONLINE, Nov. 11, 2009, http://www.businessweek.com/bwdaily/dnflash/content/nov2009/db20091110_263697.htm.

120. *See* Andrew Adam Newman, *A Different Camel Is Back in the Glossies*, N.Y. TIMES, Sept. 22, 2009, at B3; James Nash & Kathy Lynn Gray, *Tobacco Mints A Lot Like Candy?*, THE COLUMBUS DISPATCH, Sept. 25, 2009, available at http://www.dispatch.com/live/content/local_news/stories/2009/09/25/camel_mints.html.

tered by the societal stigma associated with the now widespread prohibitions of public smoking.¹²¹

The more controversial distinction that the industry is promoting, albeit less directly, is that smokeless products are less harmful to health than cigarettes. For example, in a 2008 speech at the University of Arkansas, Susan Ivey, the CEO of Reynolds American, called for “policies” that “recognize there is a continuum of risk in tobacco products,” claiming that “[t]here are significant differences between the risks of burning products, particularly cigarettes, and smoke-free tobacco and other nicotine products.”¹²² Similarly, a little over a month later at a shareholder meeting, Philip Morris CEO Michael Szymanczyk highlighted the company’s new focus on marketing smokeless products in the United States in response to declining cigarette sales, stating: “As the company looks to the future, it has clear recognition of the fact that conventional cigarettes are harmful in society, and we’d like to make some progress on improving that situation.”¹²³ Such a statement, at the very least, strongly suggests that the company is trying to portray smokeless products as a less harmful alternative to cigarettes.

U.S. Tobacco made analogous “harm-reduction” claims in a 2002 petition to the FTC requesting that the agency issue an advisory opinion approving the company’s plan to market its smokeless products as a “significantly reduced risk alternative” to cigarettes.¹²⁴ Although

121. See, e.g., Koch, *supra* note 114 (describing Reynolds American’s advertisements for Camel Snus, which include the slogan “pleasure for wherever” and an “abridged guide to snusing” stating, “Picture yourself stuck in the center seat 44B of an airplane: You can mope, or you can Snus.”).

122. Susan M. Ivey, Chief Executive Officer, Reynolds American, Remarks to the Clinton School of Public Service at the University of Arkansas (Apr. 8, 2008).

123. Assoc. Press, *Smokeless Tobacco Is Key to Future, CEO Says*, WINSTON-SALEM J., May 29, 2008, available at <http://www2.journalnow.com/content/2008/may/29/smokeless-tobacco-is-key-to-future-ceo-says>. Szymanczyk also told the shareholders that the company had made “remarkable progress” through its test marketing of Marlboro moist snuff and snus: “We’ve learned a lot that will allow us to efficiently develop our products further,” he said. *Id.*

124. Letter from Daniel C. Schwartz, Partner, Bryan Cave LLP, to Donald S. Clark, Secretary, Federal Trade Commission, at 1, 3, 5 (Feb. 5, 2002), available at <http://www.ftc.gov/os/comments/smokelesscomments/reqadvisoryop.pdf>. Specifically, the company asked the FTC to approve of statements in advertising such as the following:

The Surgeon General in 1986 concluded that smokeless tobacco “is not a safe substitute for smoking cigarettes.” While not asserting that smokeless tobacco is “safe,” many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves significantly less risk of adverse health effects than smoking cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products.

the company subsequently withdrew its request,¹²⁵ and neither it nor the cigarette companies have made such direct claims in advertisements for their smokeless products,¹²⁶ the harm-reduction message is nevertheless being conveyed to consumers by the industry in public statements such as those made by the CEOs of Philip Morris and Reynolds American¹²⁷ and implicitly in suggestive advertising techniques.¹²⁸

The main problem with the industry's new campaign is that the industry is attempting to gloss over the fact that, like cigarettes, smokeless products contain nicotine and are thus highly addictive. Furthermore, the smoking/smokeless dichotomy is being used by the industry to define the debate in terms of a narrow comparison of the health impacts of one tobacco product versus another on the individual user. Initially, more quality, independent research and assessment are necessary before claims of individual harm reduction can be made responsibly.¹²⁹ Scientific and medical experts are just beginning to

Id. at 5.

125. Letter from Daniel C. Schwartz, Partner, Bryan Cave LLP, to Donald S. Clark, Secretary, Federal Trade Commission, Aug. 12, 2002, *available at* <http://www.ftc.gov/os/comments/smokelesscomments/usstcletterwithdrawing.pdf>. According to the withdrawal letter, U.S. Tobacco withdrew its request "so that it w[ould] have the opportunity to provide for the Commission's consideration information on the proceedings of two very important upcoming scientific conferences which will include public debate directly relevant to [the company's] request." *Id.* at 1. Notably, before the company withdrew its request, the FTC received a number of letters from government officials, physicians, and public health experts urging the agency to reject the requests. *See* FTC, U.S. Smokeless Tobacco Company: Public Comments and Other Documents Placed on the Public Record, <http://www.ftc.gov/os/comments/smokeless-comments/index.shtm> (last visited Dec. 22, 2009).

126. *See* Koch, *supra* note 114 (noting that "the major tobacco companies are careful not to make any advertising claims that that their smokeless products have fewer health risks").

127. *See supra* text accompanying notes 122–23 and accompanying text; *see also*, Koch, *supra* note 114 (reporting on statements made by Tommy Payne, vice president for public affairs for Reynolds American, "that scientific studies show that smokeless products pose fewer health risks than cigarettes, largely because the tobacco is not burned and inhaled into the lungs"). *Cf.* Michelle Fay Cortez, *Snuff, Cigars Find Favor as Cigarette Prices Soar*, BLOOMBERG, July 7, 2008, <http://www.bloomberg.com/apps/news?pid=20601124&sid=A5XZHe0qxFdo&refer> (quoting Reynolds American spokeswoman Maura Payne's statement that "[t]he regulatory and tax structure should reflect the significant differences in risk between combustible and non-combustible tobacco products").

128. *See* Berman, *supra* note 115, at 13–16.

129. *See, e.g.*, INSTITUTE OF MEDICINE, CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION viii-x (2001) (calling for more independent scientific research and analysis and for regulatory oversight before advancing the use of smokeless tobacco and other tobacco products as a strategy for reducing the harm caused by cigarette use). Importantly, even after decades of experience with the epidemic of disease and death caused by cigarette smoking, scientists continue to find

uncover evidence on the health impacts of smokeless tobacco use.¹³⁰ But it is important to bear in mind that, although the tobacco in smokeless products is not consumed via the respiratory tract as it is with cigarette use, smokeless tobacco products—and their toxins—are consumed. It is already established that smokeless tobacco use causes mouth cancer.¹³¹ And there is also evidence suggesting that smokeless tobacco is a cause of pancreatic and esophageal cancers.¹³² Moreover, independent analysis of some of the new snus products indicates that they may be the most highly addictive product that the industry has marketed.¹³³

Certainly, although the full extent of the health impacts of smokeless tobacco products for users remains in question, use of smokeless products does not harm non-users in the *immediate* way

new evidence on the deleterious consequences of smoking. As the Surgeon General's most recent report (2004) on smoking stated: "Remarkably, this report identifies a substantial number of diseases found to be caused by smoking that were not previously causally associated with smoking." 2004 SURGEON GENERAL REPORT ON THE HEALTH CONSEQUENCES OF SMOKING, *supra* note 2, at 3. These diseases previously unknown to be associated with smoking include "cancers of the stomach, uterine cervix, pancreas, and kidney; acute myeloid leukemia; pneumonia; abdominal aortic aneurysm; cataract; and periodontitis." *Id.* Based on these and other similar findings, the report concludes that "[a]n increasingly disturbing picture of widespread organ damage in active smokers is emerging, likely reflecting the systemic distribution of tobacco smoke components and their high level of toxicity." *Id.* at 9.

130. See *supra* note 129 (noting the Institute of Medicine's call for more "independent scientific research and analysis" of the health impacts of smokeless tobacco use).

131. See, for example, Jeremy Pearce, *George E. Moore, Cancer Researcher, Is Dead*, N.Y. TIMES, June 14, 2008, at B6, which describes "the pioneering study of male patients with cancer of the mouth" conducted by Dr. George E. Moore of the Roswell Park Cancer Institute. Specifically, Dr. Moore and his colleagues found an early association between chewing tobacco and mouth cancer, "reporting that a majority—26 of 40 patients—had been tobacco chewers for significant periods of time, many for 15 years or more." *Id.* They further found "that other chewers, frequently those not found to have cancer, exhibited irritation of the gums as well as mouth lesions, known as leukoplakia, that can be precancerous." *Id.*

132. See, e.g., Paolo Boffetta et al., *Smokeless Tobacco and Cancer*, 9 LANCET ONCOLOGY 667, 669 (2008) (discussing European studies finding an increased risk of esophageal cancer among smokeless tobacco users); Roni Caryn Rabin, *New Smokeless Tobacco Worries Experts*, N.Y. TIMES, Nov. 27, 2008 ("[R]ecent studies have associated heavy use (of smokeless-tobacco products) with increased odds of pancreatic cancer"); see also American Cancer Society, *Smokeless Tobacco and How to Quit*, http://www.cancer.org/docroot/PED/content/PED_10_13X_Quitting_Smokeless_Tobacco.asp?sitearea=PED&viewmode=print& (last visited Dec. 22, 2009) (including pancreatic cancer among the risks of smokeless-tobacco use).

133. See Rabin, *New Smokeless Tobacco Worries Experts*, *supra* note 132 (reporting on the analyses of the nicotine content of Reynolds American's Camel Snus products, which found that the most recent version of the product was "so high in nicotine that the probability of becoming addicted to it with utilization of just one tin is going to be very high" (quoting Bruce W. Adkins, Director, Division of Tobacco Prevention of the West Virginia Bureau for Public Health)).

that smoking does. However, such a narrow comparison of the immediate impacts of the use of two particular product types is only part of the necessary analysis in assessing the public health implications of smokeless tobacco use. A proper public health assessment of whether use of smokeless products is in fact harm-reducing must also consider larger issues of usage patterns, including whether these products will lead people to start using tobacco products who otherwise would not, will act as a “gateway” to smoking for current non-smokers once they become addicted to the nicotine in the smokeless product (particularly young non-smokers), or will prevent people from quitting cigarette use who otherwise might.¹³⁴ Even though the industry’s marketing of its new spit-free tobacco product category strongly suggests it intends consequences of this very sort, the industry’s narrow harm-reduction claim assumes away these larger, population-wide health impacts of smokeless tobacco use.

Significantly, this is not the first time that the tobacco companies have introduced a new “product category” in response to public fears about the health consequences of smoking. As explained above, as evidence of the health dangers of smoking accumulated in the 1950s,

134. See INSTITUTE OF MEDICINE, *supra* note 129, at 302 (noting that “the population risks [of smokeless tobacco use] include concomitant smoking and adolescent use of smokeless tobacco as a gateway to cigarette smoking”); Letter from U.S. Representative Henry A. Waxman & U.S. Senator Richard J. Durbin, to Donald S. Clark, Secretary, Federal Trade Commission 1–2 (June 4, 2002), *available at* <http://www.ftc.gov/os/comments/smokelesscomments/waxmandurbin.pdf> [hereinafter Waxman & Durbin Letter to the FTC] (referring to smokeless tobacco as a “gateway drug to cigarette use” and discussing some of the associated studies). One of the studies cited by Representative Waxman and Senator Durbin in their letter to the FTC Secretary found that, among “a population of 7,865 Air Force recruits, smokeless tobacco users were 233% more likely to be smoking at the end of a year than non-users.” *Id.* at 2. The researchers thus “concluded that use of smokeless products ‘appears to be an important predictor of smoking initiation among young adult males.’” *Id.* In order to ensure such population-based factors are taken into account, the Institute of Medicine recommended in its report that “claims of less harm or risk associated with the use of tobacco products . . . should be available—but only if,” *inter alia*: “(1) “[t]here [are] strong and widely available programs designed to avoid initiation and to achieve abstinence,” and (2) “[t]here [is] an effective surveillance system in place to determine short-term behavioral and the long-term health consequences of the use of the new products.” INSTITUTE OF MEDICINE, *supra* note 129 at x. Moreover, recent results of the National Survey on Drug Use and Health call into question whether smokeless product use will lead to smoking cessation. See SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERVS., SMOKELESS TOBACCO USE, INITIATION, AND RELATIONSHIP TO CIGARETTE SMOKING: 2002-2007 5 (2009), *available at* <http://oas.samhsa.gov/2k9/smokelessTobacco/smokeless-Tobacco.pdf> [hereinafter SAMHSA, SMOKELESS TOBACCO USE] (“Some initiates of smokeless tobacco use may be cigarette smokers who are substituting smokeless tobacco as a way to quit smoking. Among daily smokers who initiated smokeless tobacco use, 88.1 percent were still smoking daily 6 months later.”).

cigarette manufacturers introduced new filter-tipped cigarettes and marketed them with “harm reduction” claims,¹³⁵ and sales of filtered cigarettes eventually overwhelmingly dominated the market.¹³⁶ A similar pattern played out with another—and more enduring—“health reassurance” cigarette; namely, “light” cigarettes. Based largely on industry documents unveiled as a result of the state suits alleging claims based on the industry’s practices, the U.S. Department of Justice brought suit against the major cigarette manufacturers in September of 1999 alleging that they had violated the Racketeer Influenced and Corrupt Organizations Act by engaging in a decades-long conspiracy to defraud and deceive the U.S. government and public by, *inter alia*, misrepresenting so-called “light” cigarettes as a lower risk alternative to “regular” cigarettes.¹³⁷ In August of 2006, after years of discovery and a nine-month trial, Judge Gladys Kessler concluded that the manufacturers had “maintained an illegal racketeering enterprise”¹³⁸ by “knowingly and intentionally engag[ing] in a scheme to defraud smokers, for the purpose of financial gain, by making false and fraudulent statements, representations and promises” to assuage fears about the health risks of smoking.¹³⁹ A principal part of this scheme was the deceptive marketing of “light” cigarettes. Judge Kessler noted that numerous internal documents had revealed that the defendant tobacco companies had orchestrated a “massive, sustained, and highly sophisticated” marketing campaign to promote their light brands as a healthy alternative to cigarettes knowing full well that they were still harmful to smokers’ health.¹⁴⁰

135. See *supra* notes 66–69 and accompanying text; see also BRANDT, *supra* note 46, at 244–46 (noting that, during this time period, cigarette manufacturers “began to market filters and promote apparent reductions in tar and nicotine with bold fanfare”). Brandt provides a few examples of “harm reduction” claims made by the companies in their marketing of filtered cigarettes, including Liggett & Myers’s claim that its new filtered cigarettes were “just what the doctor ordered” and Brown & Williamson’s assurance that its filtered Viceroy’s provided “Double-Barreled Health Protection.” *Id.* at 244 (internal quotations omitted).

136. See BRANDT, *supra* note 46, at 244 (“By 1954, filters made up approximately 10 percent of the cigarette market. The number would approach 90 percent by the mid-1970s.”).

137. See Redhead, *Tobacco MSA*, *supra* note 98, at 10; *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 859–61 (D.D.C. 2006); see also *supra* note 58 (discussing Judge Kessler’s opinion and the D.C. Circuit Court of Appeals opinion affirming her findings of criminal liability and most of her remedial order).

138. *United States v. Philip Morris USA, Inc.*, 566 F.3d 1095, 1108 (D.C. Cir. 2009) (affirming Judge Kessler’s factual and legal findings).

139. 449 F. Supp. 2d at 852.

140. *Id.* at 860.

Many of the statements in these documents resonate with the ones currently being made by executives of Philip Morris and Reynolds American regarding their new smokeless products and the companies' other marketing strategies for smokeless tobacco. One of Philip Morris's internal memoranda, for example, stated that it introduced "Marlboro Lights" in order to provide a "socially acceptable cigarette" that would be "a welcomed alternative to quitting, and might attract new smokers who would not otherwise choose to become product users."¹⁴¹ Like in the case of the industry's introduction of filtered cigarettes, consumers responded extremely favorably to the industry's marketing of "light" cigarettes: the market share for this product category rose from two percent in 1967 to eighty-one percent in 1998.¹⁴²

Disturbingly, it appears that as a result of the industry's recent increased marketing of smokeless products, yet another "health reassurance" tobacco product market shift may be taking place. Although cigarette sales have continued to decline since the mid-1980s, sales of moist snuff have been on the rise over the same time period.¹⁴³ A recent Harvard School of Public Health study documented this trend over the 2000–2007 time period.¹⁴⁴ Gregory Connolly, one of the researchers, explained to a reporter that "[i]t would appear that one-third of the decline in cigarette sales was reversed, by the use of other tobacco products,"¹⁴⁵ mostly moist snuff.¹⁴⁶ This development is particularly concerning given that smokeless products may act as a gateway to cigarettes,¹⁴⁷ in which case the recent increase in use of smokeless products would be followed by a resurgence in cigarette sales.

141. *Id.* at 490.

142. *See id.* at 508.

143. *See supra* notes 103, 117 (summarizing the findings of the FTC's most recent reports on sales of and advertising expenditures on cigarettes and smokeless tobacco products).

144. *See Connolly & Alpert, supra* note 102, at 2629.

145. Cortez, *supra* note 127 (quoting a phone interview with Greg Connolly, director of Harvard School of Public Health's Tobacco Control Research Program).

146. *See Connolly & Alpert, supra* note 102, at 2629 (finding that from 2000 to 2007, "sales of other tobacco products increased by 1.10 billion Cigarette Pack Equivalents (714 million moist snuff, 256 million roll-your-own tobacco, 130 million small cigar), equal to approximately 30% of the decrease in cigarette sales").

147. *See supra* note 134 and accompanying text; *cf.* SAMHSA, SMOKELESS TOBACCO USE, *supra* note 134, at 5 (reporting on survey results "indicat[ing] that, among persons who had used both smokeless tobacco and cigarettes in their lifetime, 31.8 percent started using smokeless tobacco first, 65.5 percent started using cigarettes first, and 2.7 percent initiated use of smokeless tobacco and cigarettes at about the same time").

We now most certainly know that (1) smokeless products are extremely harmful to health;¹⁴⁸ (2) there is not yet enough evidence on their health impacts to conclude that they are safer than cigarette smoking, either at the individual or population-wide level; and (3) they are at least as addictive as cigarettes, if not more so.¹⁴⁹ Further, given our experience with the industry's "disinformation plus path-dependence" strategy, we also know that the industry should not be permitted to counter or otherwise obscure these facts in its marketing of smokeless products.

Indeed, the introduction of new products by the tobacco industry must be carefully scrutinized for three key reasons that have been made apparent in the course of this country's experience with the cigarette epidemic and the industry. First, this is an industry that has until very recently been effectively free of regulation requiring it to take public safety into account in its business decisions. This is particularly remarkable given the second distinguishing feature of the industry: its products, being both addictive and harmful, are extremely

148. *See supra* notes 131–32 and accompanying text (noting the existence of medical evidence linking smokeless tobacco use to mouth, pancreatic, and esophageal cancers); *see supra* text accompanying note 32 (quoting the conclusion in the 1986 Surgeon General's report that smokeless tobacco use was not a "safe alternative" to cigarette smoking); *see also* Pearce, *supra* note 131 (stating that Dr. Moore's study of patients with mouth cancer at the Roswell Park Cancer Institute "became persuasive supporting evidence in making the American Cancer Society's case about the manifold dangers of using any tobacco products, not just cigarettes").

149. In its report on tobacco harm reduction, the Institute of Medicine compared the nicotine content and absorption rates of smokeless tobacco products and cigarettes:

In general the nicotine content per dose of smokeless tobacco product [sic] is higher than that of cigarettes, but the maximum serum nicotine levels are similar among all tobacco users. While there are inter-individual differences in nicotine absorption and metabolism, nicotine is absorbed more gradually from smokeless tobacco than from smoking, and blood concentration persists over a longer period of time and even overnight. Overall, smokeless tobacco users are exposed to a greater amount of nicotine because of continued slow absorption of nicotine up to an hour after the tobacco is taken out of the mouth as well as the more alkaline pH, causing nicotine to be present in its unprotonated form contributing to better absorption.

INSTITUTE OF MEDICINE, *supra* note 129, at 300 (citations omitted); *see also Smokeless Tobacco Is Ranked by Nicotine Levels for First Time*, N.Y. TIMES, May 5, 1994, at B12 (reporting on a university study that for the first time rated nicotine levels by brand and highlighting the report's findings that moist snuff had the highest nicotine levels, that nicotine concentration was higher in smokeless tobacco products than in cigarettes, and describing reaction to a study noting that "[r]esearchers believe that companies use additives to raise the pH levels of smokeless products, making them more alkaline and increasing their absorption through mucous tissues"); *see also supra* note 133 (describing findings by West Virginia public health officials that the nicotine content of Camel Snus was alarmingly high).

dangerous. Third, the industry's long history of concerted deception in its marketing and manufacturing is unprecedented in this country. In short, this is an industry with an extremely poor record in terms of harm reduction, and the laws to which it has historically been subject were not designed to protect the public from this sort of industry or this sort of product. That is, they were not designed to counter the "disinformation plus path-dependence" strategy. As a result, the industry's recent push to expand the smokeless tobacco market should be a cause for alarm.

B. *The "Smoking" Transnational Manifestation*

While the tobacco industry is touting smokeless tobacco products as a means of reducing the harm caused by cigarettes in this country, the companies are also heavily marketing cigarettes in other parts of the world. This second, transnational manifestation of the "disinformation plus path-dependence" strategy in response to declining domestic cigarette sales is primarily directed at low- and middle-income countries.¹⁵⁰ The fact that the residents of these countries do not have the experience of the cigarette epidemic that residents of this country do, coupled with the fact that the resource-poor governments of these countries are often unable to oversee the industry's business practices, makes this transnational manifestation of the tobacco industry's strategy particularly dangerous.

The tobacco industry adopted the transnational "smoking" manifestation of its "disinformation plus path-dependence" strategy long before it adopted the domestic "smokeless" manifestation. By the mid-1970s, the industry had already begun to look across borders for new consumers.¹⁵¹ What has coincided with the domestic manifestation of the industry's strategy, however, is an apparent modification of its transnational one: in March of 2008, Altria spun off Phillip Morris International,¹⁵² which has captured 15.6 percent of the global ciga-

150. See BRANDT, *supra* note 46, at 450.

151. See *id.*, which describes this market shift:

Between 1975 and 1994, overall cigarette sales in the United States declined by more than 20 percent During the same period, production of American cigarettes rose by 11 percent. As a result, the ratio of exported cigarettes rose sharply during this period, and opening new markets became a crucial element in the industry's growth. Cigarette exports from Philip Morris, R.J. Reynolds, and Brown & Williamson would more than triple between 1975 and 1994

152. See Altria, Philip Morris International Spin-off: Investor Information, http://www.altria.com/investors/2_2_1_pmisspinoff.asp (last visited Dec. 22, 2009); see also William Spain, *Altria Flat, but Philip Morris Jumps After Spinoff*, MARKET WATCH, WALL ST. J., Mar. 31, 2008, <http://www.marketwatch.com/news/story/altria-flat->

rette market,¹⁵³ selling more cigarettes than any other non-governmental tobacco company in the world.¹⁵⁴ The company's international tobacco product operations are consequently now separate from its U.S. tobacco product operations (Philip Morris USA). The company also announced its plans to shift all its manufacturing of products marketed outside the country to overseas operations.¹⁵⁵ Importantly, Philip Morris International and the company's other operations elsewhere in the world are not subject to U.S. legislation and are effectively immune from actions in U.S. courts.¹⁵⁶ These developments indicate that the industry is positioning itself to evade any export-based restrictions and other types of domestic tobacco control measures such as those that ultimately led to a decline in U.S. cigarette sales.

Sadly, the transnational manifestation of the industry's strategy appears to be working. According to the World Health Organization (WHO), although smoking rates are declining in the United States and other western countries, rates are on the rise at the global level because of the increasing number of smokers in the developing world.¹⁵⁷

philip-morris-intl/story.aspx?guid=%7BB92C43C5-6F5F-4900-9924-F1427F739E75%7D ("According to company executives speaking at recent investor presentations, the domestic business will be about grabbing share in a declining market, moving into non-cigarette tobacco products and cutting costs, while Philip Morris [International] focuses on growth via geographic expansion, acquisition and innovation.").

153. Philip Morris International, *Our History*, http://www.philipmorrisinternational.com/PMINTL/pages/eng/ourbus/Our_history.asp (last visited Dec. 22 2009).

154. Assoc. Press, *Altria to Spin Off Philip Morris International*, MSNBC.COM, Aug. 29, 2007, <http://www.msnbc.msn.com/id/20494757>. Philip Morris International is "the third most profitable consumer goods concern in the world after Procter & Gamble Co. and Nestle SA." Vanessa O'Connell, *Philip Morris Readies Global Tobacco Blitz*, WALL ST. J., Jan. 29, 2008, at A1.

155. See Assoc. Press, *Altria to Spin Off Philip Morris International*, *supra* note 154 (reporting on the company's plans to make this move within the year following the spin-off (in March of 2008), and that the overseas shift would "include[e] the production of about 57 billion cigarettes now made in the U.S.").

156. See Spain, *supra* note 152; O'Connell, *Philip Morris Readies Global Tobacco Blitz*, *supra* note 154 (noting that Philip Morris International's "practices would no longer be constrained by American public opinion, paving the way for broad product experimentation"); see also *infra* note 209 and accompanying text (explaining that the TCA's provisions apply only to tobacco products marketed in the United States).

157. See World Health Organization, *Tobacco Key Facts*, <http://www.who.int/topics/tobacco/facts/en/index.html> (last visited Aug. 7, 2009) [hereinafter WHO, Key Facts]; World Health Organization, Regional Office for the Western Pacific, *Smoking Statistics* (2002), http://www.wpro.who.int/media_centre/fact_sheets/fs_20020528.htm; see also, e.g., Jeffrey Kluger, *Big Tobacco Sets Its Sights on Africa*, TIME.COM, July 24, 2009, available at <http://www.time.com/time/health/article/0,8599,1911796-1,00.html> ("It's in Africa, however, that the battle for the hearts, minds and lungs of new smokers is being waged most aggressively.") (suggesting that it appears Philip Morris International is working to build a presence in Africa, noting that the company "controls

As a result, the epidemic is shifting to those countries whose health systems and governmental authorities are least able to respond: “Unchecked, tobacco-related deaths will increase to more than eight million a year by 2030, and 80% of those deaths will occur in the developing world.”¹⁵⁸

In response to this globalized tobacco crisis, the WHO for the first time in its existence exercised its authority to launch negotiations on an international treaty.¹⁵⁹ These negotiations resulted in the Framework Convention on Tobacco Control (FCTC), which entered into force in 2005.¹⁶⁰ The FCTC is noteworthy among international treaties in its explicit recognition of the need for governments to scrutinize the activities of and hold accountable industry actors in order to address the global problem motivating the existence of the treaty.¹⁶¹ Many of the FCTC’s obligations accordingly require state parties to enact and enforce various types of regulatory measures applicable to tobacco industry actors—including significant marketing and manufacturing regulation¹⁶²—and to collaborate with each other in address-

about 15% of the market across North Africa and has a scattered 10% share elsewhere,” and has also built a new factory in Senegal”); cf. BRANDT, *supra* note 46, at 428 (noting that by the late 1990s, “[i]n China alone, 70 million people had started smoking since 1987; clearly, any loss in sales in the United States could be many times compensated for by recruiting new smokers in non-Western societies”).

158. WHO, Key Facts, *supra* note 157. As Larry Gostin notes in a recent article, “[p]oor countries suffer from astonishing burdens of disease and early death, but they utterly lack the means to pull themselves out of a downward spiral of extremely poor health.” Lawrence O. Gostin, *Meeting Basic Survival Needs of the World’s Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEO. L. J. 331, 374 (2008).

159. See WHO Framework Convention on Tobacco Control, Foreword, *opened for signature* June 16, 2003, 2302 U.N.T.S. 166.

160. See World Health Organization, Full List of Signatories and Parties to the WHO Framework Convention on Tobacco Control, http://www.who.int/fctc/signatories_parties/en/index.html (last visited Dec. 22, 2009) [hereinafter *FCTC Signatories and Parties*].

161. See WHO Framework Convention on Tobacco Control, *supra* note 159, at 1–3 (“Recognizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts.”); *id.* at 7 (requiring parties “to protect” national public health policies relating to tobacco control “from commercial and other vested interests of the tobacco industry”); *id.* at 19 (obligating parties to “cooperate with competent international organizations to progressively establish and maintain a global system to regularly collect and disseminate information on . . . the activities of the tobacco industry which have an impact on the Convention or national tobacco control activities”).

162. See, e.g., *id.* at 9, 11 (regulating the contents of tobacco products, their disclosure, packaging and labeling, and restricting or banning tobacco advertising, promotion and sponsorship).

ing some of the industry's transnational activities, such as its cross-border advertising.¹⁶³

The tobacco industry's two most recent manifestations of its "disinformation plus path-dependence" strategy—its domestic smokeless manifestation and its transnational smoking one—make clear that the decline in U.S. cigarette sales does not by any means obviate the need for meaningful oversight of the industry. Indeed, they demonstrate that the need for regulation of the industry endures, and is perhaps even more urgent given that the new manifestations represent expansions both in terms of product type and of the industry's global presence. Thus, the recent enactment of the most significant piece of tobacco control legislation in the history of this country is exceedingly important.

IV.

AN ASSESSMENT OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (TCA).¹⁶⁴ Finally, this landmark legislation gives the FDA broad authority to regulate tobacco products.¹⁶⁵ Unquestionably, the TCA provides a much more effective counter than previous federal laws to the industry's domestic manifestations of its "disinformation plus path-dependence" strategy. However, while the TCA is clearly based on lessons that this country has learned through its calamitous experience with the cigarette epidemic, and consequently represents a significant and historical step in the right direction, the Act fails to go far enough to combat the industry's two new manifestations of its strategy or its possible future manifestations, which, as our experience with the industry has made apparent, will undoubtedly appear.

163. *See id.* at 12 ("Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising."); *id.* ("Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion, and sponsorship.").

164. Jeff Zeleny, *Occasional Smoker*, 47, *Signs Tobacco Bill*, N.Y. TIMES, June 23, 2009, at A15.

165. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 101-106, 123 Stat. 1776, 1783-1842 (2009) (to be codified at 21 U.S.C. §§ 387a-387u and scattered sections of 15 U.S.C.) [hereinafter TCA].

A. *The TCA*

Like the 1996 FDA rule that was struck down by the Supreme Court in *Brown & Williamson*, the TCA is based on the two major developments in knowledge that are relevant to tobacco control policy in this country, and yet did not inform the previous tobacco regulatory regime: knowledge of the highly addictive nature of nicotine and of the industry's misconduct in manufacturing and marketing its products.¹⁶⁶ However, the TCA is different from the FDA rule in two key respects. First, the Act amends the Federal Food, Drug, and Cosmetic Act (FDCA)¹⁶⁷ by providing the FDA with *sui generis* authority to regulate tobacco products, including any marketing of the "modified risk" variety of tobacco products.¹⁶⁸ Tobacco products are not regulated as "drugs" or "devices" under the FDCA as they were in the 1996 rule; rather, Congress has created a new regulatory regime specifically designed for tobacco products by adding a new subchapter to the FDCA that is devoted to tobacco products.¹⁶⁹ Second, the TCA is much more comprehensive than the 1996 rule. Like the FDA rule, prohibitions of marketing to the young are a principal part of the TCA.¹⁷⁰ But the Act also provides for much needed further marketing

166. Indeed, the legislative findings cite Judge Kessler's opinion determining that the companies had engaged in a criminal conspiracy to defraud the American public about the dangers of smoking and the addictiveness of cigarettes. TCA § 2(47)–(49), 123 Stat. at 1781 (noting that the "district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research").

167. 21 U.S.C. §§ 301-399a (2006).

168. See TCA, § 101(b), 123 Stat. at 1786 ("Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V [covering drugs and devices]."); *id.* § 101(b), 123 Stat. at 1813, 1818 (reiterating the inapplicability of chapter V to "modified risk" products and also specifying the inapplicability of chapter IV [covering food]). The Act mandates the creation of a center within the FDA—the Center for Tobacco Products—that would be responsible for implementation of the tobacco regulatory system established by the Act. *Id.* § 101(b), 123 Stat. at 1787. Under this new system, the FDA does not "approve" of the marketing of products as modified risk, but rather issues an "order" granting the manufacturer permission to do so. See *id.* § 101(b), 123 Stat. at 1814. Indeed, the TCA prohibits "any express or implied statement directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing that," *inter alia*, "the product is approved by the [FDA]" or "the [FDA] deems the product to be safe for use by consumers." *Id.* § 103(b)(13), 123 Stat. at 1834–35.

169. See *id.* § 101(b), 123 Stat. at 1784.

170. Among the Act's stated purposes is "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." *Id.*

regulation, such as establishing controls on modified risk marketing and granting the FDA broad authority to regulate the sale and distribution of tobacco products.¹⁷¹

Regarding modified risk marketing—industry claims that a given product presents less health risks than other tobacco products—the TCA defines the parameters of the tobacco harm reduction issue much more broadly than does the industry. The Act requires companies to obtain permission from the FDA before marketing any product as “modified risk.”¹⁷² In evaluating a company’s “modified risk” marketing application, the FDA must consider not only whether the individual user will benefit from using the product, but also whether use of the product “benefit[s] the health of the population as a whole.”¹⁷³ This public health analysis includes the likelihood that current tobacco

§ 3(2), 123 Stat. at 1781 (emphasis added). The Act also instructs the FDA to promulgate a rule “identical” to the 1996 rule except for certain specified changes. *See id.* § 102(a)(2), 123 Stat. at 1830–31. Among the changes to the 1996 rule is an exception to what had been a blanket prohibition on distribution of free product samples. Under the new rule, manufacturers, distributors, and retailers would be permitted to distribute free samples of smokeless tobacco products in “qualified adult-only facilities.” *Id.* § 102(a)(2)(G), 123 Stat. at 1831. The potential for this exception to provide a loophole of any significance with respect to marketing toward children and adolescents appears to be very small as a result of the very narrow definition of “adult-only facility,” which includes that entrance must be conditioned upon presenting a government-issued identification to a law enforcement officer or security guard for age-verification; that the facility cannot be “adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities”; and that the facility “is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with [the rule].” *Id.* However, as explained *infra* notes 186–207 and accompanying text, this exception for smokeless products is concerning in light of the smoking/smokeless dichotomy that is central to the industry’s recent marketing strategy.

171. *See* TCA § 101(b), 123 Stat. at 1796 (“The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.”); *see also, e.g., id.* § 101(b), 123 Stat. at 1788 (deeming tobacco products “misbranded” if their “labeling is false or misleading in any particular”); *id.* § 101(b), 123 Stat. at 1790–91 (requiring manufacturers to submit, at the HHS Secretary’s request, “[a]ny or all documents . . . relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors”).

172. *See id.* § 101(b), 123 Stat. at 1812. The Act defines “modified risk tobacco product” as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related diseases associated with commercially marketed products.” *Id.* § 101(b), 123 Stat. at 1812. The “modified risk” application process is a new process created by the TCA; it is entirely separate from the process by which the FDA evaluates applications for and “approves” drugs and devices. *See supra* note 168.

173. TCA, § 101(b), 123 Stat. at 1814, 1815.

users will use the modified risk product rather than quit tobacco use, the likelihood that non-users will start using the product, and the risks and benefits of using the product in comparison to using a product approved for the purpose of treating nicotine dependence.¹⁷⁴ The TCA specifies that such modified risk marketing can include not only claims made in product labeling and advertising,¹⁷⁵ but also any other “action” taken by tobacco product manufacturers “directed to consumers through the media or otherwise . . . respecting the product that would be reasonably expected to result in consumers believing that the tobacco product . . . may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products.”¹⁷⁶ Importantly, the public statements recently made by Philip Morris and Reynolds American executives regarding their new smokeless products, discussed above, would therefore likely be considered “modified risk” marketing under the TCA.

In addition to subjecting the industry to this increased marketing regulation, the Act for the first time in the country’s history provides for governmental oversight of tobacco product manufacturing. Notably, the Act requires the non-anonymous submission of ingredient lists by manufacturers.¹⁷⁷ More specifically, they must submit a list of the ingredients in, and the nicotine content of, each tobacco product brand and must inform the agency of any changes in the additive content of a product.¹⁷⁸

174. *See id.* § 101(b), 123 Stat. at 1816.

175. *See id.* § 101(b), 123 Stat. at 1812, which defines “[t]he term ‘sold or distributed for use to reduce harm or the risk of tobacco-related diseases associated with commercially marketed tobacco products’ ” to mean, *inter alia*:

a tobacco product . . . the label labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related diseases or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance.

Id.

176. *Id.* § 101(b), 123 Stat. at 1812–13. In addition to claims that the product presents a lower disease risk or is less harmful than other tobacco products, the Act’s modified risk requirements extend to manufacturer claims directed that the product “presents a reduced exposure to, or does not contain or is free of, a substance or substances.” *Id.*

177. *See id.* § 101(b), 123 Stat. at 1790.

178. *See id.* § 101(b), 123 Stat. at 1790–91. Furthermore, the Act instructs the HHS Secretary to prepare and make publicly available lists of the ingredients in each brand that are dangerous to health. *See id.* § 101(b), 123 Stat. at 1791–92.

The TCA provides the FDA with other important means of overseeing the tobacco industry's manufacturing practices, including: (1) the authority to inspect manufacturing facilities;¹⁷⁹ (2) the authority to require manufacturers to submit "[a]ny or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer . . . on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents . . . , ingredients, components, and additives;"¹⁸⁰ and (3) a pre-market review process under which manufacturers must apply to the FDA for permission to market a new tobacco product by submitting extensive information on the proposed product and demonstrating its compliance with any applicable product standards.¹⁸¹ The Act grants the FDA broad authority to respond to the information it gathers from the manufacturers, facility inspections, and elsewhere by establishing standards for both manufacturing processes¹⁸² and the composition of the final product that the agency determines to be necessary to protect the health of "the population as a whole."¹⁸³

In providing for significant manufacturing and marketing regulation of tobacco products by the FDA, an agency with scientific expertise that is charged with protecting public health,¹⁸⁴ the TCA represents a significant step toward finally resolving the disconnect between this country's tobacco policies and our knowledge about the nature of industry's strategy as one of "disinformation plus path-dependence." Such manufacturing regulation is vital to any effective

179. *See id.* § 101(b), 123 Stat. 1792–93 (subjecting manufacturing facilities to inspection and mandating that the FDA conduct such inspections at least every two years).

180. *Id.* § 101(b), 123 Stat. at 1790–91.

181. *See id.* § 101(b), 123 Stat. at 1807–12. As with the "modified risk" application process, *see supra* note 168, the FDA does not "approve" of the new tobacco product, but rather "issue[s] an order that the new product may be introduced or delivered for introduction into interstate commerce." TCA, § 101(b), 123 Stat. at 1809. The Act instructs the FDA to deny the application if the agency makes certain findings based on the information submitted by the manufacturer and any other relevant information, including a finding that marketing the product would not "be appropriate for the protection of public health." *Id.* § 101(b), 123 Stat. at 1809.

182. *See id.* § 101(b), 123 Stat. at 1797–99.

183. *Id.* § 101(b), 123 Stat. 1800–01. However, the TCA limits the FDA's manufacturing regulatory authority by prohibiting the agency both from banning a tobacco product and from requiring that products contain no nicotine. *Id.* § 101(b), 123 Stat. at 1803.

184. Among the congressional findings set out as the basis of the Act is that "[n]either the Federal Trade Commission nor any other Federal agency except the [FDA] possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and TCA." *Id.* § 2(45), 123 Stat. at 1781.

product safety policy, but it is particularly critical in the context of tobacco products given the industry's history of deliberately manipulating product design and its public deception about the nature of its products.

*B. Failings of the TCA with Respect to the Domestic
Smokeless Strategy*

There are, however, some provisions of the TCA that are problematic, particularly in light of the industry's recent "smokeless" manifestation of its strategy. Specifically, the Act contains three provisions that do not apply to all tobacco products, but rather *only* to cigarettes.¹⁸⁵ With these three exemptions of smokeless products from tobacco control policies, federal legislators may in effect be sanctioning the smoking/smokeless dichotomy that the industry is currently promoting in order to continue its "disinformation plus path-dependence" strategy in the United States.

The first provision that is applicable only to cigarettes is the prohibition of flavorings (other than tobacco or menthol).¹⁸⁶ This is particularly concerning given the highly important rationale for the flavorings ban, namely, preventing marketing to children and adolescents. This rationale is evident from the specific cigarette flavorings that the Act lists as included among those that are prohibited: "strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee."¹⁸⁷ Among the findings on which the Act is based is that "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products."¹⁸⁸ This is the case—notwithstanding that tobacco does not have the kind of taste that normally attracts the young—because, as the Act also states, "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products," and "[p]ast efforts to oversee these activities have not been successful in adequately preventing such increased use."¹⁸⁹ Such findings provide the basis for the Act's provisions that aim to control the industry's marketing to the young and that, other than the flavorings ban, are not specific to cigarette marketing, but

185. *Id.* § 101(b), 123 Stat. at 1799; *id.* § 201, 123 Stat. at 1845; *id.* § 102, 123 Stat. 1830–31.

186. *See id.* § 101(b), 123 Stat. at 1799.

187. *Id.* The provision further specifies that the list of flavorings does not serve to limit the FDA's authority. *See id.*

188. *Id.* § 2(4), 123 Stat. at 1777.

189. *Id.* § 2(15), 123 Stat. at 1777–78.

rather encompass all tobacco products.¹⁹⁰ The flavorings provision is thus one in which the Act veers from its overall approach to tobacco control—i.e., an approach informed by the addictiveness of nicotine and the history of the industry’s conduct, rather than product type.

In light of the industry’s history of youth marketing and its current marketing of smokeless products in various flavors, this is a particularly concerning statutory distinction. U.S. Tobacco, whose systematic targeting of young persons in its marketing has been well documented,¹⁹¹ manufactures moist snuff in a number of different flavors that would be prohibited for cigarettes under the Act, including cherry, spearmint, berry, vanilla, apple, peach, and citrus.¹⁹² Philip Morris’s new Marlboro Snus comes in spearmint and peppermint flavors,¹⁹³ and Reynolds American’s Camel Snus in a flavor called “frost.”¹⁹⁴ Finally, Conwood, the country’s second largest smokeless tobacco manufacturer that Reynolds American recently purchased,¹⁹⁵ offers its major moist snuff brands in mint and wintergreen.¹⁹⁶

190. See, e.g., *id.* § 102(a), 123 Stat. at 1830–33 (instructing the FDA to issue a rule “identical in its provisions” to its 1996 rule, which, as described *supra* notes 83–86 and accompanying text, regulated the industry’s marketing of cigarettes and smokeless tobacco products toward the young).

191. As Micah Berman explains in an article on the recent surge in the smokeless tobacco market in this country:

[U.S. Tobacco’s] internal documents have shown that the company views flavored products as “starter” products, and that smokeless tobacco users should be “graduated” to more traditional smokeless tobacco products like Copenhagen. As one former [company] sales representative not-so-subtly told the *Wall Street Journal*, “Cherry Skoal is for somebody who likes the taste of candy, if you know what I’m saying.”

Berman, *supra* note 115, at 24 (quoting Alix M. Freedman, *Juiced Up: How a Tobacco Giant Doctors Snuff Brands to Boost Their ‘Kick,’* WALL ST. J., Oct. 26, 1994, at A1).

192. See U.S. Smokeless Tobacco Co., Welcome to Skoalbrotherhood.com, skoalbrotherhood.com (last visited Jan. 4, 2009). As the new parent company of U.S. Tobacco, Altria has indicated its strong desire to continue offering a wide array of smokeless product flavorings by filing suit in federal court to block New York City’s attempt to prohibit the sale of fruit flavored snuff. See Duff Wilson & Julie Creswell, *Where There’s No Smoke, Altria Hopes There’s Fire*, N.Y. TIMES, Jan. 30, 2010, at BU1.

193. See Philip Morris USA, Marlboro Snus Fact Sheet, http://www.philipmorrissusa.com/en/cms/Products/Smokeless_Tobacco/default.aspx (follow “Marlboro” hyperlink under “Snus Products”) (last visited Dec. 22, 2009).

194. See R.J. Reynolds Camel Snus, <https://snus.tobaccopleasure.com/modules/security/Login.aspx> (last visited Dec. 22, 2009) (depicting packages of Camel Snus in “frost” and “mellow”).

195. See *supra* note 108 and accompanying text.

196. See Conwood Sales Co., LLC, Products: Moist Premium, <http://www.cwdlp.com/moistPremium.htm> (last visited Dec. 22, 2009); Conwood Sales Co., LLC, Products: Moist Price Value, <http://www.cwdlp.com/moistPriceValue.htm> (last visited Dec. 22, 2009).

Like the flavorings ban, the second provision of the TCA that is applicable only to cigarettes embodies an extremely important tobacco control measure: required warning labels on cigarette packaging. The TCA amends both the FCLAA and Smokeless Tobacco Act to require a rotation of some new warnings about the health dangers of tobacco product use on product packaging and in product advertising.¹⁹⁷ However, the Act mandates that the FDA implement regulations requiring a much-needed change in the design of the traditional black-text-on-white-background warnings *only* on cigarette packaging. Specifically, the FDA is statutorily required to “issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the [required] label statements.”¹⁹⁸ Such graphic warnings have proven effective in other countries—so effective that they are a key part of the WHO’s most recent recommendations for nations to adopt in their tobacco control policies.¹⁹⁹

As a result of the TCA’s focus on cigarette packaging, however, the benefits of this important provision will not extend to smokeless tobacco. As the history of the industry’s “cigarette” manifestation of its “disinformation plus path-dependence” strategy in this country makes clear, the traditional Surgeon General warnings have proven to be ineffectual: the industry has maintained, and even increased, its cigarette consumer base notwithstanding these warnings.²⁰⁰ Particularly at the very time when the industry is looking to smokeless products as a means of continuing its strategy in this country, Congress should not be in effect endorsing the continuation of an unsuccessful labeling policy with respect to these products.

197. See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201, 123 Stat. 1842–43 (2009) (to be codified at 21 U.S.C. §§ 387a–387u and scattered sections of 15 U.S.C.) (increasing the number of warnings rotated on cigarette packaging and advertising from four to nine, including new warnings such as “Cigarettes are addictive.”; “Smoking can kill you.”; and “Tobacco smoke causes fatal lung disease in nonsmokers.”); *id.* § 204, 123 Stat. at 1846 (adding one warning to the rotation on smokeless product packaging and advertising: “Smokeless tobacco is addictive.”).

198. *Id.* § 201, 123 Stat. at 1845.

199. See WORLD HEALTH ORGANIZATION, REPORT ON THE GLOBAL TOBACCO EPIDEMIC 33-35 (2008), available at http://www.who.int/tobacco/mpower/gtcr_download/en/index.html (“Experience in Australia, Belgium, Brazil, Canada, Thailand, and other countries shows that strong health warnings on tobacco packages, particularly pictorial warnings, are an important information source for younger smokers and also for people in countries with low literacy rates.”). The report further points out that warning label requirements cost governments very little to implement, see *id.* at 35, 48, and yet “[w]eak health warnings,” such as text-only warnings, “continue to be the global norm,” *id.* at 50.

200. See FTC CIGARETTE REPORT 2004 & 2005, *supra* note 20, at 13 tbl.1.

Although the Act does grant authority to the FDA to prohibit smokeless tobacco flavorings²⁰¹ and to implement regulations requiring graphic labels on smokeless products,²⁰² these measures are not statutorily required, as they are for cigarettes. As a result, these statutory provisions effectively mirror the smoking/smokeless dichotomy that has recently become a fundamental part of the industry's domestic manifestation of its "disinformation plus path-dependence" strategy. Unless the FDA promulgates rules imposing a parallel ban of smokeless tobacco flavorings and requiring graphic warning labels on smokeless products, the tobacco industry's smokeless tobacco campaign has a greater chance of success. Thus, as long as the smoking/smokeless distinction is effectively accorded statutory sanction, it is potentially dangerous in light of the industry's increased deceptive marketing of and increased consumer use of smokeless tobacco products.

The third TCA provision that suggests congressional recognition of the smoking/smokeless dichotomy is the Act's instruction to the FDA to issue a rule establishing a *blanket* prohibition against providing free samples of cigarettes, but not smokeless products.²⁰³ The Act specifically provides that the rule must allow companies to give out free samples of smokeless products in qualified "adult-only facilities."²⁰⁴ As a practical matter, this sampling exemption may be less troublesome than the omission of smokeless products from the flavorings ban and graphic warning label requirements because the statutory definition of an "adult-only facility" renders the exception quite narrow, and appears to effectively ensure against sampling to young persons.²⁰⁵ Nevertheless, the exception does give companies a means of attracting new *adult* users of tobacco products, and, furthermore, the very existence of the exception for smokeless products from the sampling prohibition, like in the cases of the cigarette flavorings ban and graphic warning requirement, arguably legitimizes the smoking/smokeless dichotomy.

In sum, these three provisions are highly problematic because they suggest that, notwithstanding the controls that the TCA imposes

201. See TCA, § 101(b), 123 Stat. at 1800–01.

202. See *id.* § 205(d), 123 Stat. at 1848–49.

203. See *id.* § 102(a)(2)(G), 123 Stat. 1831–32 (instructing the FDA to issue a rule "identical" to the 1996 rule, which included a ban on "distribut[ing] or caus[ing] to be distributed any free samples" of all tobacco products, but directing the agency to amend the earlier rule by providing an exception from the sampling ban for smokeless products in certain circumstances).

204. *Id.*

205. See *supra* note 170.

with respect to modified risk marketing, the government may in effect be providing support for the “harm-reduction” basis of the industry’s recent smokeless manifestation of its “disinformation plus path-dependence” strategy. After all, statutory creation of a distinction by omitting a category (here, smokeless tobacco products) from a prohibition suggests that the need to prohibit that which is excepted is not as pressing, or perhaps even non-existent.²⁰⁶ That is, the TCA’s distinctions between cigarettes and smokeless products arguably accord legitimacy to the false dichotomy that the industry has been advancing in its smokeless product push, which, in turn, appears to be the industry’s current principal strategy for maintaining, and perhaps eventually even increasing, consumer demand for all tobacco products in this country.²⁰⁷ Notably, Altria is apparently seeking to solidify and ag-

206. Similar concerns about what the cigarette flavorings provision fails to prohibit have been raised about the exemption of menthol from the flavorings ban. Notwithstanding the FDA’s authority to dissolve the distinction thereby drawn between menthol and other flavorings by issuing a regulation prohibiting menthol, a number of former federal health officials, the National African American Tobacco Prevention Network, and the Congressional Black Caucus protested the exemption on the ground that the industry has historically marketed menthol cigarettes to black smokers, most of whom smoke menthol cigarettes and who suffer from a significant proportion of smoking-related diseases. See Stephanie Saul, *Black Lawmakers Seek Restrictions on Menthol Cigarettes*, N.Y. TIMES, July 1, 2008, at C3.

207. It is important to remember that the tobacco and other industries will by and large continually adapt in response to product regulation (such as the flavorings ban, graphic-label requirements, and free-sampling prohibition)—regardless of whether the standards are established by statute or by agency regulation—and thereby render them less effective, if not entirely obsolete. Cf. *The Joint Failure of Economic Theory and Legal Regulation*, *supra* note 64, at 267 (“Government agencies do not have the incentives or the resources necessary to identify and to act against market manipulation in its many evolving forms. Indeed, the tobacco industry practices actually challenged by the FTC and other regulatory agencies may represent only those practices that have been around long enough or are egregious enough to have become transparent.”). As a result, as demonstrated by the importance of the state tobacco litigation, see *supra* Part II, *ex post* tort liability provides an important complement to regulation, serving as a decentralized and general deterrent in addition to providing remedies for product-caused injuries. See, e.g., David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 126–27 (2005) (“Tort liability serves two important and related functions unserved by regulation: tort liability compensates those injured by products found to impose an unjustified risk, and, in so doing, it deters excessive risk-taking by forcing the risk-taker to absorb the costs that come with marketing a product that imposes an unjustifiable risk of harm.”).

Importantly, the TCA in effect recognizes the importance of tort law’s role in tobacco control policy by providing that, although states may not impose tobacco product requirements that are “different from, or in addition to, any requirement under the provisions” of the new chapter of the FDCA governing tobacco products, TCA, § 101(b), 123 Stat. at 1823–24, neither this prohibition nor any other in the new 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,” *id.* § 101(b), 123 Stat. at 1824. This provision thus essentially specifies that the FDA’s

grandize the government-sanctioned dichotomy by urging the FDA to promulgate TCA “regulation based on” what the company calls a “continuum of risk” presented by cigarettes versus smokeless tobacco products.²⁰⁸ In a recent letter to the FDA, the company maintains that “[s]mokeless tobacco products are substantially lower on the risk continuum than cigarettes—closer, in fact, to medicinal nicotine and smoking cessation than to continued smoking.”²⁰⁹ A recent Marlboro Snus advertisement, however, indicates that the company does not intend to encourage consumers to choose only products on the purported “lower-risk” end of the continuum, but rather to use smokeless products in addition to, and as a means of continuing, cigarette use: “Whenever smoking isn’t an option, reach for new Marlboro Snus,” states the ad. “The (Snus) foilpack fits perfectly alongside your smokes.”²¹⁰

The structure of the tobacco market in this country does appear to be undergoing a significant change as a result of the disappearance of the historical divide between cigarette and smokeless product manufacturers and of the marked increases in smokeless tobacco product sales and advertising expenditures. But the recent smokeless tobacco product push is in essence nothing new; it is merely the most recent manifestation of the industry’s “disinformation plus path-dependence” strategy. With the TCA, however, the U.S. government has finally done something new in response. Although the Act would be better if it did not effectively recognize the smoking/smokeless dichotomy, it is nevertheless of tremendous significance for domestic tobacco control policy. It goes a long way toward making public health protections of

exercise of its authority under the new FDCA chapter does not preempt state tort law actions. Such a congressional statement is particularly important since the Supreme Court’s decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which for the first time recognized the possibility that the statutory preemption of a state “requirement or prohibition” might include state common law actions. See Vladeck, *supra*, at 105–06.

For another solution to the regulatory dilemma of keeping up with the tobacco industry’s deceptive marketing tactics, see *The Joint Failure of Economic Theory and Legal Regulation*, *supra* note 64, at 268–73, which argues that “the question for policy makers is not how to regulate tobacco markets, but how to make tobacco markets regulate themselves,” and suggests some proposals for achieving this, including the imposition of enterprise liability.

208. Letter from James E. Dillard III, Senior Vice President of Regulatory Affairs, Altria, to Food and Drug Administration (Dec. 22, 2009), at 8, available at <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a76127> (Comment in response to FDA, Request for Comments: Regulation of Tobacco Products Under the Family Smoking Prevention and Tobacco Control Act, 74 Fed. Reg. 31457 (July 1, 2009)).

209. *Id.* at 6.

210. Wilson & Creswell, *supra* note 192.

U.S. residents reflect what we have now known for almost two decades about tobacco products and the industry that produces and markets them, and thus toward effectively countering the industry's smokeless manifestation of its "disinformation plus path-dependence" strategy and other domestic manifestations of it.

C. Failings of the TCA with Respect to the Transnational Smoking Strategy

The same cannot be said, however, for the industry's transnational smoking manifestation of its strategy; the transnational activities of U.S. tobacco companies remain virtually unchecked. The United States has signed but not ratified the FCTC.²¹¹ Further, although the TCA provides for much needed oversight of the manufacture and marketing of tobacco products distributed in this country, its provisions do not apply to tobacco products that U.S. companies export.²¹²

Two of the Act's provisions do, however, at least indicate congressional recognition of the danger presented by the industry's transnational marketing of tobacco products. The first provision requires the HHS Secretary to submit an annual report to Congress on "the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act" and on "the public health implications of such exports."²¹³ The provision also suggests the possibility of a congressional response by instructing the Secretary to include in the report "recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health consequences caused by such exports."²¹⁴

211. The United States deposited its signature with the U.N. Secretariat on May 10, 2004. See *FCTC Signatories and Parties*, *supra* note 160.

212. See TCA, § 2(9)–(10), 123 Stat. at 1777–78 (basing legislative authority on Congress's interstate commerce power, and finding that "[t]he sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy"); see also, e.g., *id.* § 101(b), 123 Stat. at 1812 (prohibiting the introduction of a tobacco product in the U.S. market as "modified risk" unless an application to do so is granted) (emphasis added); *id.* § 201, 123 Stat. at 1843 (specifying that the cigarette warning requirements "do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States").

213. *Id.* § 103, 123 Stat. at 1838. The new provision also authorizes the Secretary to require industry actors to disclose any information necessary for the agency to prepare the report on export activities and their health impacts. See *id.*

214. *Id.*

A second provision of the TCA requires the U.S. Comptroller General to prepare a report on cross-border trade in tobacco products and suggests some congressional recognition of the need for international cooperation in order to monitor and control the industry's transnational activities.²¹⁵ Specifically, the Act requires the Comptroller General to "collect data on cross-border trade in tobacco products . . . and make recommendations on the monitoring of such trade;" to "collect data on cross-border advertising . . . of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising;" and to "collect data on the health effects" of such cross-border trade, particularly on the young.²¹⁶ In light of the industry's transnational activities and their devastating consequences in the developing world, however, such a report is entirely insufficient.

It is imperative that U.S. policymakers do more than the TCA to address the tremendous public health threat—both in terms of severity and scope—presented by the combination of the tobacco industry's most recent manifestations of its "disinformation plus path-dependence" strategy. In the current era of the industry's domestic and transnational implementations of its strategy, it is clear that, to be effective, tobacco control policy must extend not only to *all* tobacco product types in this country, but also to the industry's business practices in other parts of the world. In brief, Congress should enact legislation treating all tobacco product types uniformly, leaving the decision whether to make regulatory distinctions up to the FDA based on its independent and full public health assessments, and applying the same standards to products manufactured for export as those applicable to those produced for the domestic market. Additionally, given that the largest U.S. tobacco company has created an international spin-off that would evade such restrictions, the Senate should ratify the FCTC, and the United States should use the mechanisms of the treaty regime to provide developing-country parties with the resources and expertise necessary to make the treaty an effective counter to the industry's transnational strategy.

CONCLUSION

Given that the tobacco industry's two most recent manifestations of its "disinformation plus path-dependence" strategy have potentially dangerous consequences nationally and have already had disastrous

215. *See id.* § 302(a), 123 Stat. at 1851–52.

216. *Id.*

consequences worldwide, we must implement the lessons we have learned over the decades of our experience with the industry's implementation of its "cigarette" manifestation of the strategy in this country. Although the Family Smoking Prevention and Tobacco Control Act is a significant step toward achieving this, it is only an initial step. As our experience with the tobacco industry has made clear, it is crucial that the government continue down the path forged by the Act because the industry already has in place a highly malleable strategy that has outpaced, and will continue to swiftly outpace, this regulation.

The tobacco industry was able to successfully hone its highly effective and appallingly harmful strategy in this country, and to become incredibly powerful in the process, in large part because for decades it enjoyed a virtual absence of legal oversight. As a result, the U.S. government has a special responsibility not only to take effective action to protect its own residents from the consequences of the industry's strategy in all its forms, but also to assist in protecting those living elsewhere in the world.