COMMENT

THANK YOU FOR REGULATING: WHY PHILIP MORRIS'S EMBRACE OF FDA REGULATION HELPS THE COMPANY BUT HARMS THE AGENCY

KEVIN GAUNTT BARKER*

TABLE OF CONTENTS

* J.D. Candidate, 2010, American University Washington College of Law; B.A. History, The University of Georgia, 2007. I would like to thank Professor Lewis A. Grossman for his necessary guidance and advice in developing this Comment. Special thanks to Kristina P. Doan (Lighthouse), Nancy Phillips, Victoria S. Lee, and Mary Bortscheller for their precise editing and perspicacious suggestions. I am also indebted to my *Administrative Law Review* colleagues for pouring energy and staff hours into this Comment. To my family, thanks for your strong support of my endeavors—academic and otherwise.

INTRODUCTION

In February 2000, Philip Morris USA made a dramatic shift in policy: the company that had taken its war against Food and Drug Administration (FDA) supervision of the tobacco industry all the way to the Supreme Court[1] decided to pursue regulation from the agency.[2] The shift in policy has surprised and confused both supporters and opponents of FDA tobacco regulation,[3] with some public-health advocates opining that Philip Morris has changed its mind about regulation for legitimate reasons,[4] while cynics assert the company is merely acting out of self-interest.[5] The debate has been reignited by the Family Smoking Prevention and Tobacco Control Act (H.R. 1108), the most recent failed legislative attempt to give FDA

1. Philip Morris and other major tobacco companies filed suit in 1997 against the Food and Drug Administration (FDA), claiming that the agency lacked jurisdiction to regulate tobacco products because cigarette manufacturers did not attach therapeutic-benefit claims to their products. The federal district court ruled in FDA's favor, but the Fourth Circuit reversed. The Supreme Court granted certiorari and affirmed the Fourth Circuit decision. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 129–31, 161 (2000) (holding that Congress had not given FDA the authority to regulate tobacco products).

2. Patricia A. McDaniel & R.E. Malone, *Understanding Philip Morris's Pursuit of U.S. Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193, 193 (2005) (asserting that Philip Morris has been "aggressively pursuing" FDA regulation since 2000); *see also* Legacy Tobacco Documents Library, Privileged & Confidential Annual Meeting 2000—Draft Litigation Points 3 (Feb. 23, 2000) [hereinafter Legacy Tobacco Documents Library], http://legacy.library.ucsf.edu/tid/pxg77a00/pdf (tobacco industry insider memo stating that, although the industry had opposed past FDA regulatory efforts because the agency had treated tobacco like a "medical product," it supported "sensible regulation" that, inter alia, respected adult consumers' right to smoke and guided the industry toward the development of "less risky" products). Soon after the internal decision, the company publicly declared its position. *See* Barry Meier, *Executive Says Philip Morris Is Open to Some Regulation*, N.Y. TIMES, Feb. 29, 2000, at A12 (reporting that Philip Morris is open to "some" government regulation).

3. Samuel Loewenberg, *Smoke Screen: Why Is Philip Morris Supporting FDA Regulation of Cigarettes?*, SLATE, July 25, 2002, http://www.slate.com/id/2068476/ (A veteran tobacco lobbyist for a competitor of Philip Morris stated, "They are impenetrable to me. Their strategy is impenetrable, their positions are impenetrable . . . . I find their positions to be nuts."). One journalist wrote a lengthy magazine article devoted to figuring out why Philip Morris supported regulation, exploring whether a measure could benefit both Philip Morris and the general public. Joe Nocera, *If It's Good for Philip Morris, Can It Also Be Good for Public Health?*, N.Y. TIMES MAG., June 18, 2006, *available at* http://www.nytimes.com/2006/06/18/magazine/18tobacco.html.

4. *See, e.g.*, Loewenberg, *supra* note 3 (reporting that the American Lung Association chief lobbyist, Paul Billings, was initially "cynical," but now believes the company has legitimately altered its policy aims).

5. A longtime tobacco health expert remarked that H.R. 1108 could be renamed the "Marlboro Protection Act." *See The Need for FDA Regulation of Tobacco: Examining S. 625, To Protect the Public Health by Providing the FDA with Certain Authority to Regulate Tobacco Products: Hearing on H.R. 1108 Before the S. Comm. on Health, Educ., Labor, and Pensions*, 110th Cong. 57 (2007) [hereinafter *Senate Hearing*] (statement of Alan Blum, M.D., Director, University of Alabama Center for the Study of Tobacco and Society).

regulatory authority over the tobacco industry.[6] Although H.R. 1108 did not become valid law, identical or near-identical legislation is likely to appear in a future session of Congress.[7] Thus, the bill provides a relevant means of examining big business's pursuit and advocacy of regulation.

Big business's clamoring for federal regulation is by no means a recent phenomenon.[8] In the late nineteenth century, due to intense public pressure, Congress considered regulating railroads.[9] At first the railroad industry resisted regulation,[10] but after realizing that it was inevitable, the industry worked fiercely to capture regulation by maximizing benefits and mitigating harms.[11] The plan worked. Congress passed regulatory legislation that actually helped the railroads, while simultaneously satiating the public's appetite for a reined-in industry.[12]

---

6. H.R. 1108, 110th Cong. (as introduced in the House of Representatives, Feb. 15, 2007). *See generally* C. STEPHEN REDHEAD & VANESSA BURROWS, CONG. RESEARCH SERV., FDA REGULATION OF TOBACCO PRODUCTS: A POLICY AND LEGAL ANALYSIS (2007), *available at* http://www.nationalaglawcenter.org/assets/crs/RL32619.pdf (detailing the litany of tobacco-industry regulation bills proposed since 2000).

7. The 110th Congress's H.R. 1108 was simply a reintroduction of bills introduced in previous Congresses; the legislation was first introduced in the 108th Congress. REDHEAD & BURROWS, *supra* note 6, summary. Further, the FDA tobacco bills that have been introduced since the 107th Congress—and gained legislative momentum—have been either identical or very similar in content to each other and H.R. 1108. *Id.* at 19–20. Even though a future bill may well be a carbon copy of H.R. 1108, bills are assigned a different number if reintroduced in a different session of Congress. *See* GOVTRACK.US, http://www.govtrack.us/congress/bill.xpd?bill=h110-1108 (last visited Feb. 20, 2009) (explaining that congressional members often reintroduce old legislation, which is renumbered for the new congressional session).

8. Nineteenth-century railroad executives, for example, were instrumental in Congress's passage of legislation authorizing federal regulation of the industry. *See generally* GABRIEL KOLKO, RAILROADS AND REGULATION: 1877–1916 (1965). Contemporary examples of the big-business push for regulation include the Alliance of Automobile Manufacturers' advocacy of government-raised fuel efficiency standards and the Mortgage Bankers Association's advocacy of federal control over predatory lending. *See* Eric Lipton & Gardiner Harris, *In Turnaround, Industries Seek U.S. Regulations*, NYTIMES.COM, Sept. 16, 2007, http://www.nytimes.com/2007/09/16/washington/16regulate.html (observing the phenomenon of the push for regulation by "some of the nation's biggest industries" and expounding the self-interests dictating this advocacy).

9. *See* RICHARD D. STONE, THE INTERSTATE COMMERCE COMMISSION AND THE RAILROAD INDUSTRY: A HISTORY OF REGULATORY POLICY 4 (1991) (noting that united Populist farmers led the initial push to regulate railroads).

10. *See* KOLKO, *supra* note 8, at 17–20 (revealing that after many failed attempts at "self-regulation," industry executives increasingly favored federal regulation).

11. *See id.* at 232–33 (characterizing railroad executives as preempting the public's demand for action by hiding behind railroad-friendly federal regulation and as "relying on the [Interstate Commerce] Commission [(ICC)] as a means of attaining their own ends").

12. *See id.* at 44 (concluding that while the ICC bill was "conservative," the public saw it as "radical").

The railroad case informs the present debate: Philip Morris, a long time opponent of FDA regulation,[13] has acquiesced to federal oversight but only after working closely with Congress for years on the specifics of tobacco-industry regulation.[14] H.R. 1108 appears to be a comprehensive, FDA-empowering bill that revolutionizes the nation's tobacco policy. Upon closer look, however, the legislation contains crucial industry-lobbied compromises[15] that would give Philip Morris the benefits of regulation, while allowing the company to mitigate disadvantages.[16]

H.R. 1108 grants FDA "certain authority" to regulate the tobacco industry.[17] Of particular importance, the bill provides the following: (1) it gives FDA the authority to regulate the composition of cigarettes,[18] but reserves to Congress the right to ban cigarettes or to eliminate nicotine as a cigarette constituent;[19] (2) it provides for "modified" tobacco products,[20]

13. For the full procedural history of the challenges to FDA regulation of tobacco products, see Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374 (M.D.N.C. 1997), Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155 (4th Cir. 1998), and FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

14. For example, a 2000 draft of the bill eliminated federal preemption of potential state tort claim damages, which was one of Philip Morris's "requirements" for supporting FDA regulation. John Scruggs, Philip Morris's chief lobbyist at the time, manifested his stiff opposition to such a provision. In reporting to his Philip Morris colleagues, Scruggs said, "I took the opportunity to 'fall on my sword' and made it very clear [to congressional staff members] that we would do everything in our power to kill this bill and any other bill that contain[ed] such a provision." McDaniel & Malone, *supra* note 2, at 194–95.

15. As two congressional analysts note, "H.R. 1108 . . . represents an attempt to balance the competing interests of Philip Morris and leading anti-tobacco groups." REDHEAD & BURROWS, *supra* note 6, at 20. Philip Morris has intensely lobbied Congress concerning FDA regulation for years, and some of the compromises in H.R. 1108 might have been drafted by the industry. *Id.* at 194. Representatives from Philip Morris in the past have "worked with legislators, meeting with staff to explain [Philip Morris]'s views, helping to write legislation, and lobbying on behalf of [FDA regulatory] legislation [Philip Morris] supported." *Id.* at 195. When Republicans proved difficult to win over because of their ideological opposition to increased government regulation, Philip Morris representatives used polls showing that suburban swing voters—whose support was key to maintaining a Republican majority in Congress—favored FDA regulation of tobacco. Philip Morris even tried to hide its support for two early FDA regulation bills—publicly criticizing the legislation while privately rallying support—in order to "avoid the impression that it was dictating terms to Congress." *Id.* at 194–95.

16. *See Regarding "H.R. 1108, Family Smoking Prevention and Tobacco Control Act": Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 7 (2007) (submission of Alan Blum, M.D., Director, The University of Alabama Center for the Study of Tobacco and Society), *available at* http://energycommerce.house.gov/cmte_mtgs/110-he-hrg.100307.HR_1108.Tobacco.shtml (follow Alan Blum, M.D. hyperlink) (declaring that "[t]his bill is a godsend for Philip Morris").

17. *See* H.R. 1108, 110th Cong. (as introduced in the House of Representatives, Feb. 15, 2007).

18. *See id.* § 907(a) (establishing general tobacco product standards).

19. *Id.* § 907(d)(3)(A)–(B).

20. H.R. 1108 and the tobacco industry use *modified* rather than *reduced*. Since *modified risk* must mean either reduced or increased risk (and the bill certainly does not

mandating that FDA promulgate standards for reduced-risk cigarettes within two years[21] and allowing FDA to sanction cigarettes as having a "reduced exposure" to one or more cigarette substances;[22] (3) it gives FDA the power to limit tobacco-product advertising to the extent permitted by the First Amendment;[23] (4) it requires FDA to ban artificial flavorings from cigarettes within three months but explicitly exempts menthol;[24] and (5) it prevents FDA from raising the cigarette-buying age above eighteen.[25]

While H.R. 1108's public-health benefits are unclear,[26] what is more disturbing is that the bill's provisions might wreck an already-embattled FDA.[27] H.R. 1108 would logistically burden the agency[28] and potentially

---

contemplate increased-risk cigarettes), this is a semantical distinction that is potentially confusing for the reader. Accordingly, I will use *reduced* rather than *modified*. H.R. 1108 concedes this point in the bill's definitions. *Id.* § 911(b)(1).

21. *Id.* § 911(*l*).

22. *Id.* § 911(g)(2).

23. *Id.* § 906(d)(1).

24. *Id.* § 907(a)(1)(A). A cottage industry of criticism has developed around the bill's exemption of menthol from an otherwise exhaustive list of banned flavorings. Studies have suggested (but have not proved) that menthol may increase incidents of disease and makes quitting more difficult. Additionally, African-American smokers overwhelmingly choose menthol cigarettes. *See* Stephanie Saul, *Cigarette Bill Treats Menthol with Leniency*, N.Y. TIMES, May 13, 2008, at A15, *available at* http://www.nytimes.com/2008/05/13/business/13menthol.html.

25. H.R. 1108 § 906(d)(3)(A)(ii). If the buying age were raised to nineteen, then almost no high-school students could purchase cigarettes; a tobacco researcher explains that it is generally understood that raising the permissible buying age is important for "getting cigarettes out of high schools." *Senate Hearing*, *supra* note 5, at 158 (prepared statement of Anne Landman, Tobacco Document Research and Consulting).

26. *Compare Senate Hearing*, *supra* note 5, at 163 (prepared statement of Michael Siegel, M.D., M.P.H., Professor, Social and Behavioral Sciences Department, Boston University School of Public Health) ("The one thing you will never hear the supporters of this legislation do is estimate the number of lives they think this legislation will save. All they can do is talk about 'countless' lives being saved. And they are *quite correct*. The lives are countless. You cannot count them because they do not exist."), *and* Statement of FDA Commissioner Andrew C. von Eschenbach, M.D., Oct. 3, 2007, http://www.fda.gov/ola/2007/tobacco100307.html (warning that H.R. 1108 might cause the public to believe that cigarettes are safe and may encourage smoking), *with Senate Hearing*, *supra* note 5, at 105 (letter from David A. Kessler, M.D., former FDA Commissioner) (endorsing H.R. 1108 without discussing specific provisions and stating that it "is a strong bill and would significantly advance the public health").

27. FDA currently faces accusations of industry capture. For example, a 2007 Institute of Medicine report criticized FDA's focus on the *speed* of drug approval (which favors the pharmaceutical industry), finding that FDA was not concerned enough with drug *safety* (which protects the public). *See* BOARD ON POPULATION HEALTH AND PUBLIC HEALTH PRACTICE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 97–98 (2007), *available at* http://books.nap.edu/openbook.php?record_id=11750&page=97 (describing the undesirable effects of the Prescription Drug User Fee Act on FDA).

28. Commissioner von Eschenbach writes,

> Were H.R. 1108 enacted, FDA would need to create an entirely new "tobacco center" to implement the detailed program created by the bill.
>
> By far, the most important and daunting challenge would be to develop the expertise

render FDA an unwilling participant in Philip Morris's public-relations move.[29]

This Comment argues that H.R. 1108 is the latest example of big business capturing regulation. Part I describes the history of industry capture[30] and explains why Philip Morris's embrace of FDA regulation both fits within the historical model and potentially exceeds precedent by giving the company a relative advantage over its competitors. Part II analyzes key compromises in H.R. 1108 that would enable Philip Morris to mitigate the disadvantages of federal regulation. This Part evaluates the bill's tobacco-product standards, which would allow Philip Morris to frustrate FDA regulatory efforts,[31] and the reduced-risk and reduced-exposure cigarette provisions, which could revolutionize the American tobacco industry.[32] Part III argues that compromise-laden legislation would structurally burden FDA and undermine its mission of protecting the public health. Ultimately, this Comment advises Congress to refrain from authorizing tobacco-industry regulation—at least until it can pass legislation without heavy industry influence—and adopt more direct, effective means of curtailing tobacco consumption.

I. THE INDUSTRY CAPTURE MODEL

A. A Brief History of Industry Capture

The popular assumption is that industry always opposes government regulation.[33] Such a conceptualization imagines government regulatory

---

> necessary to carry out the functions called for by this bill. FDA does not have expertise regarding customarily marketed tobacco products and, therefore, would have to establish an entirely new program and hire new experts. Creating the appropriate organizational structure and hiring experts in the field of tobacco control and related sciences and other experts needed to staff the program at every level is considerably more challenging than simply filling identified vacancies in an existing program.

Von Eschenbach, *supra* note 26. *See generally* Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431 (2008) (detailing how FDA is currently scientifically and structurally overwhelmed).

29. *See* McDaniel & Malone, *supra* note 2, at 197 (positing that Philip Morris views FDA regulation as a means to improve the company's "unfavorable" public image).

30. Industry capture describes both authorizing legislation that favors big business (addressed in this Comment) and the favorable implementation of regulation. For a technical, theoretical discussion of both phenomena, see BARRY M. MITNICK, THE POLITICAL ECONOMY OF REGULATION: CREATING, DESIGNING, AND REMOVING REGULATORY FORMS 206–42 (1980).

31. *See generally* H.R. 1108, 110th Cong. § 907 (as introduced in the House of Representatives, Feb. 15, 2007) (stating the tobacco-product standards); *id.* § 912 (establishing the judicial review provision).

32. *See generally id.* § 911 (regulating "modified risk tobacco products").

33. *See* KOLKO, *supra* note 8, at 6 (arguing, in the context of the railroad industry, that

bodies as manifestations of public outrage, constraining the avaricious business practices of regulation-leery corporations.[34] History, however, disproves this assumption.[35]

The modern regulatory state was ushered in by the creation of the Interstate Commerce Commission (ICC) in 1887.[36] Nineteenth-century farmers and shippers were angry at inconsistent and seemingly arbitrary railroad freight charges;[37] Congress responded by authorizing ICC to regulate the industry and homogenize inequitable freight prices.[38] For decades misguided historians depicted the chartering of ICC as a public victory, accomplished despite industry opposition.[39]

In reality, railroad barons had supported regulation for years, always agreeing to the general principle of regulation, despite disagreeing on legislative details.[40] The industry realized that regulation was inevitable,[41] as political pressure was too acute for Congress to remain inactive.[42] Further, railroad leaders slowly understood that federal regulation might have benefits.[43] They believed that ICC regulation would signal an intra-

---

scholars have reflexively concluded that industry opposes regulation).

34. *See id.* at 2 (explaining that many historians imagined a federal government "redirect[ing] the balance of economic power on behalf of the public").

35. *See* GEORGE J. STIGLER, *The Theory of Economic Regulation*, *in* THE CITIZEN AND THE STATE 114 (1975) (claiming that as a rule, *industry* acquires the regulation which then chiefly benefits the industry).

36. *See* STONE, *supra* note 9, at 6 (describing the creation of ICC to oversee the Act to Regulate Commerce).

37. *Id.* at 3–4.

38. *Id.* at 6.

39. *See* KOLKO, *supra* note 8, at 6 (describing this historical depiction and noting the role the railroad industry played in the movement for federal regulation). Kolko's thesis that railroads were instrumental in achieving regulation and that the ICC in turn benefitted the industry, while controversial and provocative when published, has gained critical acceptance. *See, e.g.*, George W. Hilton, *The Consistency of the Interstate Commerce Act*, 9 J.L. & ECON. 87, 105 (1966) (praising Kolko's work); *see also* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 17 (1971) ("So many economists . . . have denounced the ICC for its pro-railroad policies that this has become a cliché of the literature."); *cf.* STONE, *supra* note 9, at 5–6 ("There is some indication that Kolko may be correct in that some, if not all, of the railroads thought that regulation would be beneficial to them in controlling competition by eliminating rate differences among railroads.").

40. KOLKO, *supra* note 8, at 3.

41. *See id.* at 232 (asserting that the industry's push was a means of preempting less-friendly regulation and describing federal regulation as a "safe shield"); *see also* STONE, *supra* note 9, at 5 ("[F]ederal regulation of the railroads was in the offing, as many groups in the country were pushing for it.").

42. *See* Hilton, *supra* note 39, at 87 (explaining that ICC's formation was in response to "widespread dissatisfaction" with the railroad industry).

43. Railroads tried many times to self-organize and establish rules to protect their collective interests, including attempts to collude on prices and to pool incomes in order to defuse price wars. *Id.* at 87–90. Since each attempt failed, executives increasingly believed that only the federal government could structure the industry in a manner that was not self-defeating. *See* KOLKO, *supra* note 8, at 10–11, 14, 18–19 (describing failed pooling efforts

industry ceasefire in the profit-crippling rate wars, alleviate public distrust of the railroad brand, and—most importantly—that the politically-connected industry would be able to stifle ICC measures that harmed railroad interests.[44] Indeed, one railroad company's president only partially exaggerated when he asserted that the enabling legislation itself was irrelevant: what truly counted was how it worked in practice.[45]

B. Fitting Within the Historical Model

Public opinion of tobacco companies fell sharply in the 1990s.[46] In 1994, tobacco executives swore before Congress that cigarettes were not addictive and would not admit that cigarettes caused lung cancer.[47] That same year Mississippi filed a $940 million lawsuit against the major cigarette companies.[48] In 1996, FDA tried to regulate cigarettes as drug-delivery devices, claiming that tobacco companies manipulated the way cigarettes delivered nicotine, resulting in higher nicotine yields which caused smokers to become more addicted.[49] In 1998, the four major

---

which led the industry to turn to the government for "salvation").

44. *See* KOLKO, *supra* note 8, at 15, 37 (describing the industry's hope of limiting harmful regulation, while leading the public to think much had been accomplished); *cf.* THOM HARTMANN, UNEQUAL PROTECTION: THE RISE OF CORPORATE DOMINANCE AND THE THEFT OF HUMAN RIGHTS 161–62 (2002) (quoting disenchanted Reagan-era regulators as saying that the supreme industry feat would be to attain new regulation that is perceived as meaningful, but in fact applied by a captive agency).

45. KOLKO, *supra* note 8, at 37 (quoting railroad president Charles Adams, Jr., "In the hands of the right men, any bill would produce the desired results").

46. *Compare* Sarah Smith, *America's Most Admired Corporations*, FORTUNE, Jan. 29, 1990, at 58 (ranking Philip Morris as the second most admired corporation), *with* Edward A. Robinson, *America's Most Admired Companies*, FORTUNE, Mar. 3, 1997, at 68 (dropping Philip Morris to 147th on that year's list).

47. *See, e.g.*, *Oversight Hearing on Tobacco Products*, *Before the Subcomm. on Health and the Env't of the H. Comm. on Energy and Commerce*, 103d Cong. 66, 68 (1994), *available at* http://tobaccodocuments.org/pm/2031195199-5455.html (William Campbell, then-president of Philip Morris USA, stated in response to the question of whether cigarette smoking caused lung cancer, "We don't know what causes cancer right now." Jim Johnston, then-Chairman and CEO of R.J. Reynolds, stated in response to the same question, "It may."). In the same hearing, six major tobacco companies' executives denied that nicotine was addictive. *Id.* at 78–79. A Philip Morris spokesman concedes that such miscalculations were largely responsible for the public's increasingly negative appraisal of Big Tobacco. For a candid discussion of industry mistakes, see Steven C. Parrish, *Bridging the Divide: A Shared Interest in a Coherent National Tobacco Policy*, 3 YALE J. HEALTH POL'Y L. & ETHICS 109, 109–12 (2002).

48. The suit settled in 1997 for more than $3 billion. *Tobacco Industry Settles Mississippi Lawsuit: Florida Also Makes Settlement Offer*, CNN.COM, July 3, 1997, http://www.cnn.com/US/9707/03/tobacco/index.html. For a behind-the-scenes look at the lawsuit, see Peter J. Boyer, *The Bribe: How the Mississippi Lawyer Who Brought Down Big Tobacco Overstepped*, NEW YORKER, May 19, 2008, at 44, *available at* http://www.newyorker.com/reporting/2008/05/19/080519fa_fact_boyer.

49. *See* David A. Kessler et al., *The Food and Drug Administration's Regulation of Tobacco Products*, 335 NEW ENG. J. MED. 988, 988–89 (1996) (justifying FDA's regulatory

tobacco companies executed the Master Settlement Agreement (MSA) with forty-six states and six U.S. territories for $206 billion.[50] The otherwise disastrous decade for the industry culminated with a victory, as the major cigarette manufacturers jointly contested FDA's assumption of regulatory authority.[51] After years of litigation, the Supreme Court ruled that the agency had exceeded its statutory limits, as Congress had previously considered and rejected giving FDA the authority to regulate tobacco.[52]

In response to mounting public disapproval[53] and falling stock prices,[54] Philip Morris sought to recover from the decade of negative publicity and reclaim its place as a respected American company.[55] Philip Morris USA rebranded itself under the corporate conglomerate name "Altria Group."[56] The company also began airing antismoking television commercials,[57] while admitting that cigarettes were addictive and caused cancer.[58] And even before the Supreme Court ruled that FDA had overstepped its statutory bounds, Philip Morris decided to support "sensible" regulation from the agency.[59] In fact, just as federal oversight of the railroad industry

---

assumption under this theory); *see also* PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 80 (3d ed. 2007) (affirming that documents released in 1990s litigation suggested the industry's intentional manipulation of nicotine to "satisfy" customers' addictions).

50. *See generally* Alison Frankel, *After the Smoke Cleared: The Inside Story of Big Tobacco's $206 Billion Settlement*, AM. LAW., Jan.–Feb. 1999, at 48 (describing the agreement between states that had not previously reached settlement agreements with the tobacco companies). The Master Settlement Agreement (MSA), initially assumed to be a windfall for public health, has padded state coffers more than it has curbed smoking rates. *See Senate Hearing*, *supra* note 5, at 80 (testimony of Alan Blum, M.D.) (claiming that state officials "squandered" MSA money); *see also* McDaniel & Malone, *supra* note 2, at 198 (arguing that the MSA created "perverse incentives" for states, since state income from the MSA depends on continued tobacco sales).

51. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120, 161 (2000) (rejecting FDA authority to regulate tobacco products in light of the Federal Food, Drug, and Cosmetic Act (FDCA) and other tobacco-specific legislation).

52. *Id.* at 161.

53. *See supra* note 46 and accompanying text (tracking Phillip Morris's declining reputation).

54. *See* John A. Byrne, *Philip Morris: Inside America's Most Reviled Company*, BUSINESSWEEK.COM, Nov. 29, 1999, http://www.businessweek.com/1999/99_48/b3657003.htm (noting that the company's stock value fell $83.2 billion in 1998–1999 alone).

55. *See* McDaniel & Malone, *supra* note 2, at 194 (noting that seeking regulation was part of a larger plan to be viewed as a "normal" and "legitimate" corporation to assure "continued success").

56. *See id.* (describing the name change as an "[i]mage enhancement").

57. Although required by the MSA, antismoking efforts have boosted Philip Morris's corporate reputation. *See Senate Hearing*, *supra* note 5, at 87–88 (testimony of Alan Blum, M.D.) (relating that Philip Morris has attracted college talent because students believe the company helps people quit smoking).

58. *See* Parrish, *supra* note 47, at 114 (indicating that Philip Morris adopted a policy to clarify these effects of cigarette smoking).

59. The first evidence of the company's support for regulation appeared in February

was not possible without industry support,[60] legislation authorizing FDA to regulate tobacco would be implausible without Philip Morris's backing.[61]

Moreover, like their railroad predecessors who only favored regulation after an incensed public demanded it,[62] Philip Morris executives only realized the potential benefits of FDA oversight after opposing it for four years.[63] After the 1990s, the disillusioned public no longer trusted tobacco companies; Philip Morris believed that FDA regulation would mollify critics and usher in a new era of respectability and legitimization in which the public understood the health risks of smoking but still respected the right of adults to smoke and the right of companies to sell and market cigarettes.[64]

FDA regulation, in addition to boosting Philip Morris's corporate image and deflated stock price,[65] would supplant patchwork state and local regulations,[66] defuse costly lawsuits,[67] divert resources away from more-effective tobacco-control efforts,[68] prevent new companies from entering the cigarette market,[69] and potentially stave off future, more damaging regulatory measures.[70] Indeed, just as nineteenth-century railroad men

---

2000, Legacy Tobacco Documents Library, *supra* note 2, while *FDA v. Brown & Williamson Tobacco Corp.* was decided on March 21, 2000. 529 U.S. 120, 120 (2000).

60. KOLKO, *supra* note 8, at 238.

61. *See* Saul, *supra* note 24 (suggesting that Philip Morris's lobbying efforts as an industry leader could derail FDA regulatory legislation).

62. *See supra* notes 42–43 and accompanying text.

63. *Compare supra* note 1, *and supra* note 13 and accompanying text (describing Philip Morris's prior lawsuits arguing against regulation), *with* Meier, *supra* note 2, at A12 (revealing Philip Morris's February 2000 shift in policy).

64. For an extended discussion on Philip Morris's vision of an improved industry atmosphere under FDA regulation, see generally McDaniel & Malone, *supra* note 2.

65. Based on financial performance alone, Altria Group stock is undervalued, Nocera, *supra* note 3, but amateur investors balk at buying stock in what they term an "evil" industry. E.A. Smith & R.E. Malone, *Thinking the "Unthinkable": Why Philip Morris Considered Quitting*, 12 TOBACCO CONTROL 208, 209 (2003), *available at* http://repositories.cdlib.org/cgi/viewcontent.cgi?article=3232&context=postprints.

66. *See, e.g.*, H.R. 1108, 110th Cong. § 917(a)(2) (as introduced in the House of Representatives, Feb. 15, 2007) (preempting certain state and local requirements with limited exceptions).

67. Philip Morris has advanced the prospect of "avoiding litigation" as a business benefit of FDA regulation. McDaniel & Malone, *supra* note 2, at 194. *See also Senate Hearing*, *supra* note 5, at 59 (prepared statement of Alan Blum, M.D.) (claiming the bill removes the risk of fraud litigation).

68. *See Senate Hearing*, *supra* note 5, at 58 (prepared statement of Alan Blum, M.D.) (arguing that federal funds would be better invested in a mass antismoking campaign than in FDA regulation).

69. When a company seeks regulation, one of the benefits it invariably pursues is restricting market entry. STIGLER, *supra* note 35, at 118. Tighter operational standards, easily handled by Philip Morris, would make it difficult for new competitors to break into the market.

70. *See* Meier, *supra* note 2, at A12 (quoting an anti-tobacco advocate as commenting that Philip Morris might be trying to foreclose more severe government action).

realized the danger of government regulation undertaken without industry input, Philip Morris understands that ex parte enabling legislation could have devastating consequences[71] for the proud company whose logo and cigarette packages once proclaimed "Veni, Vidi, Vici."[72]

C. Exceeding the Historical Model

While the nineteenth-century railroad industry collectively supported ICC's formation,[73] the modern-day tobacco industry is split over H.R. 1108.[74] R.J. Reynolds and Lorillard explain their opposition to the bill by claiming it would result in a competitive disadvantage.[75] Analysts speculate that FDA regulation would mean restricted advertising, which would solidify Philip Morris's dominant cigarette market share.[76] If H.R. 1108 restricts advertising, cigarette sales for brands with less name recognition than Philip Morris's Marlboro line might falter.[77]

Even if the companies opposing the bill are correct in thinking that decreased advertising would increase Philip Morris's share of the cigarette market, they do not account for the fact that less advertising would probably shrink the cigarette market as a whole.[78] Thus, while giving

---

71. *See* McDaniel & Malone, *supra* note 2, at 194 (explaining that Philip Morris regarded regulation as "inevitable" and thought it "better to act now [under a Republican-controlled Congress] than to risk more onerous regulations" under any future Democrat-controlled Congress).

72. *See* Stuart Elliott, *Uncle Sam Is No Match for the Marlboro Man*, N.Y. TIMES, Aug. 27, 1995, § 3, at 11, *available at* http://query.nytimes.com/gst/fullpage.html?res=990CEFDE163AF934A1575BC0A963958260 (describing Marlboro's former branding, developed in the 1950s, which incorporated the Latin phrase for "I came, I saw, I conquered," attributed to Julius Caesar).

73. *See* KOLKO, *supra* note 8, at 41 (quoting 1880s railroad expert William P. Shinn months before the ICC's passage as saying, "The leading railroad companies . . . are now almost without an exception in [favor of the ICC]").

74. *See* Stephanie Saul, *Reynolds Ads Say Tobacco Oversight Is Burden F.D.A. Doesn't Need*, N.Y. TIMES, Apr. 2, 2008, at C7, *available at* http://www.nytimes.com/2008/04/02/business/media/02reynolds.html (reporting that Reynolds opposes the bill); *see also* Statement from Lorillard Tobacco on FDA-Tobacco Regulation Legislation (Apr. 3, 2008) [hereinafter Lorillard Statement], http://www.reuters.com/article/pressRelease/idUS209594+03-Apr-2008+PRN20080403 (explaining that while Lorillard supports "reasonable federal regulation of the tobacco industry," it opposes H.R. 1108 because the bill has "fundamental problems").

75. *See* Saul, *supra* note 74 (indicating that tighter advertising restrictions could make it harder for Reynolds to market its Camel cigarettes); *see also* Lorillard Statement, *supra* note 74 (asserting that H.R. 1108 would provide a "competitive advantage to [Lorillard's] larger rivals").

76. *See* Saul, *supra* note 74 (indicating "the bill could benefit Philip Morris over its smaller competitors" by "imposing tighter restrictions on advertising").

77. *Id.*

78. *See* Ugur Yucelt & Erdener Kaynak, *A Study of Measuring Influence of Advertising and Forecasting Cigarette Sales*, 5 MANAGERIAL & DECISION ECON. 213, 217 (1984) (finding evidence that "increased spending on advertising . . . increases cigarette-

Philip Morris a *relative* advantage, advertising restrictions could reduce the company's overall sales.

Further, current MSA advertising restrictions have already left the tobacco industry with scant marketing outlets.[79] For example, Massachusetts's attempt to surpass the MSA's suffocating advertising terms by banning point-of-sale advertising was ruled unconstitutional by the Supreme Court.[80] Indeed, H.R. 1108 explicitly acknowledges that the First Amendment would limit FDA marketing restrictions,[81] which raises the question of how much the agency's restrictions could change the status quo without violating the Constitution. That Philip Morris anticipates regulatory scenarios years in advance,[82] and therefore might be more confident than its competitors in thriving under FDA oversight, may partially explain the industry divide. Alternatively, Philip Morris might believe that relative gains in market share would offset any decline in the overall cigarette market—or the other companies' fears might be unfounded. Ultimately, the industry discord remains a mystery.

II. A HELPED PHILIP MORRIS: MITIGATING REGULATION'S POTENTIAL PITFALLS

There is no smoking gun in H.R. 1108. Just as the railroad industry needed to align with shippers to make legislation politically palatable,[83] Philip Morris needs support from anti-tobacco groups to get an FDA-enabling bill passed.[84] Thus, legislation that gives Philip Morris a windfall is not politically feasible, as the company realized after initially promoting sham bills that outraged public-health advocates,[85] sharply reducing chances of legislative success. Indeed, while Philip Morris executives now

---

consumption").

79. *See generally* MASTER SETTLEMENT AGREEMENT, *available at* http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/1109185724_1032468605_cigmsa.pdf.

80. *See* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 589–90 (2001) (holding that state bans on point-of-sale advertising violated the First Amendment).

81. H.R. 1108, 110th Cong. § 906(d) (as introduced in the House of Representatives, Feb. 15, 2007).

82. *See Senate Hearing*, *supra* note 5, at 157 (prepared statement of Anne Landman) (noting that Philip Morris had MSA drafts prepared in 1991 "in anticipation" of cigarette advertising legislation).

83. KOLKO, *supra* note 8, at 6.

84. Even with the anti-tobacco lobby's support, several recent FDA tobacco bills have failed in Congress. *See* REDHEAD & BURROWS, *supra* note 6, at 13, 19–20 (describing failed bills and attributing some of the failures to lack of support from both the industry and the public-health community).

85. *See* Statement by Matthew Myers, former President, Campaign for Tobacco-Free Kids, *Rep. Davis' Sham FDA Bill Protects the Tobacco Industry, Not the Public Health*, June 14, 2001, http://www.tobaccofreekids.org/Script/DisplayPressRelease.php3?Display=368 (naming Philip Morris as "the main proponent of sham FDA legislation").

call for "tough but reasonable" regulation,[86] the original company byline advocated "some" regulation.[87]

The current bill is not sham legislation, and much of the public-health community backs H.R. 1108,[88] despite many dissenters.[89] Instead of blatantly benefitting Philip Morris, the bill has subtle compromises that allow the company to mitigate disadvantages.[90] In fact, Philip Morris must foresee a net gain: supporting a bill that achieves the antismoking ends advanced by some public-health advocates[91] would make the company a de facto proponent of reduced profits, and even company spokesman Steve Parrish admits that *making* profits is a driving force behind the company's support of the bill.[92]

A. H.R. 1108's Problematic Tobacco Product Standards

When FDA assumed regulatory control over the tobacco industry in 1996, it did so without explicit congressional authorization.[93] Thus, the agency was not bound by tobacco-specific legislative regulatory parameters, and it would have enjoyed a great deal of discretion, guided by its other regulatory endeavors.[94] Regulating tobacco, however, would be a fundamentally different task than regulating other products, as tobacco is already known to cause serious illness and disease.[95] If FDA regulated

86. Philip Morris USA Government Affairs, FDA & Tobacco (2008) [hereinafter 2008 Philip Morris Policy Statement], http://www.philipmorrisusa.com/en/cms/Responsibility/Government_Relations/Legislative_Issues/pdfs/fda_and_tobacco.pdf.aspx.

87. *See* Meier, *supra* note 2 (stating Philip Morris's February 2000 policy stance).

88. *See, e.g.*, *Senate Hearing*, *supra* note 5, at 33 (statement of Jack E. Henningfield, Ph.D., Vice President, Research and Health Policy, Pinney and Associates, Bethesda, MD and Professor of Behavioral Biology at Johns Hopkins University School of Medicine, Baltimore, MD) (asserting that regulation is necessary because FDA authority could lead to less harmful, less addictive tobacco products and could reduce deception); *see id.* at 72–73 (testimony of Matthew L. Myers, former President, Campaign for Tobacco-Free Kids) (defending H.R. 1108's merits).

89. See *Senate Hearing*, *supra* note 5, at 127, 157–58, 162, for examples of public-health figures who have issued statements opposing H.R. 1108.

90. *E.g.*, H.R. 1108, 110th Cong. §§ 907(a), 911(*l*) (as introduced in the House of Representatives, Feb. 15, 2007); *see infra* Part II.A (discussing H.R. 1108's compromises).

91. *See, e.g.*, *Senate Hearing*, *supra* note 5, at 11 (statement of Matthew L. Myers) (claiming the bill might save millions of lives).

92. Parrish, *supra* note 47, at 110.

93. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 129–31, 161 (2000) (holding that Congress had not given FDA the authority to regulate tobacco products).

94. *See* REDHEAD & BURROWS, *supra* note 6, at 5–6 (noting that FDA planned to use its drug-device regulatory formula to promulgate tobacco rules).

95. *See* von Eschenbach, *supra* note 26 (describing the dire health effects, including a litany of diseases, caused by tobacco use).

tobacco like other products (failing to account for its inherent dangers),[96] regulation would be simple: since cigarettes offer no therapeutic benefits and are a critical factor in more than 400,000 deaths a year in the United States,[97] FDA would have to remove them from the market.[98]

To work around this problem, H.R. 1108 gives FDA unique, tobacco-specific guidelines that require the agency to consider a number of factors when promulgating tobacco product standards.[99] Any tobacco product standard created by FDA would be susceptible to appeals,[100] especially in the modern administrative state, which primarily employs informal rulemaking. This widely used rulemaking form is subject to "searching" judicial review that has made rule promulgation increasingly burdensome.[101] Court challenges should especially concern FDA since, as its reputation has declined, judicial deference to agency rulemaking has followed suit.[102] For FDA to promulgate regulations that disfavor Philip Morris is for FDA to invite litigation with a company that has demonstrated both its willingness to sue and its proficiency in doing so.[103]

---

96. When the Kessler-led FDA undertook regulation, it altered its usual methods, claiming it could regulate cigarettes as "devices" without violating FDA's statutory dictate to ban unsafe drugs. HUTT, MERRILL & GROSSMAN, *supra* note 49, at 80.

97. *Senate Hearing*, *supra* note 5, at 1 (opening statement of Sen. Ted Kennedy, Chairman, S. Comm. on Health, Education, Labor, and Pensions). *See also* Centers for Disease Control and Prevention, Smoking and Tobacco Use, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm ("In the United States, cigarette smoking is responsible for about . . . 438,000 deaths per year.").

98. *See Brown & Williamson*, 529 U.S. at 121 (citing an FDA declaration—before the agency's assumption of regulatory control in 1996—that if the agency regulated cigarettes, it would have to remove them from the market because "it would be impossible to prove they were safe for their intended use"); *cf.* Cheryl Healton, *Keynote Speech on the Application of Harm Reduction to Other Public Health Problems: What Is Similar or Different About the Issue of Tobacco?*, 11 J. HEALTH CARE L. & POL'Y 93, 97 (2008) (asserting that if tobacco were a new product, it would never make it to the market).

99. H.R. 1108, 110th Cong. § 907(a) (as introduced in the House of Representatives, Feb. 15, 2007).

100. *See id.* § 912(a) ("[A]ny person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial . . . .").

101. *See* Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 904 (2008) (remarking that in order to circumvent the hassles of informal rulemaking, where judicial challenges typically arise *before* rules go into effect, FDA has increasingly resorted to "nonbinding guidelines").

102. *See* James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 940, 973–76 (2008) (arguing that executive branch mismanagement led to the decrease in deference to FDA); *cf.* David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 983 (2008) (agreeing that FDA has lost deference, but blaming the loss on FDA's lack of scientific expertise, underfunding, and overmandating); HUTT, MERRILL & GROSSMAN, *supra* note 49, at 1556 (remarking that while historically FDA successfully fended off litigation, its success has recently declined).

103. *See, e.g.*, *supra* notes 1, 13 and accompanying text (describing Philip Morris's

H.R. 1108 authorizes FDA to "adopt tobacco product standards" if such standards are "appropriate for the protection of the public health."[104] Rather than providing only this ambiguous directive—which would leave a gap in the statutory scheme ensuring judicial deference to FDA's judgment[105]—the bill propagates specific considerations to be undertaken by the agency.[106] FDA must determine tobacco product standards

> with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product [while considering] the increased or decreased likelihood that existing users of tobacco products will stop using such products and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[107]

Additionally, FDA must consider "all [other] information submitted in connection with a proposed standard, including information concerning . . . the creation of a significant demand for contraband or other tobacco products."[108] These directives seem unremarkable until their pragmatic ramifications are considered. In giving FDA specific analytical dictates, H.R. 1108 would allow Philip Morris to vigorously challenge rules that harm the company, as the bill's specific "considerations" would give

---

litigation history); Arnold & Porter LLP, Light Cigarette Class Action Litigation, http://www.arnoldporter.com/experience.cfm?action=view&id=845&owner=practice (last visited July 20, 2008) (listing the firm's successful litigation efforts on behalf of Philip Morris). In addition to Philip Morris's propensity to sue, FDA has generally faced more litigation in recent years. O'Reilly, *supra* note 102, at 942.

104. H.R. 1108 § 907(a)(3).

105. Such a standard would undoubtedly warrant *Chevron* deference. *See* Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984) (holding that if an enabling statute is ambiguous, courts should defer to the agency's statutory construction so long as it is reasonable). One administrative law scholar elaborates: "The key to *Chevron* is that, when a statute contains either an ambiguity that the Court cannot decipher using its arsenal of interpretive devices, *or a 'gap' in the statutory scheme*, Congress is signaling its intent that the agency, rather than the Court, should supply the missing meaning." John S. Kane, *Refining* Chevron*—Restoring Judicial Review to Protect Religious Refugees*, 60 ADMIN. L. REV. 513, 530 (2008) (emphasis added).

106. H.R. 1108 § 907(a)(3). The Federal Food, Drug, and Cosmetic Act (FDCA) requires that valid performance standards for drugs and devices contain "provisions to provide reasonable assurance of [a product's] safe and effective performance" and "where necessary to provide reasonable assurance of [a product's] safe and effective performance, include . . . provisions respecting the construction, components, ingredients, and properties [of the product.]" 21 U.S.C. § 360d(a)(2) (2006). In other words, current food and drug law demands that Congress provide specificities for evaluating a product. Although it is arguable whether H.R. 1108's tobacco-product-standard directives follow logically from the FDCA's performance-standard guidelines, such a contention ignores the uniqueness of FDA's regulation of tobacco, given cigarettes' inherent dangerousness. *See* von Eschenbach, *supra* note 26 ("Tobacco products . . . are intrinsically injurious to health."). Since there is no way to reasonably assure that a cigarette is "safe," the FDCA's performance-standard provisions are outmoded; different requirements should be used for tobacco, and the traditional performance-standard provisions should be abandoned.

107. H.R. 1108 § 907(a)(3).

108. *Id.* § 907(b)(1)(E).

courts a legitimate avenue to scrutinize FDA's decisions in a judicial atmosphere where the agency receives "declining deference."[109] While such judicial review of agency rulemaking may be desirable to ensure a fair regulatory process,[110] it is problematic to issue specific analytical guidelines that might discourage deference and produce even more contentious FDA rule promulgations.[111] Although many courts may defer to the agency, in the current FDA regulatory climate, deference is no longer guaranteed[112]—a reality that would likely incentivize litigation.

For example, H.R. 1108 authorizes FDA to regulate cigarette nicotine yields.[113] If FDA determined that it would be beneficial for the overall public health to reduce nicotine levels by fifty percent—a drastic cut that Philip Morris would find unacceptable[114]—the company could challenge the ruling in court.[115] Since there are health professionals who think that reducing nicotine levels would harm current smokers,[116] Philip Morris could assert that FDA had incorrectly decided to mandate nicotine reductions. In this scenario, H.R. 1108's directive to determine what promotes the public health by considering current users of tobacco products

109. *See* Vladeck, *supra* note 102, at 983 (claiming that courts' "declining deference" to FDA decisions is not just the result of "ill-considered, politically motivated decisions" but also relates to eroding resources and increasing responsibilities).

110. *See* Cass R. Sunstein, *In Defense of the Hard Look: Judicial Activism and Administrative Law*, 7 HARV. J.L. & PUB. POL'Y 51, 53 (1984) (arguing that judicial review of agency action is a healthy practice which promotes the separation of powers). *But see* Frank B. Cross, *Shattering the Fragile Case for Judicial Review of Rulemaking*, 85 VA. L. REV. 1243, 1244 (1999) (arguing that there is no valid justification for judicial review of agency rulemaking).

111. Some analysts argue that tobacco-product standards promulgated under H.R. 1108 would automatically cue *Chevron* deference. *E.g.*, Christopher N. Banthin & Richard A. Daynard, *Room for Two in Tobacco Control: Limits on the Preemptive Scope of the Proposed Legislation Granting FDA Oversight of Tobacco*, 11 J. HEALTH CARE L. & POL'Y 57, 62 (2008). Such an assertion, however, seems predicated on the old FDA model, when the agency was the gold standard for regulatory bodies and courts rarely questioned its scientific bases. The modern FDA does not retain such a privilege, and the agency has lost many cases in the past decade that it would have won under a traditional deference review.

112. *See* O'Reilly, *supra* note 102, at 973–76 (cataloging examples of judicial decisions that do not defer to FDA).

113. H.R. 1108 § 907(a)(4)(A)(i).

114. One of the company's biggest fears is that cigarettes will be regulated to the point of unpalatability. *See* Parrish, *supra* note 47, at 115 (noting that Philip Morris supports the removal of harmful components so long as cigarettes remain fit for adult consumption).

115. *See* H.R. 1108 § 912(a)(1) (stating that "any person adversely affected by such regulation or denial" may file for judicial review).

116. *See, e.g.*, *Senate Hearing*, *supra* note 5, at 59 (prepared statement of Alan Blum, M.D.) (explaining that reducing nicotine levels would cause smokers to ingest more cigarettes to calm cravings). Experts disagree whether reducing nicotine levels would be desirable for the public health. This example merely demonstrates that if FDA *did find* the reduction to be desirable, its findings could be challenged more aggressively than if Congress gave the agency tobacco-product-standard guidelines that are more general.

would give the claim merit.[117] The requirement that FDA consider increases in the demand for contraband tobacco products[118] would further legitimize Philip Morris's claim, since the company could argue that any reduction in nicotine levels would dissuade consumers from buying regulated cigarettes and increase black-market tobacco demand.[119]

Indeed, an FDA regulation that harmed Philip Morris's cigarette business would make litigation likely, unless the company was willing to sacrifice profits.[120] While prevailing in the courtroom would likely be Philip Morris's initial goal, overwhelming FDA with drawn-out appeals processes would discourage future industry-harming regulatory measures and could be almost as effective as winning on appeal.[121]

B. Reduced-Risk Tobacco Products

As one tobacco-industry observer noted, "It was clear from the behavior of the Philip Morris representatives that their attitude was 'Just tell us what the rules are, and I can beat my competition.'"[122] H.R. 1108 aligns with this mantra by requiring FDA to promulgate rules within two years that establish a minimum threshold for reduced-risk tobacco products.[123] To be considered reduced risk, a cigarette must "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users."[124] Alarmingly, FDA would rely primarily on "the scientific evidence submitted by the applicant"—i.e., the approval-seeking tobacco

117. *See* H.R. 1108 § 907(a)(3)(A)–(B) (directing FDA to consider the risks and benefits to the population as a whole, including current tobacco users).

118. *Id.* § 907(b)(1)(E).

119. *See Senate Hearing*, *supra* note 5, at 176 (memorandum of Joel L. Nitzkin, M.D., M.P.H., D.P.A., Chairman, American Association of Public Health Physicians Tobacco Control Task Force) ("This [contraband] provision stands as an open invitation to tobacco companies to assert in court that any proposed change in the composition of its tobacco products that change the taste, reduce the attraction to nicotine addicts or significantly increase the cost of manufacture could increase the demand for contraband.").

120. *But see* Parrish, *supra* note 47, at 110 (admitting that Philip Morris seeks regulation to make profits).

121. Indeed, given a tobacco product standard directive that invites litigation, FDA might not issue regulations at all or might issue industry-friendly rules. Senator Coburn's remarks are instructive: "The only problem with [assuming FDA will take on the industry] is the Bureaucrats' Law of Washington—never do what is right when you can do what is safe. . . . The FDA is like a balloon. You push in one place, it goes out somewhere else." *Senate Hearing*, *supra* note 5, at 82 (testimony of Sen. Tom Coburn, Member, S. Comm. on Health, Education, Labor, and Pensions); *cf.* Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 443 (1998) (asserting that FDA has escaped "unrealistic [congressional] directives" in the past).

122. Nocera, *supra* note 3.

123. H.R. 1108 § 911(*l*)(1).

124. *Id.* § 911(g)(1)(A).

company—when determining whether tobacco products qualify as reduced risk.[125]

Convincing consumers that cigarettes are less harmful would increase tobacco sales and profits,[126] and may represent the industry's future.[127] Indeed, making implicit lowered-risk health claims has long been part of Big Tobacco's marketing strategy, dating back to the use of "light" and "low tar" descriptions in the 1970s.[128]

Adding to the need for reduced-risk products is the industry's steady regression.[129] Each year Philip Morris USA reduces production, and sales decline as fewer Americans choose to smoke.[130] The reason is fairly clear: smoking cigarettes causes fatal diseases,[131] and as consumers become more aware of smoking's health risks,[132] they are less likely to smoke.[133]

---

125. *Id.* § 911(g)(3)(A). The tobacco industry has a documented history of knowingly deceiving the public about health risks. *See* United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 852 (D.D.C. 2006) (discussing Philip Morris's persistent attempts to deceive the public by concealing or distorting the health risks of cigarettes). Compare the current proposal with HARTMANN, *supra* note 44, at 162–63 (noting that 1990s legislation gave FDA authority to regulate genetically modified foods, yet problematically required the agency to rely on manufacturers' science).

126. *See Senate Hearing*, *supra* note 5, at 59 (statement of Alan Blum, M.D.) ("[S]moking prevalence is directly proportional to the degree of perceived harm from smoking. . . ."); *see also* Andrew Steptoe et al., *An International Comparison of Tobacco Smoking, Beliefs and Risk Awareness in University Students from 23 Countries*, 97 ADDICTION 1561, 1569 (2002), *available at* http://www3.interscience.wiley.com/cgi-bin/fulltext/118957918/PDFSTART (replicating past studies that had found a "robust association between smoking and beliefs in the importance of not smoking for health").

127. *See* Nocera, *supra* note 3 (observing Philip Morris's efforts to grow the company in a declining market through development of "reduced harm" tobacco products and noting a $350 million reduced-risk tobacco product research-and-design facility at company headquarters).

128. In *United States v. Philip Morris USA, Inc.*, the court found that tobacco companies had engaged in a long-term conspiracy to conceal smoking's health risks, noting that the companies had "suppressed research [and] distorted the truth about low tar and light cigarettes." 449 F. Supp. 2d at 852.

129. Altria Group projects that cigarette sales will decline 3.5% this year. This projection, in addition to shareholders' complaints that the company was too focused on cigarettes, in part motivated Altria's recent $10.3 billion acquisition of United States Tobacco, Inc., the world's largest snuff manufacturer. Chris Burritt, *Altria to Buy UST for $10.3 Billion, Gaining Skoal (Update2)*, BLOOMBERG.COM, Sept. 8, 2008, http://www.bloomberg.com/apps/news?pid=20601103&sid=anOAnSGfaSQM.

130. *See* Thomas M. Anderson, *Altria Versus Philip Morris International*, KIPLINGER.COM, Apr. 18, 2008, http://www.kiplinger.com/columns/picks/archive/2008/pick0418.htm (noting a declining demand for tobacco in the United States, but increased demand in emerging nations).

131. *See* Parrish, *supra* note 47, at 114 (acknowledging the Philip Morris position that smoking causes lethal health problems).

132. In 1954, 40% of Americans said that smoking causes cancer. In 1969, the number was 70%. In the 1980s, 80% believed in the link. By 1999, 90% of Americans agreed that smoking causes cancer. David W. Moore, *Americans Agree with Philip Morris: Smoking Is Harmful: But Public Blames Smokers More Than Tobacco Companies for Smoking-Related Health Problems*, GALLUP NEWS SERVICE, Oct. 14, 1999,

The development of a tobacco product that could be marketed as reduced risk would be a boon for the industry, as tobacco's perceived health risks and cigarette sales negatively correlate.[134] Requiring FDA to quickly promulgate threshold reduced-risk standards favors the industry,[135] especially Philip Morris, the tobacco company most heavily invested in reduced-risk products.[136]

Currently, however, three factors prevent Philip Morris from marketing a cigarette as a reduced-risk tobacco product: (1) making explicit, unproven health claims in advertising is prohibited by the Federal Trade Commission;[137] (2) making explicit health claims would expose Philip Morris to fraud liability;[138] and (3) consumers are skeptical of Big Tobacco claims.[139]

The high level of public distrust explains why Philip Morris needs FDA regulation as propounded in H.R. 1108 in order to successfully market reduced-risk or reduced-exposure products. By requiring the agency to establish reduced-risk standards within two years, the bill notifies the industry of a reduced-risk threshold.[140] Given an established threshold,

---

http://www.gallup.com/poll/3538/Americans-Agree-Philip-Morris-Smoking-Harmful.aspx.

133. *See Senate Hearing*, *supra* note 5, at 59 (prepared statement of Alan Blum, M.D.) (noting that increasing perception of smoking's perils decreases consumption).

134. *Id.*

135. The prospect of litigation may incentivize bargained rulemaking by FDA that would be accepted by tobacco companies. *See* von Eschenbach, *supra* note 26 (reciting H.R. 1108's "perverse incentive effects"); *see also supra* note 121 and accompanying text (describing FDA's response to industry and observing that FDA maneuvers around its conflicts).

136. *See* Anna Wilde Mathews & Vanessa O'Connell, *Philip Morris Gears Up for FDA Regulation: Using Science, It Tries to Prove Its Products Can Be Lower-Risk*, WALL ST. J., June 21, 2007, *available at* http://online.wsj.com/article_email/SB118235450194442081-lMyQjAxMDE3ODIyMTMyNTE0Wj.html (noting that Philip Morris's reduced-risk investment is larger than that of its peers).

137. *See* H.R. 1108, 110th Cong. § 2(45) (as introduced in the House of Representatives, Feb. 15, 2007) (incorporating Federal Trade Commission's (FTC) mission to protect consumers and regulate competition).

138. Implicit health claims, such as "light" and "low tar," have created litigation. *See, e.g.*, United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 852 (D.D.C. 2006) (holding Philip Morris liable for fraud for "distort[ing] the truth about low tar and light cigarettes"); Brown v. Brown & Williamson Tobacco Corp., 479 F.3d 383, 392–93 (5th Cir. 2007) (holding that state claims of consumer fraud relating to "light" cigarettes were preempted by FTC approval).

139. A recent Canadian study found that 79% of adults and 59% of youths believed that tobacco companies "rarely" or "never" told the truth. Bronwen J. Waller et al., *Youth Attitudes Towards Tobacco Control: A Preliminary Assessment*, 25 CHRONIC DISEASES CANADA 97, 98 tbl.1 (2004), *available at* http://www.phac-aspc.gc.ca/publicat/cdic-mcc/25-3/a_e.html. Perhaps illustrating this point, Philip Morris's latest attempt at marketing a "safer" cigarette has gone awry. *See* Vanessa O'Connell, *Altria Drops New Filter Cigarettes in Strategy Setback*, WALL ST. J., June 23, 2008, at B1 (describing the failed attempt to sell the Marlboro Ultra Smooth, a cigarette with a "high-technology" filter).

140. H.R. 1108 § 911(*l*)(1).

Philip Morris believes it can get its reduced-risk products approved and outperform the competition with a superior reduced-risk cigarette.[141]

This is not to say that Philip Morris would deceive FDA into approving pseudo-reduced-risk Marlboros.[142] However, H.R. 1108 mandates that FDA develop a reduced-risk standard within two years, and this timeframe would allow Philip Morris to tailor its nearly half-billion-dollar,[143] reduced-risk research-and-design operation accordingly.[144] Further, if the public knows that FDA has sanctioned a tobacco product as reduced risk, then suspicions of a Big Tobacco ploy would likely diminish.[145] Industry executives hope that the reduced-risk revolution will sustain an industry that—while currently still thriving—is ever on the decline.[146]

C. Reduced-Exposure Tobacco Products

In addition to requiring FDA to promulgate a reduced-risk-cigarette threshold within two years,[147] H.R. 1108 allows FDA to sanction cigarettes as "reduced exposure,"[148] a provision that has incensed health advocates.[149]

---

141. *See* Associated Press, *Philip Morris in Quest for Lower-Risk Tobacco Items*, L.A. TIMES, Oct. 29, 2007, at C2 (reporting Citigroup analyst Bonnie Herzog's claim that Philip Morris's reduced-risk innovation, which would put the company at "the head of the pack," prompted Philip Morris to seek FDA regulation).

142. Some public-health advocates applaud the development of reduced-risk tobacco products and argue that the bill, with its long-term epidemiological science requirements, makes it difficult (or as one advocate terms it "actually impossible") for reduced-risk cigarettes to be approved, and thus will (problematically) allow only for approval of reduced-exposure products. *Senate Hearing*, *supra* note 5, at 59, 164 (prepared statements of Alan Blum, M.D. and Michael Siegel, M.D.). While these public-health figures favor the development of reduced-risk cigarettes, which would be proven to lower overall disease incidence, they do not take into account H.R. 1108's two-year deadline for issuing reduced-risk standards.

143. The research-and-design facility itself cost $350 million, a figure that does not include the collateral expenses of the reduced-risk operation, which encompasses the salaries of an estimated 500 scientists, engineers, and support staff. Michael Felberbaum, *Philip Morris Opens New Research Center*, USATODAY.COM, Oct. 29, 2007, http://www.usatoday.com/money/economy/2007-10-28-3266642839_x.htm.

144. *See* Parrish, *supra* note 47, at 115 (declaring that FDA oversight is essential to guide manufacturers of reduced-risk and reduced-exposure products).

145. *See* McDaniel & Malone, *supra* note 2, at 194 (implying that consumers trust Philip Morris more after learning that the company supports FDA regulation; when consumers were informed that Philip Morris favors a federal regulatory regime, public disapproval of the company decreased from 50% to 35%).

146. *See* Anderson, *supra* note 130 (noting that tobacco use in the "developed world" has "waned for decades").

147. H.R. 1108, 110th Cong. § 911(*l*)(1) (as introduced in the House of Representatives, Feb. 15, 2007).

148. *Id.* § 911(g)(1).

149. *See Senate Hearing*, *supra* note 5, at 56 (statement of Alan Blum, M.D.) (exhibiting Dr. Blum's skepticism of the bill); *see also id.* at 164 (prepared statement of Michael Siegel, M.D.) (noting that the bill would "allow[] reduced exposure products to essentially be falsely marketed as reduced risk products (thus institutionalizing the very

In order to gain the reduced-risk moniker, H.R. 1108 requires tobacco products to be backed by epidemiological evidence demonstrating a significant reduction in incidents of tobacco-related disease—a fairly substantial evidentiary burden.[150] Alternatively, in order to gain the reduced-exposure moniker, H.R. 1108 only requires a demonstrated reduction in a certain *substance* found in a cigarette—whether the reduction actually decreases long-term disease incidence is irrelevant.[151]

For example, if a cigarette produced less cyanide than the average cigarette,[152] it could be branded as reduced exposure. This would be despite a lack of scientific evidence demonstrating that smokers of the cigarette would be at any less risk for developing disease than smokers of cigarettes with standard cyanide levels.[153] Disturbingly, however, consumers may easily conflate *reduced exposure* with *reduced risk*.[154] Even though there is no scientific proof that filtered cigarettes (which reduce exposure to toxic substances) are less harmful than unfiltered cigarettes, ninety-five percent of filtered-cigarette smokers believe they are ingesting a safer product.[155] Thus, reduced-exposure branding, like reduced-risk branding, may persuade the public that smoking is safer. Yet while empirical data would support the fact that reduced-risk cigarettes produce fewer incidents of disease,[156] reduced-exposure branding would only foster consumers' unscientific, unfounded inferences.[157]

III. A HARMED FOOD AND DRUG ADMINISTRATION

A. A Structurally Overwhelmed FDA

The current status of FDA is less than ideal. According to recent intra-agency assessments, FDA is not fulfilling its regulatory obligations and is

problem that the health organizations have expressed so much concern about)").

150. H.R. 1108 § 911(g)(1)(A).

151. *Id.* § 911(g)(2)(A)(ii).

152. *See Senate Hearing*, *supra* note 5, at 56 (statement of Alan Blum, M.D.) (explaining that H.R. 1108 has no mandate to eliminate cyanide gases from cigarettes).

153. *Id.*

154. *Id.* at 59 (statement of Alan Blum, M.D.); *see also* Richard J. O'Connor et al., *Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products*, 29 AM. J. PREVENTATIVE MED. 85, 85, 89 (2005) (finding that 25% of smokers who could name a cigarette brand that claims to reduce exposure to cigarette-smoke constituents believed that the products were less harmful—a belief in conflict with scientific evidence).

155. *Senate Hearing*, *supra* note 5, at 56 (testimony of Alan Blum, M.D.).

156. *See* H.R. 1108 § 911(g)(1)(A) (allowing approval of modified risk products if the applicant can demonstrate that the product significantly reduces the harm and risk of tobacco-related disease).

157. *See Senate Hearing*, *supra* note 5, at 58–59 (prepared statement of Alan Blum, M.D.) (explaining that consumers would believe reduced-exposure cigarettes decrease the risks of getting disease).

falling further behind each year.[158] The current FDA is underfunded, over-mandated, and in many ways ill-performing.[159] Congress has gradually entrusted more responsibilities to FDA since assigning its original duties in 1906.[160] But while the agency's list of administrative tasks has increasingly diversified,[161] expansions in responsibility have often come without a corresponding hike in agency appropriations.[162]

Although H.R. 1108 provides for additional agency funding, and even for user fees from the industry,[163] FDA leaders believe the funding is insufficient,[164] and general critiques of the user-fee system have found it rife with problems.[165] But while underfunding is merely a logistical dollars-and-cents issue solved by increased appropriations, H.R. 1108 would pose organizational challenges for FDA that exceed monetary shortfalls.[166]

While the FDA of the 1990s was willing to endure years of litigation to regulate on its own terms,[167] the present-day FDA does not want to regulate tobacco under H.R. 1108. Notably, Andrew von Eschenbach, FDA's

158. *See* Hutt, *supra* note 28, at 431 (noting that the author is a member of FDA's Science Review Subcommittee); *id.* at 432 (declaring that FDA is "an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates").

159. *Senate Hearing*, *supra* note 5, at 6 (opening statement of Sen. Enzi, Ranking Member, S. Comm. on Health, Education, Labor, and Pensions).

160. JOHN P. SWANN, HISTORY OF THE FDA, http://www.fda.gov/oc/history/historyoffda/default.htm.

161. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1767–68 (1996) (noting FDA's expanded duties, placing the agency in a gatekeeping position).

162. *See* Hutt, *supra* note 28, at 432 ("The FDA has become a paradigmatic example of the 'hollow government' syndrome—an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.").

163. H.R. 1108, 110th Cong. § 920 (as introduced in the House of Representatives, Feb. 15, 2007).

164. *See* von Eschenbach, *supra* note 26 (indicating that the projected FDA appropriations for 2008–2010 will be insufficient to implement H.R. 1108's complex program).

165. One critic claims the system has worsened FDA's low public confidence numbers and "should be abandoned." For a discussion of the "Destructive Impact of User Fees," see Hutt, *supra* note 28, at 452–54.

166. Commissioner von Eschenbach writes,

> By far, the most important and daunting challenge would be to develop the expertise necessary to carry out the functions called for by this bill. FDA does not have expertise regarding customarily marketed tobacco products and, therefore, would have to establish an entirely new program and hire new experts. Creating the appropriate organizational structure and hiring experts in the field of tobacco control and related sciences and other experts needed to staff the program at every level is considerably more challenging than simply filling identified vacancies in an existing program.

Von Eschenbach, *supra* note 26.

167. *See supra* notes 1, 13 and accompanying text (discussing litigation between the tobacco industry and FDA).

current Commissioner, publicly opposes the measure.[168] Although antiregulatory politics under the Bush Administration may have contributed to von Eschenbach's disapproval,[169] his concerns are valid, politics aside.[170]

A minority of the public-health community, skeptical of a historically deceptive company's motives, is fueling opposition to H.R. 1108.[171] One of the bill's most vocal critics claims that Philip Morris will support FDA regulation in principle and then impede substantive regulation in practice.[172] Indeed, a prominent supporter of H.R. 1108 has implied that successful FDA regulation depends on a cooperative tobacco industry.[173] Thus, if the industry behaves belligerently by aggressively challenging unfavorable rules, FDA's regulatory power would exist primarily on paper. Serving in a superficial role does not help FDA, and extended appeals would distract the troubled agency from its existing mandates.

FDA is already riddled with problems, and regulating tobacco would only exacerbate the agency's plight.[174] From criticism of the agency's preemption of state tort claims in the midst of regulatory failure[175] to allegations that FDA favors industry profits over public-health concerns,[176]

---

168. *See* von Eschenbach, *supra* note 26 (reasoning that regulating under H.R. 1108 would undermine FDA's public-health role).

169. *See* Noah, *supra* note 101, at 923–24 (noting that the Administration's preference for minimal regulation caused an "about-face" in FDA philosophy).

170. FDA is overmandated, underfunded, and ill-performing. Hutt, *supra* note 28, at 432. The tobacco industry has successfully "outwitted" government regulatory efforts for decades. *Senate Hearing*, *supra* note 5, at 87 (statement of Alan Blum, M.D.). H.R. 1108 has crucial compromises that were most likely lobbied-for by the tobacco industry. *See supra* notes 14–15 and accompanying text (describing Philip Morris's extensive lobbying efforts to promote legislation authorizing FDA regulation over the tobacco industry). Given such a confluence of undesirable circumstances, it is understandable that FDA does not want to regulate. Further, one legal scholar argues that FDA's recent spate of regulatory failures more likely resulted from "structural weaknesses and resource limitations" than from an antiregulatory political mindset. Vladeck, *supra* note 102, at 984; *see also id.* at 994–97 (describing FDA's regulatory failures). Thus, agency problems might transcend politics.

171. *See, e.g.*, *Senate Hearing*, *supra* note 5, at 56–58 (statement and prepared statement of Alan Blum, M.D.) (noting the industry's history of making implicit, untrue lowered-risk claims); *cf. id.* at 176 (memorandum of Joel L. Nitzkin, M.D.) (asserting that the proposed requirements under H.R. 1108 "strongly favor" Philip Morris, thus explaining its support of the bill).

172. *See id.* at 87 (testimony of Alan Blum, M.D.) ("[Philip Morris has] done wonders with any regulation. They have outwitted us.").

173. *See* Nocera, *supra* note 3 (relating Matthew Myers's opinion that FDA regulatory success may depend on Philip Morris's not obstructing meaningful rules).

174. *See id.* at 84–85 (testimony of Alan Blum, M.D.) (commenting on the absurdity of giving FDA authority over tobacco given the agency's recent failures). *Compare Senate Hearing*, *supra* note 5, at 176 (memorandum of Joel Nitzkin, M.D.) (noting that H.R. 1108 invites litigation), *with id.* at 32 (opening statement of Sen. Hatch) (expressing concern about giving the struggling agency more responsibilities with "maybe not enough finances to take care of it").

175. *E.g.*, Vladeck, *supra* note 102, at 994–97.

176. FDA's critics already cry industry capture, pointing out, for example, that the agency relies on science from experts with relationships with prescription drug

the agency faces attacks from multiple directions. Consumer confidence is at an all-time low, and public distrust of the agency has steadily risen.[177] An underperforming, underfunded FDA with flagging public confidence would not be prepared to battle a deep-pocketed company trying to make its way back to the top of the corporate ladder.[178]

For health advocates, supporting regulatory legislation alongside Philip Morris is a calculated risk.[179] Although initially skeptical of the company's motives, many prominent public-health advocates have resolved to support FDA regulation along with Philip Morris.[180] Their risk-taking is understandable. At worst, if FDA regulation fails, the public would likely commend health advocates for their efforts and blame the misfire on a too-powerful tobacco industry; at best, regulation could succeed if Philip Morris's corporate-speak of "tough but reasonable" regulation is genuine,[181] or if a courageous (and properly funded) FDA took on the industry.[182]

For FDA, though, the risks are more grave.[183] The risks include the headaches of organizational expansion,[184] coupled with the prospect of dealing with a well-funded, historically uncooperative industry[185] whose livelihood depends on selling cigarettes. Should H.R. 1108's regulatory approach fail, public-health advocates would likely change course and develop other tactics for battling the industry. For FDA, however, it could take decades to recover from such a high-profile, large-scale debacle.[186]

---

manufacturers. Cristina Rodríguez, *The FDA Preamble: A Backdoor to Federalization of Prescription Warning Labels?*, 41 J. MARSHALL L. REV. 161, 165 (2007).

177. *See* Hutt, *supra* note 28, at 442–43 (demonstrating that while FDA had a public-confidence rating of 80% in the 1970s, by 2006 it had slipped to 36%).

178. *See* Burritt, *supra* note 129 (describing Altria Group's marketing strategy); *see also* McDaniel & Malone, *supra* note 2, at 197 (positing that the tobacco industry supports FDA regulation to boost its public image).

179. *See* Nocera, *supra* note 3 (Matthew Myers explained that the real test of Philip Morris's commitment to regulation would come only after regulation begins).

180. *See Senate Hearing*, *supra* note 5, at 14 (prepared statement of Matthew Myers) (claiming that the bill has the support of every major public-health organization).

181. 2008 Philip Morris Policy Statement, *supra* note 86, at 32.

182. *But see supra* note 121 and accompanying text (demonstrating Sen. Coburn's doubt that the FDA bureaucracy will take aggressive action).

183. One FDA expert asserts the agency is at a "critical point in its history" and that the picture of FDA's future he gleans from recent assessments is "alarming." Vladeck, *supra* note 102, at 997, 999.

184. *See* von Eschenbach, *supra* note 26 (noting that "the most important and daunting challenge" would be to develop FDA expertise to implement H.R. 1108).

185. *See Senate Hearing*, *supra* note 5, at 57 (statement of Alan Blum, M.D.) (detailing the tobacco industry's history of circumventing regulation and of consumer deception).

186. When the FTC tried (and failed) to impose restrictions on the industry after the Surgeon General's 1964 warning, it took "decades" for the agency to recover. PBS, *Inside the Tobacco Deal*, FRONTLINE ONLINE, http://www.pbs.org/wgbh/pages/frontline/shows/settlement/interviews/myers.html (interview with Matthew Myers) (last visited Oct. 14, 2008). A similar failure for FDA could make an

B. Undermining FDA's Mission of Protecting the Public

FDA is responsible for protecting and advancing the public health.[187] The tobacco industry has a well-documented history of deception that has harmed the public health.[188] After public concern over the health hazards of cigarette smoking began to climb in the 1960s and 1970s,[189] cigarette manufacturers responded by marketing "light" and "low tar" cigarettes.[190] These initiatives were supported by massive advertising campaigns that attempted to mislead the public into believing that certain cigarette brands posed fewer health problems.[191]

Despite the industry's history of using lowered-risk health claims to persuade the public that cigarette smoking could be part of a healthy lifestyle, H.R. 1108 provides for the marketing of reduced-risk and reduced-exposure tobacco products.[192] While it is debatable whether a reduced-risk cigarette is possible (skeptics argue that smoking cessation is the only proven way to reduce harm),[193] the public-health community uniformly condemns approval of reduced-exposure cigarettes,[194] which would be unsupported by epidemiological evidence.[195]

Even conceding, *arguendo*, that a cigarette can pose a reduced risk, *forcing* FDA to issue standards for approving what would still be deadly products creates an ideological crisis.[196] Cigarette companies' survival

---

already hostile regulatory atmosphere worse, portending a bleak future for the agency. *See supra* note 102 and accompanying text (discussing increased judicial distrust of the agency).

187. Food & Drug Administration, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Oct. 14, 2008); *cf.* HUTT, MERRILL & GROSSMAN, *supra* note 49, at 5 (declaring that FDA's perpetual assignment has been to ensure the products it regulates are safe).

188. *See, e.g.*, United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 852 (D.D.C. 2006) (discussing Philip Morris's persistent attempts to deceive the public by concealing or distorting the health risks of cigarettes).

189. The Surgeon General issued the epochal warning in 1964 that smoking caused cancer and disease. *See* Parrish, *supra* note 47, at 111 (regretting that the tobacco industry publicly denied the conclusion and describing the "reservoir of public anger" emanating from the denial).

190. *Senate Hearing*, *supra* note 5, at 58 (prepared statement of Alan Blum, M.D.).

191. *Id.*

192. H.R. 1108, 110th Cong. § 911(h)(5) (as introduced in the House of Representatives, Feb. 15, 2007).

193. *See Statement on the Science of Reduced Risk Tobacco Products Before the H. Comm. on Government Reform* (2003) (statement of Scott J. Leischow, Ph.D., Chief, Dep't of Health & Human Services), *available at* http://www.hhs.gov/asl/testify/t030603a.html (declaring that "all tobacco products are hazardous . . . there is no safe level of tobacco use").

194. *See, e.g.*, *Senate Hearing*, *supra* note, at 59, 164 (listing health advocates' arguments that FDA should not be allowed to approve reduced-exposure products).

195. *See* H.R. 1108 § 911(g)(2)(A)(ii)–(iv) (permitting FDA approval of tobacco products without support from long-term epidemiological studies).

196. *See* von Eschenbach, *supra* note 26 (commenting that the bill makes the public-health-minded FDA regulate a product that causes disease even when "used as intended").

depends on maintaining smoking rates. The public health depends on reducing smoking rates.[197] Since reduced-risk-branded cigarettes would inform the public that the product had been made safer, it is likely that more people would smoke.[198] If more people smoke because of an FDA rule, then the agency would be complicit with the tobacco companies in harming the public health.[199]

RECOMMENDATIONS

Despite passing the House by a 326–102 vote,[200] the Family Smoking Prevention and Tobacco Control Act stalled in the Senate, and did not become valid law.[201] Again, while H.R. 1108 failed to pass, it is likely that nearly identical legislation will be introduced in the future.[202] Additionally, Philip Morris will continue lobbying for FDA regulation despite a changed political landscape—the Democratic assumption of congressional control has not deterred regulatory pursuits[203]—and the company's support will be

197. *See Senate Hearing*, *supra* note 5, at 159 (prepared statement of Anne Landman) (declaring "a healthy tobacco trade is antithetical to public health").

198. H.R. 1108 stipulates that FDA take into account "users and non-users" when approving reduced-risk products; namely, the proposal considers the probability that users would be less likely to quit smoking or that non-users would begin smoking. H.R. 1108 § 907(a)(3)(A)–(B). However, FDA decisions would be based in large part on tobacco-industry scientific data. *Id.* § 911(g)(3)(A). Furthermore, consumer perception of the products' dangerousness would not be measured until after approval in postmarket surveillance. *Id.* § 911(g)(2)(C)(ii).

199. *See Senate Hearing*, *supra* note 5, at 57 (statement of Alan Blum, M.D.) (opining that while currently only the tobacco companies commit consumer fraud, H.R. 1108 will necessarily implicate FDA in fraudulent behavior).

200. Rob Stein, *House Votes to Let FDA Regulate Tobacco Industry*, WASH. POST, July 31, 2008, at A2, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/07/30/AR2008073002674.html ("The White House has signaled that President Bush will veto the legislation if it is approved by the Senate, which may not have a veto-proof majority in support of it."). As illustrated by the vote margin, regulating tobacco is not a purely partisan issue. Persuading Republicans to support regulation that the party generally frowns upon has long been a goal of Philip Morris. *See* McDaniel & Malone, *supra* note 2, at 194–95 (observing that over a recent ten-year period the company donated $8.1 million to Republicans and developed lobbying tactics designed to appeal to the party's members).

201. *See* Govtrack.us, H.R. 1108 (110th Cong.), http://www.govtrack.us/congress/bill.xpd?bill=h110-1108 (explaining that the bill as H.R. 1108 is dead, but could be introduced in a future session of Congress under a different bill number).

202. *See* REDHEAD & BURROWS, *supra* note 6, summary (explaining that the Family Smoking Prevention and Tobacco Control Act was first introduced in the 108th Congress, and that the 110th Congress's H.R. 1108 was simply a reintroduction of that original bill). The FDA tobacco bills that have been introduced since the 107th Congress—and gained the support of both Philip Morris and the public-health community—have been either identical or very similar in content to each other and H.R. 1108. *Id.* at 19–20.

203. *See id.* at 20 (noting that H.R. 1108, introduced in February 2007 in a Democratic-majority House of Representatives, was "an attempt to balance the competing interests of

politically necessary for regulatory legislation to succeed.[204]

In a controversy with many unknown variables, one thing is certain: Philip Morris will not sign off on a suicide pact.[205] As the last eight years suggest, any bill that is supported by Philip Morris will be influenced by Philip Morris, which will result in compromises that harm FDA and allow the company to impede substantive regulation.[206]

Even without Philip Morris's influence, FDA regulation may not be desirable.[207] Rather than appropriating funds to the agency for tobacco industry regulation, Congress could spend the money on more effective means of reducing tobacco consumption.[208] For instance, California, the state that spends the largest amount of money combating cigarette smoking, has achieved a smoking rate of 13.5%, the second lowest in the country.[209] Federal action mirroring California's efforts could be similarly effective.[210]

Alternatively, as one Senator urges, Congress could directly pass the rules that health advocates hope FDA will promulgate.[211] Instead of

---

Philip Morris and leading anti-tobacco groups"). Further, Philip Morris issued a policy statement that advocated FDA regulation as of April 2008. 2008 Philip Morris Policy Statement, *supra* note 86. By April 2008, the company must have appreciated the possibility of a Democratic Congress and Democratic President beginning in 2009, as Gallup polls from that month had Barack Obama and John McCain in a statistical dead heat. *See* Lee Byron, Chris Barnes & Henry Corrigan-Gibbs, *Presidential Polls Over Time*, NYTIMES.COM, Nov. 2, 2008, http://elections.nytimes.com/2008/president/whos-ahead/polling/index.html.

204. *See* Saul, *supra* note 24 (proffering that legislation requires Philip Morris's support).

205. *See* Parrish, *supra* note 47, at 114 (conceding that any regulation must still allow his company to make profits, as it is an obligation the company has to its shareholders).

206. Senator Coburn offers his H.R. 1108 assessment: "We're going to shuffle this [bill] over and in 10 years, we're going to be back here talking about the same thing because Marlboro will be Marlboro tomorrow." *Senate Hearing*, *supra* note 5, at 83.

207. *See* Healton, *supra* note 98, at 98 (lamenting that "[i]t is very difficult to have enlightened public policy if the majority of our state legislators and federal legislators . . . are receiving tobacco industry donations").

208. Current tobacco-control theory focuses less on regulating the composition of cigarettes and more on reducing the harm to second-hand smoke recipients and "denormalizing" cigarette smoking. *Senate Hearing*, *supra* note 5, at 158 (prepared statement of Anne Landman).

209. *See* Heather Knight, *S.F. Pushes Legislation to Promote Good Health*, SFGATE.COM, Aug. 4, 2008, http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/08/04/MNBG122T4F.DTL (noting that the money is spent on massive statewide advertising, increased cigarette taxes, and limits on permissible smoking areas); Victoria Colliver, *Employers Ponder Tough Tactics to Halt Smoking*, SFGATE.COM, June 17, 2008, http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/06/16/BUKG11A2VO.DTL&tsp=1 (indicating that only Utah's smoking rate is lower than that of California).

210. *See, e.g.*, Healton, *supra* note 98, at 94 (explaining that the national "truth®" mass-media advertising campaign was crucial in slashing youth smoking by 22% in its first two years).

211. *See Senate Hearing*, *supra* note 5, at 83 (testimony of Sen. Coburn) ("[Health advocates are] going to trust an agency to do what we don't have the courage to do as a

involving the agency in the exacting task of regulating the tobacco industry, subject to the demanding notice-and-comment rulemaking process[212] and "searching" judicial review,[213] along with the attendant transition costs and redirection of FDA's mission,[214] Congress could make tobacco rules itself through legislation.

However, if FDA regulation is the means chosen to combat cigarette smoking and tobacco-related health problems, Congress must give broad regulatory authority to the agency. The bill cannot have compromises with the industry and certainly cannot contain a tobacco product standard that invites courtroom challenges, nor can it have a deadline that requires FDA to issue rules that might ultimately harm the public health. While reporters, industry competitors, and public-health advocates have tried to understand for years why Philip Morris supports FDA regulation, the answer is somewhat obvious: when legislation provides for tamed regulation, the agency is already captured.

Congress. . . . We don't have the courage to do what is really necessary.").

212. *See* STEVEN P. CROLEY, REGULATION AND PUBLIC INTERESTS: THE POSSIBILITY OF GOOD REGULATORY GOVERNMENT 184, 186–87 (2008) (noting that during the 1995–1996 FDA notice-and-comment rulemaking period concerning tobacco regulation, the agency received "seven hundred thousand pieces of written commentary" and that the tobacco industry submitted a "single 'comment' objecting to [FDA's] proposed rule that consisted of some two thousand pages of written commentary and another forty-seven thousand pages of supporting documents").

213. *See* Noah, *supra* note 101, at 904 (noting that the hassles of informal rulemaking, including judicial review, have led FDA to resort to "nonbinding guidelines").

214. *See* von Eschenbach, *supra* note 26 ("Associating the Agency with the approval of these inherently dangerous products would undermine the Agency's mission" and regulating tobacco would require an "entirely new program" from the ground up.).

> By far, the most important and daunting challenge would be to develop the expertise necessary to carry out the functions called for by this bill. FDA does not have expertise regarding customarily marketed tobacco products and, therefore, would have to establish an entirely new program and hire new experts. Creating the appropriate organizational structure and hiring experts in the field of tobacco control and related sciences and other experts needed to staff the program at every level is considerably more challenging than simply filling identified vacancies in an existing program.

Id.