

Book Review

Tobacco Unregulated: Why the FDA Failed, and What To Do Now

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A Question of Intent: A Great American Battle with a Deadly Industry. By David Kessler.* *New York: Public Affairs*, 2001. Pp. 492. \$27.50.

The book jacket promises drama. David Kessler, former Commissioner of the Food and Drug Administration (FDA), is said to tell “a gripping detective story,” a story of “right and wrong” and “moral courage.” The “unlikely heroes” are a small team of FDA employees who set out to battle the “lethal” tobacco industry. Kessler himself plays a role akin to James Stewart’s Mr. Smith.

This was real life, however, and the good guys did not win. Based on its investigations of the tobacco industry, the FDA answered the “question of intent”—whether tobacco manufacturers intended to produce nicotine’s drug-like addictive effects—positively. This finding meant, for the FDA, that tobacco was a drug, and that tobacco therefore fell within its jurisdiction. The Agency acted on its claimed authority to promulgate rules aimed at reducing the incidence of youth smoking. These rules, for example, restricted underage purchases, prohibited billboard advertising near schools, and banned all but text-only ads in print publications that

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reach the young.¹ The Supreme Court, however, taking the position that Congress did not intend to place tobacco within the Agency's jurisdiction, struck down the regulations.²

Of course, the FDA's battle, despite its ultimate failure to create a regulatory scheme for tobacco, was not wholly without effect. Its investigation brought to light information about the mechanisms manufacturers use to control the level of nicotine in their products. Industry documents obtained by the Agency showed plainly how tobacco products are designed to "deliver nicotine, a potent drug, with a variety of physiological effects."³ The Agency's evidence demonstrated, as the Supreme Court observed, "that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States."⁴ Collectively, the information produced through the FDA's investigation "changed popular thinking forever."⁵ The investigation also spurred a televised congressional hearing at which tobacco executives denied the addictive nature of cigarettes, a position that helped further to discredit the industry in the public mind.⁶ The Kessler-led effort, in short, has put tobacco reform on the public agenda in a way that promises continuing change.

Nevertheless, the fact remains that the FDA's regulatory effort failed. One aim of this Review is to explain why. I maintain that Kessler, perhaps driven by the sort of black-and-white dynamics that color the book jacket, sought too much. He claimed an essentially open-ended jurisdiction with unidentified aims. Had he argued for a more limited vision of the Agency's authority, one that, for example, confined itself to the youth smoking that was, in any case, the subject of the Agency's proposed regulations, the Supreme Court might have supported the Agency.

When he announced the regulatory effort, President Clinton stated that the "cigarette companies still have a right to market their product to adults. But today we are drawing the line on children."⁷ The restrictions promulgated by the FDA did indeed specifically target youth smoking. However, the FDA's jurisdictional claim, based on the addictive effects of

1. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,616-18 (1996).

2. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). Although this decision and the FDA rule dealt both with smokeless tobacco and with cigarettes, this Review often refers to cigarettes alone, since they were the principal product affected.

3. DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* 260 (2001) (citing a memorandum by Claude Teague, an R.J. Reynolds (RJR) executive) (internal quotations omitted).

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

5. KESSLER, *supra* note 3, at 383.

6. *Id.* at 170-74. Only Jim Johnston of RJR qualified his answer by observing that tobacco is not addictive because it does not intoxicate. *Id.* at 172.

7. Remarks Announcing the Final Rule To Protect Youth from Tobacco, 1996 PUB. PAPERS 1332, 1334 (Aug. 23).

nicotine in tobacco, was more sweeping. For Kessler, gaining jurisdiction “was far more important than” any rule, since any rule “was likely to be relatively modest, at least initially.”⁸ The implication of this and other comments⁹ is that Kessler intended for the FDA eventually to regulate adult smoking and quite possibly to reduce nicotine levels in cigarettes generally. The breadth of the FDA’s jurisdictional claim allowed the industry to raise the stakes of tobacco regulation to unacceptable levels. The industry argued that the Agency’s findings on the harmful effects of nicotine would necessitate an absolute ban on the sale of tobacco products, but that such a ban was not intended by Congress. Whether the FDA could ever have regulated adult use of tobacco products is debatable, but if the Agency wanted to leave the issue open it should have done so in a way that made further regulation subject to independent judicial review, by, for example, framing its initial jurisdictional assertions in a way that precluded the possibility of any de facto ban. By arguing for open-ended authority, Kessler ironically allowed the tobacco industry to inject its own question of intent, one that looked not to the minds of the manufacturers but to the thinking of congressional lawmakers.

The first two Parts of the Review elaborate this thesis. Part I summarizes Kessler’s account of the Agency’s decision to take on tobacco and its search for evidence to support its jurisdictional claims. The summary points out the discoveries that the FDA made and highlights the ways in which Kessler designed the FDA’s effort to regulate youth smoking as a sympathetic hook upon which to capture wide jurisdictional authority. Part II examines the Supreme Court decision that invalidated the FDA’s rule. The Court’s decision merits only brief mention in Kessler’s discussion, which dismisses it as a straightforward outcome of conflicting ideologies. Whatever the Justices’ motives, their opinions respond to basic questions about congressional intent and the scope of an agency’s delegated authority. My analysis of the Court’s opinion suggests that, given an agency’s ability to adapt its legal powers to new circumstances in light of the statutory purpose of its enacting legislation, the FDA’s youth-centered rule could have survived had the Agency argued for it on narrower jurisdictional grounds. In any case, the conflicting approaches expressed by the majority and the dissent regarding agency discretion, both generally and in the tobacco context, provide signposts for the FDA in determining its future role in the realm of tobacco regulation.

Part III considers directly the future of tobacco policy. Echoing the crusading chords of the book jacket, Kessler makes a stark proposal: He

8. KESSLER, *supra* note 3, at 269.

9. *E.g., id.* at 268 (remarking on conversations centered on “the possibility of reducing the level of nicotine in cigarettes over time, with an eye towards eventually weaning smokers from the addictive agent”).

suggests that tobacco companies “be spun off from their corporate parents” and transferred to a congressionally chartered corporation that satisfies the industry’s product liability obligations and sells tobacco in brown paper wrappers.¹⁰ If, as one tobacco lawyer suggested, the industry must now “obtain[] permission from society to continue to exist,” Kessler seems unwilling to grant such permission.¹¹ I argue that his approach is riddled by too many unknowns, and is also constitutionally problematic, since First Amendment protections of commercial speech ordinarily preclude a total restriction on product promotion.

Furthermore, the proposal ignores the advent of new types of risk-reduced tobacco products, “safer” cigarettes that may help those who cannot or will not quit smoking. A recent FDA-funded report by a committee of the Institute of Medicine (IOM) in the National Academy of Sciences found that these “reduced exposure” products could potentially be beneficial, if accompanied by an adequate regulatory scheme.¹² Philip Morris, which is developing a smokeless cigarette, has also issued a new position paper acknowledging the need for legislation authorizing limited FDA regulation of tobacco.¹³ In the remainder of Part III, I argue that the FDA should be given regulatory authority over reduced-risk products. Moreover, even if no new authority is granted, the Agency’s existing authority may by itself permit regulation. Although the Supreme Court rejected the FDA’s broad jurisdictional claim, the Court was dealing with tobacco products generally, not with products specifically intended to reduce risk.

I conclude by suggesting that tobacco companies should have an obligation, because of tobacco’s addictive nature, not only to reduce smokers’ risk but also to assist smokers who wish to quit. Most promising would be industry development and marketing of cigarettes containing progressively lower quantities of nicotine as part of a graduated program of cessation. Measures such as this would restore to tobacco users the choice of which addiction robs them.

10. *Id.* at 392.

11. *Id.* at 388 (quoting Steve Parrish, General Counsel, Philip Morris).

12. IOM REPORT, *supra* note †, at 6.

13. Press Release, Philip Morris, FDA & Tobacco: Why Philip Morris U.S.A. Supports Passage of Legislation in the 107th Congress Granting FDA Regulatory Authority over Tobacco Products (Mar. 22, 2001), http://www.philipmorrisusa.com/company_news/company_news.asp?press_id=76; see *infra* Subsection III.D.2.

I. THE FDA'S BASIS FOR REGULATION

A. *Taking On Tobacco*

Kessler claims that he did not come to the FDA with the intent to regulate smoking. The goal originated, rather, in a staff suggestion that the FDA “take on tobacco.”¹⁴ A petition from the Coalition on Smoking and Health (the Coalition) that asked for FDA regulation of tobacco provided further impetus. In an Agency letter responding to the petition, Kessler opened the door to regulation by indicating that some evidence “‘suggest[ed] that vendors intend the obvious—that many people buy cigarettes to satisfy their nicotine addiction.’”¹⁵ The letter noted that if the FDA compiled an adequate record, “‘it would have a legal basis’” to regulate tobacco products as drugs.¹⁶ Kessler believed that this letter would force Congress’s hand, compelling it to decide what the FDA should do either by supporting the Agency or by stopping it.¹⁷

However, when Congressman Waxman, a former smoker, learned of the letter, he insisted on a prompt hearing at which the FDA would set out the case for regulation.¹⁸ Waxman’s response placed upon the FDA the burden of building support for a controversial regulatory initiative. Kessler had not anticipated this demand and was surprised by its short time frame. Subsequent events further complicated Kessler’s task. One of the most important sources that the FDA had relied upon in its letter was an informant, “Deep Cough,” who, soon after talking with the Agency, appeared on a *Day One* television broadcast on ABC-TV, accusing tobacco companies of “fortifying” their products through the addition of nicotine.¹⁹ When Philip Morris sued the station for libel, ABC-TV apologized and settled.²⁰ This blow to the fortification theory was important, since the deliberate addition of an addictive substance would have made the case for manufacturer intent much more straightforward. Instead, Kessler was forced to launch an intensive effort to gather additional evidence showing that manufacturers intended that tobacco function as a drug.

14. Kessler identifies Jeff Nesbit, a former aide of Dan Quayle, as the one who first suggested that Kessler “take on” tobacco. KESSLER, *supra* note 3, at 26.

15. *Id.* at 87 (quoting the letter).

16. *Id.*

17. *Id.* at 88. The FDA also alerted the *New York Times* and the *Washington Post* to the letter. The *Times* responded with a front page story, and the *Post* with an inside story. *Id.* at 94. Sidney Wolfe, director of Public Citizen’s Health Research Group, privately urged Kessler to deny the Coalition’s petition. Arguably, Wolfe believed that legislation was a more promising route than regulation, and therefore wished to see the Coalition directing its efforts toward Congress. *Id.* at 51.

18. *Id.* at 97-98.

19. *Id.* at 104.

20. *Id.* at 104-05, 156, 375.

The FDA's investigation of cigarette production and distribution processes occupies a large portion of Kessler's narrative. This is the book jacket's "gripping detective story," a story marked, in the words of the text, by "cloak-and-dagger" elements.²¹ Although the details of the investigation are not relevant for the purposes of this Review, the manner in which the Agency conducted the investigation is nevertheless noteworthy, because it demonstrates the difficulties involved in acquiring information about the tobacco industry, and thus points to the continuing need for adequate regulatory authority. Kessler hired staff with backgrounds very different from the traditional FDA inspector's.²² The new recruits had experience in the FBI and Secret Service, and could administer polygraph tests. The FDA assigned code names to informants in order to protect their identities.²³ These informants required such protection because, having signed confidentiality agreements with their employers, they feared lawsuits and more extreme consequences should their breaches come to light.²⁴ The Agency maintained that the duty of confidentiality under employee confidentiality agreements did not extend to law enforcement investigations, and successfully resisted attempts by the industry to force disclosure of the informants' identities.²⁵

Commissioner Kessler maintained an active and personal involvement with the investigation. He listened in via speakerphone to a telephone conversation in which Agency officials questioned informants,²⁶ and participated in other telephone interviews.²⁷ With one informant, Jeffrey Wigand, he met personally.²⁸ Kessler's intense involvement with the project extended beyond the investigation stage. When the regulatory and legal staff were drafting the justification for the FDA proposal, he acted the role, as he puts it, of a "research assistant."²⁹ He "almost camped out" at the warehouse where the FDA reviewed the comments on the proposed rule.³⁰ These somewhat unorthodox efforts by the FDA and its Commissioner

21. *Id.* at 184 (noting that when Kessler met with informant Jeffrey Wigand, Kessler's calendar did not reveal Wigand's name); *see also id.* at 134-35 (describing how FDA investigators met an informant in a public place, where he requested placement in a witness protection program).

22. *See id.* at 26, 75, 79, 81, 100, 233, 406.

23. The code names for informants included "Deep Cough," *id.* at 128-29, "Veritas," *id.* at 174, "Research," *id.* at 183, "Cigarette," *id.* at 115, "Saint," *id.* at 237-38, and "Philip," *id.* at 115. For the views of "Philip" on ways to reduce risk, see John Schwartz, *Reengineering the Cigarette*, WASH. POST MAG., Jan. 31, 1999, at 8.

24. KESSLER, *supra* note 3, at 134-35 (stating that company lawyers promised a "living hell" to one informant if he violated the agreement).

25. *Id.* at 223, 290.

26. *Id.* at 138-39.

27. *Id.* at 116-17.

28. *Id.* at 183-90.

29. *Id.* at 271.

30. *Id.* at 337.

enabled them to assemble a large body of evidence concerning the manufacture and distribution of tobacco products. The next Section describes this evidence and the legal theory that this evidence was designed to support.

B. Establishing Intent Without Express Claims

To assert regulatory authority over tobacco, the FDA had to prove that tobacco met the statutory definition of a drug: an article “intended” to prevent or treat disease, or “intended to affect the structure or any function of the body.”³¹ Such intent is ordinarily established by express claims attributable to the manufacturer in the product’s labeling, in advertising, or in other relevant materials.³²

But such direct expressions are not the only means for establishing intent. A finding of intent can also rest upon external factors, the most important of which is consumer use.³³ On the consumer use approach, a substance satisfies the intent requirement as long as consumers use the substance as a drug, and manufacturers can reasonably foresee that consumers will use the substance with this intent. The FDA has, however, found difficulty adequately establishing consumer use in practice.³⁴ The FDA’s first tangle with tobacco, in response to a 1977 citizens’ petition that urged the FDA to regulate cigarettes as drugs, marginalized the consumer use approach. The Agency rejected the petition, citing the lack of any express claims by manufacturers that tobacco affected the body. The D.C. Circuit upheld the Agency’s decision on review, but read it as leaving open the possibility that intent could be established through consumer use, even in the absence of express claims by the manufacturer. The court set, however, a very high threshold: Consumer use needed to occur “predominantly and in fact nearly exclusively with the appropriate intent.”³⁵ Furthermore, the FDA had historically accepted that consumers

31. 21 U.S.C. § 321(g)(1) (1994).

32. *See, e.g.,* *Kordel v. United States*, 335 U.S. 345 (1948) (ruling that manufacturer intent can be demonstrated by pamphlets authorized by the manufacturer for purchasers); *United States v. Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (describing other relevant sources of manufacturer intent); *Alberty Food Prods. v. United States*, 194 F.2d 463 (9th Cir. 1952) (same).

33. Judge Friendly, for example, in a case that considered whether certain vitamin and mineral supplements should be classified as drugs, found that the FDA was not bound by a manufacturer’s subjective claims but could also make use of such “objective evidence” as consumer use. *Nat’l Nutritional Foods Ass’n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974). Therapeutic use, however, had to “far outweigh[]” other uses in order to count as objective evidence for drug classification. *Nat’l Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325, 336 (2d Cir. 1977).

34. *Mathews*, 557 F.2d at 337-38.

35. *Action on Smoking & Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980).

smoke tobacco merely for “pleasure,” and thus that mere smoking provides in itself a negative answer to the question of intent.³⁶

Under Kessler’s direction, the FDA reopened the consumer use approach. Concerned no doubt by the need to have a strong showing in order to infer manufacturer intent in the absence of express manufacturer claims, the FDA, in spite of the fast pace of its investigation, managed to assemble an impressive record in support of its jurisdictional claim. The Agency identified numerous scientific studies that indicated that tobacco does not merely provide “smoking pleasure,” but also affects the body and brain in ways that cause and sustain addiction.³⁷ The FDA took the position that, since a reasonable manufacturer would realize that tobacco’s addictive properties motivated consumer use at least in part, these studies went to the question of intent.³⁸ The Agency supported this argument with internal industry documents that indicated that the manufacturers understood tobacco’s addictive effects, and with evidence that suggested that the industry took account of these effects in designing their products.³⁹

The FDA relied especially heavily upon a collection of Brown & Williamson (B&W) internal documents that had been “pilfered” by Merrell Williams, a paralegal working for a product liability law firm representing the company.⁴⁰ Williams had sought to use the papers in his own personal injury suit against the company for heart problems, but was restricted by a gag order because his copying of the papers violated the attorney-client privilege. The *New York Times* obtained these documents from a congressional source to whom they were leaked and published a story based on them. The FDA accessed the documents through the same congressional source.⁴¹ Their significance in the FDA’s evidentiary position is illustrated by a quote from one of the documents, a memorandum by Addison

36. KESSLER, *supra* note 3, at 51 (citing William K. Hubbard, Associate Commissioner for Policy Coordination, FDA).

37. Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,620, 44,690-739 (Aug. 28, 1996) [hereinafter Jurisdictional Statement]; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 127 (2000).

38. Jurisdictional Statement, *supra* note 37, at 44,632-36.

39. *Id.* at 44,687.

40. KESSLER, *supra* note 3, at 251.

41. *Id.* at 252-54. The subsequent fate of these documents, although not discussed by Kessler, is of some interest. See STANTON A. GLANTZ ET AL., *THE CIGARETTE PAPERS* 6-11 (1996), for a description of B&W’s unsuccessful efforts to use subpoenas to discover the source of the leaks and to prevent their public release. Glantz, who received the papers unsolicited in the mail at his office at the University of California, San Francisco, later made them available, after litigation, at the University Library, and on the Internet at the Library’s website. His book is an analysis of the papers. See also Tucker S. Player, Note, *After the Fall: The Cigarette Papers, the Global Settlement, and the Future of Tobacco Litigation*, 49 S.C. L. REV. 311, 322-32 (1998) (describing the events leading to the release of the papers).

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Yeaman, the company's general counsel in 1963: "We are, then, in the business of selling nicotine, an addictive drug"⁴²

RJR internal documents, at one point under court seal in a product liability case, also demonstrated an awareness of nicotine's addictive nature and of the role that addiction plays in consumer use. Most significant was a memorandum by Claude Teague, an RJR executive, that stated:

"Nicotine is known to be a habit-forming alkaloid. . . .

Thus, a tobacco product is, in essence, a vehicle for delivery of nicotine. . . .

. . . .

If . . . nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business. . . .

Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects."⁴³

The FDA, to obtain the RJR documents, took advantage of a friendly relationship between an FDA staffer and a team of product liability lawyers.⁴⁴ Although the role of product liability litigation in uncovering information is beyond the scope of this Review,⁴⁵ it is worth observing the symbiotic relationship between the Agency investigation and litigation efforts. Kessler met with Mike Moore, the Mississippi Attorney General, and Dick Scruggs, the private attorney who handled the state's lawsuit against the tobacco companies to recover for smoking-related Medicaid costs. The FDA's activities "encouraged them" in their suits, and Kessler found that they were "becoming allies in [their] related battles."⁴⁶

42. KESSLER, *supra* note 3, at 252.

43. *Id.* at 259-60 (quoting Teague's memorandum). The Teague memo was cited in the Jurisdictional Statement, *supra* note 37, at 44,867-71. The FDA relied also upon internal memoranda of Philip Morris that the Agency found in an obscure archive in Houston. These memoranda described research on the pharmacological effects of nicotine. KESSLER, *supra* note 3, at 256.

44. KESSLER, *supra* note 3, at 258.

45. See PETER PRINGLE, CORNERED: BIG TOBACCO AT THE BAR OF JUSTICE 270-71 (1998) (describing the discovery, in the course of tort litigation, of documents that indicated that the industry had concealed health information from juries and thereby affected their decisions); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2069-70 (2000) (observing that discovery in tort litigation can serve an educational role by uncovering documents about concealed health risks in regulated and unregulated industries).

46. KESSLER, *supra* note 3, at 304.

The Agency uncovered evidence that the industry not only was aware of nicotine's addictive effect, but also took advantage of this fact in designing its cigarettes. Kessler was concerned that the nicotine levels in tobacco products might be "simply natural products" of plant biology.⁴⁷ This would have made it much more difficult for the Agency to show that manufacturers intended nicotine's addictive effects. As a result of its investigation, the FDA in fact found that different types of tobacco contained different proportions of nicotine and that the manufacturers could control nicotine levels in their products through blending.⁴⁸ An Agency laboratory also determined that nicotine levels within a brand possessed a uniformity similar to that found in drugs, and inconsistent with the variability associated with agricultural products.⁴⁹ Tobacco industry representatives maintained that nicotine in tobacco occurs in an inviolate 1:15 ratio of nicotine to tar and cited this constancy as evidence that the company did not manipulate nicotine levels.⁵⁰ However, the FDA discovered that the ratio of nicotine to tar in the Merit cigarette, the lowest-tar cigarette, was 1:10,⁵¹ and that within the Merit family of cigarettes, concentrations of nicotine and tar varied inversely.⁵² In its rulemaking proceeding, the FDA explained the pattern of increased nicotine in low-tar cigarettes as a consequence of the fact that nicotine levels satisfy users only until they fall below 0.5 to 0.8 mg per cigarette. When progressive tar reductions in low tar cigarettes had reduced the nicotine ratio below this level, the manufacturers took steps to boost nicotine concentrations to pharmacologically active levels.⁵³

In support of its rule, the FDA also identified specific methods used by manufacturers artificially to enhance the impact of nicotine.⁵⁴ Kessler had received from an unidentified source B&W's confidential *Handbook for Leaf Blenders*, which stated that ammonia, when added to tobacco,

47. *Id.* at 118. Uniformity can be sought in agricultural products, as indicated by ERIC SCHLOSSER, *FAST FOOD NATION* 131 (2001), which explains that sugar is added or leached out of McDonald's french fries in order to maintain a uniform taste and appearance.

48. KESSLER, *supra* note 3, at 148-49. See Jurisdictional Statement, *supra* note 37, at 44,950-94, and *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 127 (2000), for a full description of the information on which the FDA relied to show that manufacturers designed cigarettes to provide pharmacologically active doses of nicotine to consumers. See KESSLER, *supra* note 3, at 63, for the analysis of David Adams, an FDA attorney: "Cigarette manufacturers can take the nicotine out, but they leave it in. That goes to the question of intent."

49. KESSLER, *supra* note 3, at 132.

50. *Id.* at 143-44, 152-53.

51. *Id.* at 147.

52. *Id.* at 152; see also Jurisdictional Statement, *supra* note 37, at 45,067-75 (noting the Agency's grounds for contesting the industry's position on the tar-to-nicotine ratio).

53. Jurisdictional Statement, *supra* note 37, at 45,068-69.

54. See *id.* at 45,076-82, 44,970-75. In its rulemaking process, the FDA placed in a confidential docket the material that reflected trade secret processing methods. The Agency rejected comments from the industry that the confidential nature of the material precluded the opportunity to comment on the record. *Id.* at 45,279-88.

“‘liberate[s] free nicotine’”⁵⁵ and thus produces a smoke richer in nicotine.⁵⁶ The FDA also went to considerable lengths to document instances of genetic manipulation of nicotine levels, though ultimately the Agency discovered only one such instance, B&W’s cultivation of a genetically modified high nicotine plant, Y-1, in South America. The project was still in its experimental stages, although some of the genetically modified tobacco had already been used in cigarettes sold in the United States.⁵⁷

The FDA’s efforts tended to show that the cigarette is not simply a repackaged tobacco plant. It is a device designed to deliver controlled amounts of nicotine to the body. Together with the compelling evidence for the claim that nicotine in tobacco had foreseeably addictive effects, the implication of this conclusion was that manufacturers intended nicotine’s addictive effect, and that cigarettes were a combination drug and device subject to the jurisdiction of the FDA.

C. The FDA’s “Kids-Only Rule”

The FDA directed its regulatory efforts against youth smoking, though on its reasoning, the Agency’s jurisdiction was far broader. The proposed rule restricted the accessibility, promotion, and labeling of tobacco products to the young. Access regulations, among other things, prohibited the sale of cigarettes to those under eighteen, required retailers to verify the age of all purchasers younger than twenty-seven through the use of photo identification, and limited the presence of vending machines to adult-only locations. Promotional regulations required text-only, black-and-white advertisements in print publications having other than an almost exclusively

55. KESSLER, *supra* note 3, at 188 (quoting B&W’s *Handbook for Leaf Blenders*).

56. *Id.* at 188-89, 246. While the tobacco companies admit to the use of ammonia in tobacco processing, they, and in particular Philip Morris, maintain that the chemical’s function is not to intensify addiction but to enhance flavor. In any case, the potential health risk associated with additives provides an illustration of the need for regulatory authority to conduct a toxicological review of tobacco ingredients. See IOM REPORT, *supra* note †, at 224-25.

57. KESSLER, *supra* note 3, at 194-96, 214-25, 239-44. There is an irony in Kessler’s advocacy for the position that genetic modification of tobacco is an indication of artificial manipulation of the product. Kessler was FDA Commissioner when the Agency took the position that genetically modified foods could be presumed to be the same, and as safe, as their traditional counterparts, a finding that made premarket approval for safety as a food additive unnecessary. See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992); see also *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000) (upholding the Statement of Policy against procedural and substantive challenges). The FDA policy recognized that genetic modification could in some cases raise constituents to abnormally high levels and trigger regulatory concern, see Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990; the genetic modification of tobacco provides a striking instance of this possibility. The Agency has since proposed a rule to mandate notice of new bioengineered foods. See *Premarket Notice Concerning Bioengineered Foods*, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

adult readership, prohibited outdoor billboard advertising within 1000 feet of schools or playgrounds, and precluded brand name promotion at sporting events. Labeling rules required a statement that cigarettes were a nicotine-delivery device intended for those eighteen or older.⁵⁸ The youth-centered thrust of these restrictions derived from Kessler's position that tobacco use was principally a pediatric disease. He emphasized the fact that most smokers become regular users before eighteen, and that one who did not smoke as an adolescent was unlikely to begin later.⁵⁹ In his view, long-term reduction of tobacco addiction could occur only by preventing children and adolescents from starting to use tobacco.

The FDA's rule did not treat adult smoking. Nor did it attempt to mandate nicotine concentration, even though manipulation of nicotine concentration constituted an important part of the Agency's jurisdictional argument. However, the book does indicate that had the FDA's rule survived judicial scrutiny, the Agency would have considered additional restrictions going beyond teen smoking. Kessler and the FDA staff had discussed the possibility of "reducing the level of nicotine in cigarettes over time, with an eye toward eventually weaning smokers from the addictive agent."⁶⁰ When Kessler first testified before Congress in 1994 about the FDA initiative, he observed likewise that the FDA might use its regulatory power eventually to bring about "the possible removal of nicotine-containing cigarettes from the market, the limiting of the amount of nicotine in cigarettes to levels that are not addictive, or restricting access to them, unless the industry could show that nicotine-containing cigarettes are safe and effective."⁶¹

By restricting the scope of the regulations to children, however, the FDA greatly enhanced their political attractiveness. President Clinton's consultant, Dick Morris, saw the rule as an opportunity for the President to steal momentum from the Republican Congress and to boost his reelection

58. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 127-30 (2000); Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,616-18 (1996).

59. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 127-28; KESSLER, *supra* note 3, at 319-20 (describing his speech at Columbia Law School on the subject of tobacco use as pediatric disease).

60. KESSLER, *supra* note 3, at 268. Kessler notes that he considered the possibility of the weaning strategy, but set the matter aside because he was not convinced that there was adequate scientific understanding of the strategy's effectiveness. *Id.* This suggests that, if it had the right support, the FDA would have been willing to use its jurisdiction to mandate permissible nicotine levels.

61. *Id.* at 161. The broader ambitions of the FDA's regulatory effort are discernable, too, in Kessler's recommendation that Congress reject the global tobacco settlement that was submitted to it for approval, even though the settlement provided for industry acceptance of many provisions of the FDA's rule. Kessler was concerned about the tort immunity that the settlement provided and for the restrictions it would impose on the FDA's authority over tobacco. *Id.* at 361.

prospects.⁶² Morris, after conducting polls, confirmed that the only viable regulatory route was a kids-only rule; a broader crusade that touched adult use might be “political suicide.”⁶³ In the end, Clinton gave his support to the Agency’s rulemaking effort, and announced from the White House that the FDA would issue proposed and final rules regulating tobacco.⁶⁴ In his announcement, he described the rules as aimed at youth smoking and made clear that they did not address sale to adults.⁶⁵ With the rules having survived executive oversight, the battle over the FDA’s jurisdictional authority to regulate tobacco shifted to the courts.

II. THE SUPREME COURT AND CONGRESSIONAL INTENT

A. *Kessler’s Assessment*

The book mainly addresses the development of the Agency’s regulations, and deals but briefly with the litigation that tested these regulations and ultimately found them wanting. In the cursory analysis that Kessler offers of the Supreme Court decision that invalidated the rule, *FDA v. Brown & Williamson Tobacco Corp.*,⁶⁶ he focuses on the oral arguments, which he attended, and refers only in passing to the reasoning offered by the Justices in their opinions.⁶⁷ Kessler says he knew the Agency had lost from the questions the Justices asked at oral arguments, since these questions suggested that they did not understand the strength and significance of the evidence that the Agency had found to show the manufacturers intended to utilize nicotine’s addictive effects in a way that brought cigarettes within the legal definition of a drug.⁶⁸ He attributes the loss to the majority’s attitude toward regulation, and more generally to its ideology.⁶⁹ Judicial decisions of course reflect the judge’s philosophy. But this was a hard case, and one that involved fundamental questions about the determination of congressional intent and the ability of agencies to adapt

62. *Id.* at 304-05. Other members of the President’s staff felt that tobacco was too dangerous an issue on which to take a strong stand during the reelection campaign, and argued, instead, that tobacco regulation should wait until the President’s second term. *Id.* at 305-06.

63. *Id.* at 322-23.

64. *Id.* at 333, 353-54.

65. See *supra* note 7 and accompanying text; see also Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965, 965-66, 984 (1997) (criticizing the personal role taken by Clinton in announcing agency regulatory decisions such as the tobacco regulation, insofar as such announcements suggested that he, rather than the agency, was authorized to issue the rule).

66. 529 U.S. 120 (2000).

67. Five pages discuss oral arguments, KESSLER, *supra* note 3, at 379-83, and less than one page the decision, *id.* at 384. Kessler devotes even less space to the proceedings in the district court (three pages to oral arguments, and one half-page to the decision), *id.* at 355-58, and the court of appeals (four pages to the oral arguments, one paragraph to the decision), *id.* at 361-66.

68. *Id.* at 381-83.

69. *Id.* at 384.

their congressional mandates to new circumstances and policies. The decision also merits close analysis because it is the starting point in determining the remaining scope of the Agency's regulatory authority over tobacco.

B. *Manufacturers' Intent Not Addressed*

Justice O'Connor, writing for the majority, pointedly did not rely on the tobacco industry's argument that, no matter how foreseeable a product's effects, and no matter how strong the circumstantial evidence of intent, the product could not fall under the statutory definition of a drug absent express claims of drug-like function by the manufacturer. The Court found that it did not need to address this claim, since, even if the FDA's theory of intent was correct, its rule failed on other grounds.⁷⁰ Thus, the FDA's revival of a broad approach toward manufacturers' intent, integrating foreseeable consumer use with evidence of manufacturer knowledge, was not invalidated, and may find application in contexts other than tobacco.⁷¹ The Agency's broad reading of intent gains additional support from the Court's tendency, in recent years, to utilize dictionaries in order to identify the meaning of a text.⁷² The dictionary here favors the FDA, defining intention so that it encompasses "'hav[ing] in mind'" and "'design[ing] for a particular purpose.'" ⁷³

C. *Congressional Intent and Its Consequences*

In the end, the crucial issue for the Court was not manufacturer intent but congressional intent: Was the FDA's rule consistent with congressional intent as manifested in the Agency's jurisdictional statute and in the

70. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 131-32.

71. A broader theory of intent may, for example, enable the FDA to regulate a manufacturer's distribution to physicians of medical journal reprints that describe new "off-label" uses. See Richard M. Cooper, *The WLF Case Thus Far: Not with a Bang but a Whimper*, 55 FOOD & DRUG L.J. 477 (2000) (criticizing such a theory). While the Supreme Court's decision merely failed to invalidate the FDA's theory of intent, the district court at least in part endorsed that theory. The court upheld the Agency's jurisdiction on the basis of the foreseeability of tobacco's drug-like effects and of the role of such effects in consumer use, but it found that the statements of executives in internal documents did not provide a sufficient "objective" basis for establishing intent. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1391-92 (M.D.N.C. 1997), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000).

72. Note, *Looking It Up: Dictionaries and Statutory Interpretation*, 107 HARV. L. REV. 1437 (1994).

73. *Brown & Williamson Tobacco Corp.*, 153 F.3d at 177-78 (Hall, J., dissenting) (quoting WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984)); see also Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013 (1998) (noting that the FDA's theory of intent has strong textual support).

statutory regime surrounding tobacco? The starting point for statutory interpretation in the context of administrative agencies is *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,⁷⁴ whose two-stage test first asks whether Congress has directly spoken to the question at hand, and then defers to the agency on matters where Congress is silent or ambiguous.⁷⁵ My discussion, patterning itself roughly after the *Chevron* test, divides into two parts. First, I analyze the Justices' various treatments of congressional intent and their consequences in the tobacco context. Then, I examine more generally the issue of agency delegation: Under what circumstances should courts assume that an agency has been given discretion by Congress to adapt a statute in the face of new circumstances?

1. *The Statutory Framework*

The Court, surveying the FDA's statutory mandate and various federal laws respecting tobacco, offered an argument almost formalistic in its simplicity: If the FDA obtained jurisdiction over tobacco, the Agency's statutory framework would force the FDA to ban the product altogether. However, tobacco-specific statutes enacted by Congress subsequent to the Agency's enabling legislation indicated clearly that it did not intend such a ban.⁷⁶ To flesh out this argument: The Agency's rule rested its restrictions concerning tobacco use by youths on its determination that "there [could not] otherwise be reasonable assurance of [tobacco's] safety and effectiveness."⁷⁷ The Court reasoned that, given the FDA's conclusions about the danger of tobacco, the Agency, were it to acquire jurisdiction over tobacco, would have to classify tobacco products as "Class III" devices. Class III devices cannot be sold unless they have been demonstrated "safe" under the conditions of intended use.⁷⁸ Since tobacco products were, on the FDA's logic, unsafe under the conditions of intended use, the Agency could do nothing but ban them.

The FDA argued that, since a ban would create "a black market [that was] even more dangerous,"⁷⁹ the Agency could utilize less drastic regulatory means. Justice O'Connor acknowledged that the FDA regularly

74. 467 U.S. 837 (1984).

75. *Id.* at 842-43.

76. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 134-43. The Court argued separately that, irrespective of the FDA's ability to fashion some remedy other than an outright ban, various statutes indicated that Congress intended to reserve tobacco regulation to itself. *Id.* at 143-59. I do not examine this claim separately, although I incorporate parts of the Court's reasoning into the analysis of the above argument.

77. 21 U.S.C. § 360j(e)(1)(B) (1994).

78. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 136 (citing 21 U.S.C. § 360e(d)(2)(A)). For a similar analysis, see Richard A. Merrill, *The FDA May Not Regulate Tobacco Products as "Drugs" or as "Medical Devices,"* 47 DUKE L.J. 1071, 1075 (1998).

79. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 139.

evaluates drugs on a relative basis, approving them when they produce more benefit than harm. The Agency conducts this sort of risk-benefit analysis, for example, in the case of toxic drugs used to treat cancer.⁸⁰ The majority did not, however, consider this analogy applicable to a product like tobacco that lacked any therapeutic or pharmacological benefit. The FDA could not take cognizance of a benefit that arose not from the intended use of the drug itself but from the failure to proscribe its intended harmful use. The black market approach was problematic because it relied upon the “implausible” notion that “continued use” of tobacco was a “benefit,” and thus that “the very evil [the FDA sought] to combat was a ‘benefit to health.’”⁸¹ Justice Breyer, in dissent, defended the FDA’s reasoning, arguing that the Agency’s safety determination could not occur in isolation, merely in terms of the risks created by use of the product, but also had to take into account the risks associated with a ban, such as patronage of more dangerous alternatives.⁸² On his reading, the Agency’s jurisdictional statute could be read to leave the FDA with remedial discretion in regulating even a Class III device, so long as the selected measure provided “‘reasonable assurance of . . . safety.’”⁸³

Food and drug law precedent seems to favor O’Connor’s position in this debate. Under the regulatory framework for a drug, the FDA has traditionally been concerned with intended uses, and has been found to be without authority to address other uses. Thus, for example, so long as methadone remained safe for its intended function in heroin detoxification, the FDA was unable to impose restrictions directed toward potential misuse, even on the theory that misuse was foreseeable.⁸⁴ And while the Agency has developed alternative theories that may reach drug misuse,⁸⁵ the black market argument is different from and tougher to make than a misuse argument. In the case of misuse, the drug under consideration directly causes harm. In the black market scenario, the drug under consideration causes no harm, and indeed is not used at all; some other drug causes the harm. Moreover, insofar as black market harm assumes nonuse of the drug under consideration, it is impossible to say that the drug’s manufacturer intends such harm.

The black market rationale is problematic, too, because it provides the public an unprecedented role in determining the scope of drug regulation. If the FDA must take into account the fact that consumers may resist a ban by

80. *Id.* at 142.

81. *Id.* at 141.

82. *Id.* at 178-79 (Breyer, J., dissenting).

83. *Id.* at 176 (quoting 21 U.S.C. § 360c(a)(1)(A)-(B)).

84. *Am. Pharm. Ass’n v. Weinberger*, 377 F. Supp. 824, 828 (D.D.C. 1974), *aff’d per curiam*, 530 F.2d 1054 (D.C. Cir. 1976).

85. See Margaret Gilhooley, *When Drugs Are Safe for Some but Not for Others: The FDA Experience and Alternatives for Product Liability*, 36 HOUS. L. REV. 927, 940-45 (1999).

creating a black market, then Breyer's position on how safety is to be determined effectively provides consumers with "freedom of choice." Even if the FDA believed, on scientific and medical grounds, that the harms involved in the intended use of a drug outweighed its benefits, strong consumer dissent—of an intensity so high that consumers would turn, in the case of prohibition, to black markets—could prevent the FDA from issuing a ban. This may be sensible policy. It is not, however, the current practice, which confines the FDA to medical and scientific criteria. If freedom of choice is to become a relevant factor in food and drug regulation, this should occur in a more conscious and comprehensive process that defines the role of consumer preference and makes provisions for adequate disclosure.⁸⁶

More fundamentally, the problem with Breyer's black market rationale is that although it eliminates the possibility of an absolute ban as a practical matter, it does not deny to the Agency, on a theoretical level, the power to ban. If, for example, it were possible for the FDA effectively to eliminate any black market for tobacco, the logic of the Agency's position would lead to a total prohibition on tobacco products, since their continued use would then provide no benefit capable of outweighing their harms. The Agency indeed observed in its brief that it could ban tobacco if it determined that there existed no reasonable assurance of safety.⁸⁷

The insufficiencies of the black market rationale support the Court's contention that, if Congress indeed intended no absolute ban on tobacco products, such products could not lie within the FDA's regulatory authority. To determine Congress's intent, the Court turned to various statutes passed subsequent to the FDA's enabling legislation. This investigation of congressional intent was also relevant to a second, related argument offered by the majority: Even if the FDA could, under its mandate, regulate tobacco products without banning them, Congress had implicitly excepted tobacco from the Agency's jurisdiction.

The Court pointed to statutes that seemed implicitly to recognize the tobacco industry's right to exist. The Court observed, for example, that, in requiring that cigarette labels include information about the Surgeon General's warnings, Congress assumed that cigarettes would remain on the market and would not be banned by regulatory action.⁸⁸ The inherent plausibility of this reading was supported by the position taken by the Secretary of Health, Education, and Welfare (today the Secretary of Health

86. See Margaret Gilhooley, *Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice*, 49 FLA. L. REV. 663, 715-22 (1997) (offering factors that should be considered if legislation is to be adopted that allows access to potentially harmful drugs upon disclosure of their risks).

87. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 159.

88. *Id.* at 138-39.

and Human Services), whose department housed the FDA. In his testimony during the legislative sessions preceding the enactment of the labeling provision, he urged Congress not to amend the law in a manner that gave the FDA authority over tobacco. Given the risks associated with tobacco products, he warned, such a provision “‘might well completely outlaw at least cigarettes,’” an outcome “‘contrary to what, we understand, is intended or what . . . would be acceptable to the American people.’”⁸⁹

The Secretary’s testimony not only implied congressional opposition to a total ban, but, more generally, disclaimed FDA jurisdiction over tobacco. Congressional endorsement of this position was suggested by a preemption provision that prohibited any federal agency from requiring any statement relating to smoking and health on cigarette packages.⁹⁰ Since labeling requirements are an “integral aspect” of the FDA’s drug and device regulation arsenal, the Court considered this provision “an important factor” in its determination that Congress did not contemplate a regulatory role for the FDA.⁹¹ Of course, the preemption provision might have been interpreted merely as directed at label statements, and the Secretary’s testimony might have been read as a determination that cigarettes, on the evidence then available, were not drugs. However, it is plausible to suppose that Congress was, with the Secretary’s imprimatur, carving out from the FDA’s jurisdiction some regulatory power over cigarette availability that might otherwise have fallen into it.⁹² Against this backdrop, the Court determined that the statutory framework that Congress erected around tobacco implied that it had “effectively ratified the FDA’s previous position that it lacks jurisdiction to regulate tobacco.”⁹³

Justice Breyer, analyzing the same history, found it “critically ambivalent” with respect to the question of FDA authority over tobacco.⁹⁴ While the congressional enactments could be read to mean that Congress had reserved tobacco for itself, they could as easily be read to mean that

89. *Id.* at 146 (quoting *Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. 18 (1964) (statement of Secretary Celebrezze)). Then-Commissioner Edwards contended that “‘the regulation of tobacco is to be the domain of Congress,’” and that “‘labeling or banning cigarettes is a step that can be take[n] only by the Congress.’” *Id.* at 152 (quoting *Public Health Cigarette Amendments of 1971: Hearings Before the Commerce Subcomm. on S. 1454*, 92d Cong. 239, 243 (1972) (statement of Commissioner Edwards)).

90. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 5(a), 79 Stat. 283 (1965). The preemption was later made permanent, and is codified at 15 U.S.C. § 1334(a) (1994).

91. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 148-49.

92. It may be possible, however, to read the preemption provision more narrowly, so that it does not apply when therapeutic intent is established on the basis of express claims or other evidence.

93. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 156. The Court also cited a long history of agency statements disclaiming jurisdiction over tobacco in the absence of express therapeutic claims. *Id.* at 144-57.

94. *Id.* at 182 (Breyer, J., dissenting).

Congress was simply proceeding “without interfering with whatever authority the FDA possessed.”⁹⁵ Since Congress had nowhere explicitly excepted tobacco from the Agency’s jurisdiction, argued Breyer, the latter reading controlled.⁹⁶ While Breyer’s objection is persuasive, it does not touch the Court’s argument that Congress did not intend a ban, and that the FDA, were it to have jurisdiction, could not, under its enabling legislation, do anything but enforce a ban. Challenges to this argument must move away from statutory texts to broader questions of congressional delegation and agency discretion.

2. *Determining the Scope of Delegation*

If placing tobacco within the jurisdiction of the FDA means a ban on tobacco, then, since Congress has implicitly indicated that it intends no ban, the Court’s argument against jurisdiction is persuasive. A close textual reading of the FDA’s enabling legislation indeed suggests that the FDA, were it to have jurisdiction over tobacco, could do nothing but ban it. But the situation is complicated by the principle of delegation. The FDA was presumably assigned, at its formation, powers sufficient to its jurisdiction. At that time, however, the available evidence placed tobacco outside the Agency’s jurisdiction. According to the FDA, new evidence suggests that tobacco does meet the statutory definition of a drug. The Court did not reject this point; it merely argued that tobacco cannot enter the FDA’s jurisdiction because the ban remedy, given congressional intent, is too drastic. But Congress arguably may be deemed to have implicitly delegated to the Agency the authority to respond to the changed legal circumstances—the new status of tobacco—by developing less drastic remedies to protect the public.

The extent to which an agency may adapt its statutory authority to new circumstances should depend upon the importance of the matter and the relationship of the adaptation to the agency’s statutory aims. It is unremarkable for an agency to adapt its enacting law, with Congress’s implicit acquiescence, to situations not specifically addressed within it.⁹⁷ The FDA has, for example, regulated genetically modified foods under laws enacted at the beginning and middle of the last century, long before current biotechnology techniques were developed.⁹⁸ The challenge of statutory interpretation is to determine when the agency’s resolution of a new issue is so far beyond the legislative aims that, even in light of Congress’s implicit

95. *Id.*

96. *Id.*

97. See Sunstein, *supra* note 73, at 1019, 1059-63.

98. See Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

delegation to agencies of the authority to adapt the laws they administer to new situations unless inconsistent with the specific provisions, the agency's innovation should be found to be unauthorized. This challenge has grown greater in the post-New Deal era, as the concerns that led to the passage of important enacting statutes fade further into the past.

Neither the majority nor the dissent provided a fully satisfactory approach to this most difficult and fundamental issue. For the majority, legislative developments subsequent to the passage of the FDA's enabling statute ruled out the possibility of pushing tobacco into the Agency's jurisdiction. Moreover, the Court found, as a matter of "common sense,"⁹⁹ "that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."¹⁰⁰ If the Court's concern about impact meant that any regulation that has a significant effect on an important industry needs a specific statutory basis, its decision would have constrained to an undesirable extent agencies' presumed authority to modify their operation in response to emerging issues.¹⁰¹ More plausibly, however, the Court was simply applying an eminently reasonable principle of statutory interpretation: With respect to decisions of great significance, it is more difficult to infer delegation.¹⁰² But the Court gave little guidance as to how to apply this principle.¹⁰³

99. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133.

100. *Id.* at 160. The Court classified the case among the "extraordinary cases" where "there may be reason to hesitate before concluding that Congress has intended . . . an implicit delegation." *Id.* at 159. Presumably, the existence of large numbers of addicted smokers is what made it difficult to believe that Congress would have delegated the power to ban smoking or to restrict smoking in a manner functionally equivalent to a ban.

101. See *The Permian Basin Area Rate Cases*, 390 U.S. 747 (1968) (upholding the Federal Power Commission's authority to set prices charged by field producers based upon its statutory authority to regulate transportation).

102. See *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240 (2d Cir. 1977), for a neat illustration of the significance calculation. In this case, the Second Circuit found that the FDA could require food processing plants to remove the risk of botulism from whitefish. The Agency was acting under its statutory authority to address "'insanitary conditions' whereby [the food] may have been rendered injurious to health." *Id.* at 245 (quoting 21 U.S.C. § 342(a)(4) (1994) (emphasis added)). The problem was that the botulism existed in the fish before the fish entered the plant. Nevertheless, the court determined that statutory language encompassed, if admittedly "inelegant[ly]," not just insanitary conditions within the plant but also "inadequate sanitary conditions of prevention." *Id.* at 247. The court's linguistically generous reading was no doubt predicated, at least in part, on the assumption that Congress had delegated lower-magnitude decisions such as this one to the Agency.

103. The majority's discussion of interpretive methodology gave no express recognition to statutory purpose. While it recognized that a statute's function is an important guide in interpreting its meaning, for it, function was determined not by identifying the legislators' intent at the time of the statute's passage, nor by imagining what they would have intended in the new circumstances, but by examining the broader statutory context of the relevant provisions and the subsequent legislation. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 132-33 (noting that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme" and that "the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand").

The dissent offered a classic statement of the broad delegation position.¹⁰⁴ Breyer observed that the FDA came into being in 1938, during the Second New Deal, when Congress and the President believed in broad delegations.¹⁰⁵ While he acknowledged the improbability that Congress, at the time, expected tobacco to fall under the Agency's jurisdiction, he believed it "inherent in the very nature of a broad delegation" that an agency can, in light of the statutory purpose, apply general provisions to existing products when new evidence and circumstances justify so doing.¹⁰⁶ For Breyer, the canon of express congressional authorization would be limited to regulations that affect civil rights and those with "enormous social consequences," and would not extend to decisions of lesser import such as the regulation of tobacco.¹⁰⁷ Breyer of course recognized that tobacco regulation was a very significant issue. Ironically, however, its significance made it more suitable for delegation. Although delegation would reduce legislative accountability, the issue's visibility would ensure executive accountability through the election process, so that there would be, in the end, "the kind of public scrutiny that is essential in any democracy."¹⁰⁸

The Court's position seems to reflect a wariness about the approach of the earlier legal process theorists, who directed the interpreter to determine "what purpose ought to be attributed to the statute" and then to interpret the words so as to carry out that purpose. HENRY M. HART & ALBERT M. SACKS, *THE LEGAL PROCESS* 1374 (Foundation Press 1994) (1958); *see also id.* at 1378 (urging the court to "put itself in imagination in the position of the legislature"); LOUIS L. JAFFE, *JUDICIAL CONTROL OF ADMINISTRATIVE ACTION* 572-73, 576 (1965) (relying on clear statutory purpose as the primary basis for statutory interpretation). The legal process approach finds expression in Judge Learned Hand's opinion in *United States v. Klinger*:

When we ask what Congress "intended," usually there can be no answer, if what we mean is what any person or group of persons actually had in mind. Flinch as we may, what we do, and must do, is to project ourselves, as best we can, into the position of those who uttered the words, and to impute to them how they would have dealt with the concrete occasion. He who supposes that he can be certain of the result is the least qualified for the attempt.

199 F.2d 645, 648 (2d Cir. 1952). This position's faith in the ability to discern purpose now seems perhaps "a tad naive." Daniel R. Rodriguez, *Jaffe's Law: An Essay on the Intellectual Underpinnings of Modern Administrative Law Theory*, 72 CHI.-KENT L. REV. 1159, 1182 (1987). Justice Scalia, in particular, has viewed the statutory purpose test as too subjective. *See* Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 517 (arguing that the "quest for 'genuine' legislative intent is probably a wild-goose chase anyway," since such intent is merely "fictional, presumed"); Cass R. Sunstein, *Justice Scalia's Democratic Formalism*, 107 YALE L.J. 529, 540 (1997) (maintaining that resort to purpose, according to Scalia, seems "highly ideological" and a matter less of finding intent than of "making things up").

104. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161-62 (Breyer, J., dissenting); *see also* James T. O'Reilly, *Tobacco and the Regulatory Earthquake: Why the FDA Will Prevail After the Smoke Clears*, 24 N. KY. U. L. REV. 509, 526-29 (1997) (noting judicial deference to the FDA on health-related matters).

105. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 165-66 (Breyer, J., dissenting).

106. *Id.* at 166; *see also id.* at 179 (arguing that the FDA should be allowed to take into account "the realities of consumer behavior").

107. *Id.* at 190 (citation omitted).

108. *Id.*

Breyer's invocation of executive authority points to the basic difficulty with his broad delegation approach. Delegation assigns legislative authority to agencies pursuant to a statute. Reliance on executive accountability to justify deference to an agency's decision infringes upon Congress's legislative role unless the agency's decision can be said to lie within the scope of the statute. Generally, the ability of courts to rein in agency discretion by interpreting statutes in the light of an independent determination of the statute's meaning tends to alleviate this problem. Breyer, however, while rightly recognizing the importance of statutory purpose in determining intent, framed the goal of the FDA's enacting statute as "Congress' overall desire to protect health," and declared his willingness to interpret the statute in light of that goal "where linguistically permissible."¹⁰⁹ Breyer thus endorsed a mandate so broad as largely to eliminate the possibility of meaningful judicial review.¹¹⁰

Furthermore, Breyer's broad delegation did not adequately take into consideration the open-ended nature of the FDA's jurisdictional claim. Borrowing a metaphor from Judge Learned Hand, Breyer observed that an interpretation of a statute, even if it "gets the words right," may yet "lack[] a sense of their 'music.'"¹¹¹ In the tobacco case, this analogy reverberates with the FDA's silence about its future intentions. Had the Agency won, its victory would have opened the door to future regulation. The Agency, however, failed to articulate a policy principle defining the direction and goals of its regulatory program. One justification for broad delegation is that agencies can use their experience to develop a public consensus toward a rational policy that meets emerging needs.¹¹² However, if an agency can remain silent with respect to hard questions, it can stall the consensus-building process. True, it is often sensible for agencies to approach a new issue one step at a time. Nevertheless, unless an agency at least roughly establishes its aims up front, it can arrogate undue power to itself by establishing a jurisdictional foothold in a minor test case, then expanding that authority in more significant ways. This possibility was especially worrisome in this case because of the crucial differences between youth

109. *Id.* at 181.

110. See Cynthia R. Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452, 487-88 (1989) (noting that an expansive test for agency discretion weakens the power of the judiciary to police the scope of delegations and "is fundamentally incongruous with the constitutional course by which the Court came to reconcile agencies and separation of powers").

111. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 189 (citing *Helvering v. Gregory*, 69 F.2d 809, 810-11 (2d Cir. 1934) ("[T]he meaning of a statute may be more than that of the separate words, as a melody is more than the notes.")).

112. JERRY MASHAW, GREED, CHAOS, AND GOVERNANCE: USING PUBLIC CHOICE TO IMPROVE PUBLIC LAW 156 (1997) (arguing that delegation to expert agencies "becomes a form of consensus building that, far from taking decisions out of politics, seeks to give to political choice a form in which potential collective agreement can be discovered and its benefits realized").

smoking, the subject of the regulation under consideration, and adult smoking, the potential subject of future regulation.¹¹³

The FDA's silence also undermined the executive accountability that was Breyer's rationale for deference.¹¹⁴ If the Agency could justify its authority in the most persuasive case, without stating clearly what else that authority encompassed, the public would not be able to hold the administration accountable for the later implications of the policy. This argument seems especially relevant in the case of tobacco. As noted above, President Clinton, in publicly endorsing the Agency's rule, described it as aimed at youth smoking, and declared that "cigarettes are a legal product for adults," and that adults "have a perfect right to decide whether to smoke."¹¹⁵ The President's statement here skirted around the very large gap between the Agency's broad jurisdictional assertions and the much narrower scope of its rule.

It is true that if the FDA had taken further action in the future to restrict adult use, the president in office at the time would have been called to account. This is, however, uncertain; after all, the president would then have done nothing proactive, but merely would have allowed the Agency to implement a broad jurisdictional authority already upheld in principle. Public debate would have been muted, since the Agency would have been making no novel jurisdictional claim. Judicial review would have focused narrowly on the question of whether the Agency had acted reasonably.

Given, then, the FDA's open-ended claim, the Court was right not to apply a generous notion of delegation. In noting "the breadth of the authority that the FDA ha[d] asserted,"¹¹⁶ the Court seemed in fact to suggest that the FDA may have been more successful had it claimed a more limited authority. Had the Agency made clear that it was only seeking to regulate the use of tobacco by youths, and renounced any authority to ban adult use of tobacco, it might have prevailed. The Agency would still have built its claim to jurisdiction on its showing that manufacturers intended the addictive effects of tobacco, although it would perhaps have placed greater emphasis upon such youth-targeted indications of intent as the promotion of

113. Had the FDA prevailed, the broad jurisdictional basis of its argument would, for example, have permitted regulations requiring gradual reductions in the nicotine levels of all cigarettes, so long as such reductions did not trigger a black market in riskier products. Though arguably tantamount to a ban, such a regulation would have been valid in that it would have provided a "reasonable assurance" of safety. *See supra* text accompanying note 77.

114. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 190 (Breyer, J., dissenting) ("Insofar as the decision to regulate tobacco reflects the policy of an administration, it is a decision for which that administration, and those politically elected officials who support it, must (and will) take responsibility.")

115. Remarks Announcing the Final Rule To Protect Youth from Tobacco, 1996 PUB. PAPERS 1332, 1334 (Aug. 23).

116. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 160.

tobacco to teens through Joe Camel and similar ads.¹¹⁷ The Agency would not have had to fall back upon the questionable black market theory in order to explain why its regulations did not extend to adult use. Instead, the Agency would have been able to acknowledge that a ban was beyond its existing authority in light of a common sense reading of its enacting statute and in light of subsequent legislative enactments.

The Court's decision established that the FDA cannot, on the basis of tobacco's addictive effects, regulate it "as customarily marketed."¹¹⁸ Tobacco of course continues to cause harm. Other approaches must therefore be considered. Many of the FDA's initiatives with respect to youth smoking were incorporated into a settlement agreement between the tobacco industry and the state attorneys general.¹¹⁹ Product liability litigation is a powerful if unpredictable agent of public health reform.¹²⁰ Nevertheless, the legislative process obviously remains an important, and perhaps the most appropriate, mechanism for shaping the future of tobacco.¹²¹ The next Part of this Review considers possible legislative approaches to dealing with tobacco risks, beginning with Kessler's proposal and then turning to the potential role of reduced-risk products. Especially relevant with respect to such products is the scope of FDA regulation. The

117. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,509, 44,476-86 (1996) (noting the effect of Joe Camel and other advertisements on youth smoking).

118. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 155-56.

119. The settlement arose when certain states demanded compensation from the industry for Medicaid costs incurred by the states in caring for smokers whose illnesses were ostensibly due to the industry's failure to place adequate warnings on their tobacco products. Under the settlement, the companies agreed to make regular billion-dollar payments to the states, to contribute to a foundation devoted to the reduction of youth smoking, to cease using cartoon characters in advertising, and to limit certain other forms of tobacco promotion directed toward youths. See W. Kip Viscusi, *A Postmortem on the Cigarette Settlement*, 29 CUMB. L. REV. 523, 537-43 (1999). For analysis of selected elements of the settlement, see *The Multistate Master Settlement Agreement and the Future of State and Local Tobacco Control* (Graham Kelder & Patricia Davidson eds., 1999), <http://www.tobacco.neu.edu/msa/index.html>.

120. See Robert L. Rabin, *The Third Wave of Tobacco Litigation*, in REGULATING TOBACCO 176, 204 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) (characterizing litigation as a "highly unpredictable ally" in reducing tobacco use).

121. Many commentators argue for legislation over litigation on democracy grounds. See, e.g., MARTHA L. DERTHICK, UP IN SMOKE: FROM LEGISLATION TO LITIGATION IN TOBACCO POLITICS 5 (2002) (finding the shift from legislation to litigation "problematic" for a democracy); HANOCH DAGAN & JAMES J. WHITE, *Governments, Citizens and Injurious Industries*, 75 N.Y.U. L. REV. 354, 424-29 (2000) (characterizing the settlement as a tax enacted in violation of the democratically established state tax laws); see also ROBERT B. REICH, *Regulation Is Out, Litigation Is In*, USA TODAY, Feb. 11, 1999, at 15A (observing the general tendency of litigation to replace regulation). But see HUBERT H. HUMPHREY III, *State Attorney General Litigation: Regulation Through Litigation and the Separation of Powers*, 31 SETON HALL L. REV. 598 (2001) (finding the settlement consistent with the Attorney General's role under state law to enforce the law and settle cases); JASON LYNCH, Note, *Federalism, Separation of Powers, and the Role of State Attorneys General in Multistate Litigation*, 101 COLUM. L. REV. 1998 (2001) (concluding that the tobacco settlement, and multistate litigation more generally, do not violate principles of federalism and separation of powers).

Court's decision does not preclude the possibility that the FDA can, even in the absence of new legislation, regulate reduced-risk products on the ground that they are intended to prevent disease.

III. THE FUTURE OF TOBACCO POLICY

A. *Kessler's Dismantling Solution*

At the conclusion of his book, Kessler presents his vision of the direction of tobacco policy. He observes that product liability litigation, rather than regulation, is the "strongest weapon" against the industry's power, but notes that lawsuits also tend to encourage the companies to continue operating in order to pay off their liability debts.¹²² The state governments involved in the tobacco settlement also want to keep the industry in business, in order to collect the payments promised them.¹²³ Kessler is wary of such incentives, since he believes that, as long as tobacco is a for-profit business, its use will inevitably be encouraged. Therefore, Kessler argues for legislation that would force tobacco companies out of the tobacco business. Their nontobacco businesses would be spun off, and freed from liability judgments arising from tobacco suits. A nonprofit government corporation would take over control of the tobacco businesses. Given the existence of addicted smokers, Kessler would allow the government to sell tobacco, but only in "brown paper wrappers."¹²⁴ This would help to strip the product of any vestige of social acceptability.¹²⁵ Profits from the sale of tobacco would go toward satisfying judgments.

The dismantling scheme is riddled with logistical and legal problems that require further explication if Kessler's proposal is to be taken seriously. Would smokers turn to black markets if familiar brands were no longer sold, and, if so, what would the government do? What sorts of provisions for public participation and judicial review, if any, would constrain the decisionmaking of the monopolistic nonprofit? Is it feasible or appropriate to shield the nontobacco businesses of tobacco companies from liability for tort judgments?¹²⁶ What happens if the nonprofit generates insufficient

122. KESSLER, *supra* note 3, at 393.

123. *Id.* at 392.

124. *Id.*

125. *Id.* at 388.

126. See Lynn M. LoPucki, *The Death of Liability*, 106 YALE L.J. 1, 1-3 (1996) (maintaining that new techniques that permit businesses to become judgment-proof are undesirable because potential litigation is a powerful means of controlling human behavior); James J. White, *Corporate Judgment Proofing: A Response to Lynn LoPucki's The Death of Liability*, 107 YALE L.J. 1363, 1406-07 (1997) (noting that the vagueness of fraudulent conveyance law may have influenced cigarette companies' decision not to spin off their food subsidiaries); see also Charles W. Mooney, Jr., *Judgment Proofing, Bankruptcy Policy, and the Dark Side of Tort Liability*, 52 STAN. L. REV. 73, 76 (1999) (stating that "a new debate should emerge about the effects of tort

funds to compensate the victims?¹²⁷ And how will plain brown wrappers satisfy the First Amendment, which limits even Congress's ability to protect potential youth smokers by restricting billboard advertising that reaches adults?¹²⁸

B. *Low-Tar and Light Cigarettes: "Reduced-Risk Gone Wrong"*¹²⁹

Noticeably absent from Kessler's vision is any role for reduced-risk products such as light cigarettes. And not without some reason. Low-tar and light cigarettes have been available for nearly fifty years and now represent a large share of the market.¹³⁰ While some at the National Cancer Institute (NCI) and in the scientific community believed at one time that the risk of cancer from tobacco would decline as the popularity of such products grew,¹³¹ this hope seems to have been disappointed by subsequent experience. The IOM Committee found that "[m]ost current assessments . . . suggest that low-yield products are associated with far less health benefit, if any, than would be predicted based on estimates of reduced toxic exposure using FTC yields."¹³² The disparity between projected benefit and experience is in part a result of the way the Federal Trade Commission "smoking machine" that calculates these projections

claims when viewed through the goals underlying tort law, fraudulent transfer law, and bankruptcy policy"). One relevant precedent is the silicone breast implant context. For a report on a challenge to a bankruptcy court judge's allowance of an independent tort suit against the parent corporation of implant maker Dow Corning, see *Dow Appeals Ruling on Implant Cases*, CHI. TRIB., Jan. 7, 2000, at N4.

127. Past experience with massive tort settlements suggests, not surprisingly, that equitable distribution among victims becomes difficult in this scenario. See Frank J. Macchiarola, *The Manville Personal Injury Settlement Trust: Lessons for the Future*, 17 CARDOZO L. REV. 583 (1996) (discussing the need to consider alternative compensation schemes).

128. See *Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001). The state regulation struck down in *Lorillard* precluded billboards within 1000 feet of a school. It was modeled on the FDA rule struck down on statutory grounds in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). On some of the constitutional pitfalls involved in restricting tobacco advertising, see, for example, *Lorillard*, 121 S. Ct. at 2426, which notes that tobacco use by adults is "a legal activity," and that manufacturers and retailers have an interest in conveying, and adults in receiving, truthful information; and Kathleen M. Sullivan, *Cheap Spirits, Cigarettes, and Free Speech: The Implications of 44 Liquormart*, 1996 SUP. CT. REV. 123, 150-56, 158-60, which identifies difficulties under strict scrutiny and lesser standards. The First Amendment problem might be sidestepped if the legislation were understood not as targeting promotion, but as targeting the object itself by limiting its availability. See Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TULANE L. REV. 815, 869-81 (2000).

129. John Slade & Jack E. Henningfield, *Tobacco Product Regulation: Context and Issues*, 53 FOOD & DRUG L.J. 43, 50 (1998).

130. *Id.* at 52 (reporting that light brands "dominate" the market, with cigarettes containing twelve or fewer milligrams of tar comprising 53.6% of the market in 1995).

131. KESSLER, *supra* note 3, at 247. For more on the NCI project, see GLANTZ ET AL., *supra* note 41, at 155-62; and Slade & Henningfield, *supra* note 129, at 52.

132. IOM REPORT, *supra* note †, at 2.

measures reductions in exposure to tar.¹³³ Reduction in practice may be smaller than projected because smokers compensate by inhaling more deeply, and because the ventilation holes in the cigarette paper may be covered when used in a way that increases the amount inhaled.¹³⁴ The disappointing results may also be due to consumer ignorance of the risks that still inhere in light cigarettes.¹³⁵

Less misleading testing and marketing procedures must emerge. To account for inhalation variability among smokers, for example, cigarette filters might contain a color indicator strip showing the inhalation pattern measured by the FTC smoking machine, and an adjacent clear strip that the smoker would use to compare her own inhalation pattern.¹³⁶ The FTC should use its authority over misleading advertising¹³⁷ to seek to correct confusion with respect to low-tar claims.

The FDA may also be able to play a role in ensuring that reduced-risk products have adequate scientific support. To obtain jurisdictional authority, the Agency could invoke the theory that low-tar and light labeling imply a benefit in preventing disease or in stopping smoking, and thus constitute therapeutic claims subject to FDA regulation.¹³⁸ This approach is rendered somewhat problematic by the Agency's failure, during the half-century that low-tar products have been sold, to regulate reduced-exposure claims as therapeutic claims.¹³⁹ The Agency could perhaps use the

133. *See id.* at 67 ("The weight of the evidence indicates that lower-tar and nicotine yield cigarettes have not reduced the risk of disease proportional to their FTC yields, in part because smokers compensate to obtain more nicotine and in part because the products themselves contain higher concentrations of selected carcinogens." (citations omitted)).

134. *See* Jurisdictional Statement, *supra* note 37, at 44,963-70 (observing that the filtration and ventilation features of cigarettes can increase nicotine levels above those measured by the FTC smoking machine); KESSLER, *supra* note 3, at 147-48 (describing the design of the smoking machine and its potential failures).

135. IOM REPORT, *supra* note †, at 2 (noting how light cigarettes may encourage smoking "because of perceptions that the risk with low-yield products [i]s minimal").

136. The FTC has been concerned for some time that the current test methods may be misleading, but believes that specialized scientific expertise is necessary to make improvements. It has asked the Department of Health and Human Services to review FTC methodology, and has recommended to Congress that it consider giving authority over cigarette testing to a science-based public health agency. FED. TRADE COMM'N, REPORT TO CONGRESS FOR 1997 (1999), <http://www.ftc.gov/os/1999/9907/1997/cigarettereport.pdf>.

137. 15 U.S.C. § 45 (1994) (assigning authority over misleading advertising to the FTC).

138. *See* IOM REPORT, *supra* note †, at 70 (citing a 1993 Gallup Poll which found that fifty-six percent of smokers stated that terms like "low-tar," "low-nicotine," and "low-yield" indicated a positive health benefit); *id.* at 71 (citing a 1998 study which showed that thirty-nine percent of smokers of light cigarettes and fifty-eight percent of smokers of ultralight cigarettes claimed that they smoked their respective brands in order to reduce risk without having to give up smoking). For the FDA's statutory authority over therapeutic claims, see 21 U.S.C. § 321(g)(1)(B) (1994), which covers drugs; and 21 U.S.C. § 321(h)(2), which covers devices. *See also* Joseph A. Page, *Federal Regulation of Tobacco Products and Products That Treat Tobacco Dependence: Are the Playing Fields Level?*, 53 FOOD & DRUG L.J. 11, 40-41 (1998) (explaining that a low-tar claim may be considered a disease-prevention claim if the claim implies help with cessation, but arguing that a claim merely of reduced exposure is more problematic to classify as therapeutic).

139. *See* Page, *supra* note 138, at 39-40.

emerging consensus on the gap between test and practice to justify its reevaluation of the labeling claims.¹⁴⁰ If reduced-risk products come to be classified as drugs, however, the testing and approval requirements that follow upon such classification may create disincentives against offering reduced-risk products.¹⁴¹ Moreover, any effort to prevent deception about labeling claims for low-tar cigarettes is complicated by the preemption provisions governing tobacco, which preclude federal agencies from originating labeling statements on cigarettes relating to smoking and health.¹⁴² These difficulties make desirable the enactment of a new and more flexible framework for FDA regulation of reduced-risk products.

C. *New Reduced-Risk Products*

Creating a role for reduced-risk products in the future of tobacco policy is especially important because new and perhaps more effective reduced-risk products are continuously emerging. RJR and Philip Morris are developing smokeless cigarette-like products that heat tobacco instead of burning it and contain lesser amounts of the carcinogenic substances known to occur in cigarettes.¹⁴³ Vector, Liggett's parent company, plans to market a genetically modified nicotine-free cigarette that reduces the carcinogens in tobacco.¹⁴⁴ B&W has manifested an interest in a new curing process that produces tobacco with reduced amounts of tobacco-specific nitrosamines, a known carcinogen.¹⁴⁵

These products may fall into any of at least three regulatory regimes, depending on how they are marketed. If the product comes with an express claim to disease prevention, as did RJR's smokeless cigarette during its test marketing period,¹⁴⁶ then the FDA should have regulatory authority under its therapeutic claim jurisdiction.¹⁴⁷ If the industry markets the products

140. See IOM REPORT, *supra* note †, at 2. The FDA's broad theory of manufacturer intent could provide additional support. See *supra* Section II.B.

141. See Page, *supra* note 138, at 41; see also *id.* at 34-35, 39-41 (suggesting that device classification might provide some more flexibility).

142. 15 U.S.C. § 1334(a) ("No statement relating to smoking and health [other than the warnings provided in accordance with the statute] shall be required on any cigarette package."). The Federal Trade Commission's role in determining exposure levels based on the smoking machine could also affect the FDA's regulation. See IOM REPORT, *supra* note †, at 87-88, for the operation of the machine, and FED. TRADE COMM'N, TOBACCO PRODUCTS (1992), <http://www.ftc.gov/bcp/online/pubs/products/baccy.htm>, for the FTC's authority over tobacco.

143. IOM REPORT, *supra* note †, at 93-95.

144. Gordon Fairclough, *Vector Produces Nicotine-Free Cigarette Using Genetically Modified Tobacco*, WALL ST. J., Jan. 16, 2001, at A2; Andrea Knox, *Nicotine-Free Tobacco Product Opposed by Industry, Health Advocates*, PHILA. INQUIRER, Apr. 15, 2001, at 1.

145. IOM REPORT, *supra* note †, at 91-92.

146. *Id.* at 94 ("A Cigarette that responds to concerns about certain smoking-related illnesses. Including Cancer.").

147. 21 U.S.C. § 321(g)(1)(B) (1994); see Page, *supra* note 138, at 40. The new-generation products that heat tobacco rather than burning it may fall within the FDA's jurisdiction even in the

based on their reduced levels of tar or other constituents, without any express health claims, just as it markets low-tar and light cigarettes, then the considerations discussed above in the context of the first-generation reduced-risk products apply. If the products are marketed as “smokeless,” manufacturers may argue that their claim concerns only an amenity, and therefore lies beyond the FDA’s jurisdiction.¹⁴⁸ The regulatory authority of the FDA in this area remains unresolved,¹⁴⁹ an open question that will become ever more pressing as these new reduced-risk products become a larger presence in the market.

Before turning to specific proposals’ place in tobacco reform, it is important to point out that the value of reduced-risk products in general is the subject of some debate. Some believe that such products are counterproductive because they encourage smokers who would otherwise have quit to continue and entice others who would not have become smokers to do so.¹⁵⁰ The new-generation products, especially, may make smoking more socially acceptable by reducing second-hand smoke. All this raises concern, since reduced-risk products, though safer than conventional tobacco products, are hardly free from health risks.¹⁵¹ However, reduced-risk products are undeniably beneficial to those who will not quit, and to those who will in any case take up smoking. The policy choice is a difficult one, and could be made either on a utilitarian basis, in light of a determination about the overall effect of reduced-risk products on public health, or on an individualist basis, in a manner that would inform potential users of the options and allow them to choose.¹⁵² Legislative proposals should take into account this two-edged nature of reduced-risk products.

absence of any therapeutic claim, since these products arguably do not constitute tobacco products “as customarily marketed,” the only category that the Supreme Court expressly placed beyond the Agency’s jurisdiction. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 129 (2000). We return, in this scenario, to the question of intent: Can the FDA regulate in the absence of express drug-related intent?

148. *See, e.g.*, IOM REPORT, *supra* note †, at 65 (noting a cigarette advertisement that promised “a smooth satisfying taste with less smoke around you, virtually no lingering odor, and no ashes”); Christopher Hitchins, *We Know Best*, VANITY FAIR, May 2001, at 92 (criticizing no-smoking requirements for bars and the smoke-free policy at the White House that made it necessary for Vaclav Havel, Lech Walesa, and the late Yitzhak Rabin to go outside to smoke while on official visits).

149. *See* Page, *supra* note 138, at 38-40; *see also* KESSLER, *supra* note 3, at 28-29 (reporting that the FDA debated the regulatory status of Premier, an early smokeless cigarette, before it failed in the market).

150. IOM REPORT, *supra* note †, at 2.

151. *See id.* (observing that the IOM Committee refrained from using the term “safer cigarettes” in describing reduced-risk products “in order to avoid leaving the impression that any product currently known is ‘safe’”).

152. For a review of the ethical issues of paternalism, see Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulation*, 61 U. PITT. L. REV. 419 (2000).

D. Programmatic Recommendations for Legislation

While various proposals for legislation and tobacco reform have emerged,¹⁵³ the discussion below focuses on two recommendations particularly pertinent to reduced-risk products and to the policy issues that Kessler raises.

1. *The IOM Report*

The IOM Committee recently issued a 600-page report on the history of reduced-risk products and the science of smoking. The Committee found that reduced-risk products “are potentially beneficial.”¹⁵⁴ However, since their public health impact is “unknown,” regulation of these products “is a necessary precondition for assuring a scientific basis for judging [their] effects.”¹⁵⁵ The difficulty in assessing the effect of reduced-risk products lies in part in the number of toxic ingredients associated with tobacco, each of which may behave differently,¹⁵⁶ and in part in our present ignorance of nicotine’s precise cardiovascular effect.¹⁵⁷ The Committee cautiously concluded that reducing risk is “feasible,” but that the reduced risk products “have not yet been evaluated comprehensively enough (including for a sufficient time) to provide a scientific basis for concluding that they are associated with a reduced risk of disease compared to conventional tobacco use.”¹⁵⁸

153. See, e.g., S. 190, 107th Cong. (2001) (proposing to amend the Food, Drug, and Cosmetic Act to grant the Secretary of Health and Human Services the authority to regulate tobacco products); H.R. 1043, 107th Cong. (2001) (proposing to amend the Food, Drug, and Cosmetic Act to provide the FDA jurisdiction over tobacco); Leonard Glantz & George J. Annas, *Tobacco, the Food and Drug Administration, and Congress*, 343 NEW ENG. J. MED. 1802 (2000) (criticizing the FDA’s tobacco regulation and urging that a new agency other than the FDA be created with the aim of ensuring risk reduction); Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163 (1998) (critiquing regulation and proposing a compensation scheme or the continuation of tort liability); Paul A. LeBel & Richard C. Ausness, *Toward Justice in Tobacco Policymaking: A Critique of Hanson and Logue and an Alternative Approach to the Costs of Cigarettes*, 33 GA. L. REV. 693, 694-95 (1999) (suggesting that the reform scenario may need to consist of “patching together the best features of a range of diverse responses, and employing an incremental trial-and-error process in which the lessons of experience are carefully folded into the insights of theory”).

154. IOM REPORT, *supra* note †, at 6.

155. *Id.* The Committee classified these products as Potential Reduced Exposure Products or PREPs. The IOM Committee also examined pharmaceutical products, such as the nicotine patch, *id.* at 95-116, but, since these products are already subject to regulation as drugs, this Subsection focuses on the Committee’s recommendations concerning tobacco products.

156. *Id.* at 214; see also *id.* at 215 (stating that some products may decrease nitrosamines but not other carcinogens, and that another may decrease exposure to carcinogens but increase exposure to carbon monoxide).

157. See *id.* at 252-53, 470-71.

158. *Id.* at 5.

To ensure adequate regulation of the tobacco products, the Committee advised that products claiming to reduce exposure to harmful tobacco constituents or to reduce health risks should be subject to prior agency review in order to ensure that there is a substantial reduction in exposure and a scientific basis for the specific health claims.¹⁵⁹ The Committee recommended that a scientifically expert agency like the FDA be granted broad authority to promulgate performance standards and labeling requirements for older and newer products alike.¹⁶⁰ The agency would also be empowered to conduct toxicological reviews of additives to existing products.¹⁶¹ The recommended regulatory structure would build on existing food and drug laws with adaptations that “take into account the unique history and toxicity of tobacco products.”¹⁶²

The Committee acknowledged that reduced-risk products could increase tobacco exposure. Their ultimate value, then, will depend on “individual and community behaviors with respect to their use.”¹⁶³ Consequently, epidemiological studies on the health effects of the reduced-exposure products, and an adequate post-marketing surveillance system, are necessary.¹⁶⁴ A federal agency should monitor these data. If the growing use of reduced-risk products led to an increase in tobacco-related diseases, the agency could set in motion “appropriate public health interventions.”¹⁶⁵ The need for regulatory reform is pressing because there is an “already emerging market” for the newest reduced-risk products.¹⁶⁶

2. *The Philip Morris Position Paper*

Philip Morris has also now taken a public position in support of legislation that responds to the “unique challenges” of tobacco by giving the FDA “meaningful, tough and effective regulatory authority.”¹⁶⁷ Manufacturers, in Philip Morris’s picture, would be required to provide to the scientific community information about animal and other testing conducted in the course of developing reduced-risk products.¹⁶⁸ The FDA could not compel the industry to do epidemiological studies, but could

159. *Id.* at 10, 208.

160. *Id.* at 11, 201-30. The Committee assumed that the authority to set performance standards would not include banning nicotine from products. *Id.* at 225.

161. *Id.* at 11, 224-25. This would enable the agency to respond, for example, to the use of ammonia in tobacco processing that was discovered in the course of the FDA investigation. *See supra* text accompanying note 55.

162. *Id.* at 8.

163. *Id.* at 6.

164. *Id.* at 8.

165. *Id.* at 6.

166. *Id.* at 202.

167. Philip Morris, *supra* note 13.

168. *Id.*

undertake such testing itself.¹⁶⁹ In an apparent response to the FDA's difficulties in obtaining information during its investigation, as well as to the Agency's concerns about additives like ammonia, the position paper would empower the Agency to obtain information necessary to assess health risks and to demand that added ingredients not increase risk or addictiveness.¹⁷⁰ The FDA would also have the ability to provide information to consumers about tar and nicotine yields from light and other cigarettes.¹⁷¹

Although the Philip Morris position paper has its critics among antismoking groups and rival companies,¹⁷² it is similar in many respects to the IOM Committee's regulatory program.¹⁷³ Most notably, the company acknowledges that tobacco is addictive and harmful, and that "the best option from a health perspective is to quit or not to start in the first place."¹⁷⁴ In this respect, the position paper responds to criticisms about the industry's past "strategy of denial."¹⁷⁵ Philip Morris does insist, however,

169. *Id.*

170. *Id.*

171. *Id.*

172. Antismoking groups "doubt the sincerity" of the company's proposal, while rival tobacco companies claim it is a ploy designed to give Philip Morris "a competitive advantage." Gordon Fairclough, *Philip Morris Pushes for FDA Tobacco Regulation*, WALL ST. J., Apr. 11, 2001, at A2. Philip Morris points to the tobacco settlement with the states as a factor in its change of position on FDA regulation. Philip Morris, *supra* note 13. The company may also be motivated by a desire for legal certainty with respect to the regulation of its new tobacco products. One product with especially uncertain status is a device that is, in contrast to the typically finger-held cigarette, hand-held. See *Nova: Search for a Safe Cigarette* (PBS television broadcast, Oct. 2, 2001) (describing the operation of the hand-held product). Whether the device is a tobacco product "as customarily marketed," and therefore within the scope of the *FDA v. Brown & Williamson Tobacco Corp.* ruling that denied the FDA jurisdiction over such products, is an open question. A third possible motive for the company's change of heart is the effect of regulation on tort liability. Philip Morris may see regulation as an ally in holding down liability, since compliance with an applicable statute or regulation is "properly considered" in determining whether a product is defective. RESTATEMENT (THIRD) OF TORTS § 4(b) (1997); see Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119 (2000) (cautioning against compliance defenses for products not subject to individual approval); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2084 (2000) (providing reasons for a "cautious approach" to a compliance defense). Compliance may also preclude punitive damages. See N.J. STAT. ANN. § 2A:58C-5(c) (West 2000) (precluding punitive damages for drugs, devices, and foods regulated by the FDA). *But see* Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335 (1993) (arguing that it is inappropriate to bar punitive damages); *cf.* Rabin, *supra*, at 2073 n.108 (expressing agnosticism on punitive damages absent data on their impact).

173. This is not to deny that there are important differences. Such differences occur, for example, in the area of epidemiological testing, see *supra* text accompanying note 169, and with respect to prior agency review of reduced-risk and reduced-exposure claims, compare *supra* text accompanying note 159 (describing IOM recommendations for review), with Philip Morris, *supra* note 13 (providing no form of prior review).

174. Philip Morris, *supra* note 13.

175. KESSLER, *supra* note 3, at 391. Kessler includes several discussions of the wisdom of the strategy. *Id.* at 252 (reporting the recommendation by Addison Yeaman, the B&W general counsel, that the company disclose smoking hazards so that it could openly conduct scientific research directed at eliminating the toxic compounds); *id.* at 228-29 (describing the view of S.J.

on “the right of adults to smoke,” and urges that, so long as society “continues to respect the values of tolerance and freedom, the decision as to whether or not to smoke should be left to individual adults.”¹⁷⁶ Consequently, the company would oppose any legislation that would ban tobacco or “achieve a de facto prohibition by systematically imposing ever-lower tar and nicotine yields that would render the product unpalatable to adult smokers.”¹⁷⁷

IV. CONCLUSION

In describing the direction of future tobacco policy in the aftermath of the FDA’s failed regulatory attempt, this Review has focused heavily on reduced-risk products. Smokers may most effectively reduce risk by ceasing to smoke. The problem, of course, is that while deciding to smoke may be, as Philip Morris contends, “an adult choice,”¹⁷⁸ nicotine’s addictive character tends, as Kessler observes, to “rob[] people of choice.”¹⁷⁹ Though some smokers manage to quit after repeated attempts, most fail.¹⁸⁰ Philip Morris recognizes an obligation to operate in a manner that conforms to “society’s expectations of what a responsible cigarette manufacturer should be.”¹⁸¹ The industry, as responsible marketers of an addictive product, ought properly to aid smokers who desire to quit. If smoking is acceptable because it is an adult choice, the industry must

Green, a British tobacco executive, that “it would be best to be in a position to say in public what was believed in private”); *id.* at 370-71 (referring to the “quandary” of a tobacco lawyer concerned that admitting the harmfulness of smoking would lead to liability for the industry, and even criminal charges); *id.* at 367-70 (discussing theories of legal ethics). The American Bar Association’s recent proposals to expand lawyers’ ability to disclose client’s confidences when necessary to prevent “reasonably certain death or substantial bodily harm” has been criticized for its uncertain application in the tobacco context. It is an open question, for example, whether it permits disclosure of a change in nicotine levels that “causes three extra deaths over 30 years.” Sarah Boxer, *Lawyers Are Asking, How Secret Is a Secret?*, N.Y. TIMES, Aug. 11, 2001, at B7 (quoting attorney Lawrence J. Fox).

176. Philip Morris, *supra* note 13.

177. *Id.*

178. *Id.*

179. KESSLER, *supra* note 3, at 155. Both the definition and the extent of nicotine addiction are matters of debate. For various definitions of addiction, see Jurisdictional Statement, *supra* note 37, at 44,719-27; and KESSLER, *supra* note 3, at 120, 160, 172.

180. Though the industry cites a fifty percent quit rate, this figure does not take into account the length of time and the number of attempts that a successful cessation may require. *See* Hanson & Logue, *supra* note 153, at 1195. Justice Breyer cited FDA data indicating that only 2.5% of smokers successfully quit each year, even though 70% say they would like to quit and 34% actually attempt to quit. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 191 (2000) (Breyer, J., dissenting); *see also* Kenneth E. Warner, *Reducing Harm to Smokers: Methods, Their Effectiveness, and the Role of Policy*, in *REGULATING TOBACCO*, *supra* note 120, at 111, 115 (noting that less than three percent of smokers quit each year, and that of those who go “cold turkey,” the success rate is only ten percent).

181. Philip Morris, *supra* note 13.

ensure that this choice remains continually viable by preventing addiction from foreclosing the nonsmoking option.

Drastic cessation measures are of questionable value,¹⁸² and threaten to give rise to black markets in riskier products. Slower and smaller measures show more promise. Pharmaceutical companies have developed various products useful in nicotine replacement therapy, such as nicotine gum, the patch, and inhalers, and have also made strides toward nonnicotine drug treatment.¹⁸³ Smokers must be made more aware of these alternatives. In its position paper, Philip Morris expresses support for some other cessation-directed policies. For example, the company would have the FDA sponsor research on various cessation techniques and utilize the results to guide smokers wishing to quit.¹⁸⁴ The position paper also would give the FDA the authority to require that the packaging of tobacco products indicate tar and nicotine content.¹⁸⁵ This information would enable users to develop their own plans for reducing and ending tobacco use. The problem with the latter approach, however, is that while low-tar and low-nicotine cigarettes exist, they do not reach levels sufficiently low to permit smokers easily to quit, and an express goal of cessation does not accompany their sale. One promising possibility, therefore, is the development of a staged reduction program. Cigarette manufacturers would produce cigarettes containing varying quantities of nicotine, and market them as cessation aids.¹⁸⁶

The defeat of the FDA's Kessler-led effort to obtain general jurisdiction over tobacco hardly spells the end of tobacco reform. On the contrary, the Agency's attempt, by raising awareness of tobacco's dangers among the public and intensifying pressure upon the industry, promises to accelerate the pace of change. Tobacco reform should move forward along two fronts. Those willing to quit should be aided and encouraged through the continued development and marketing of cessation products and programs. Those unwilling to quit should have informed access to reduced-risk products. The FDA should ensure the efficacy of movements on both fronts. For this, new legislation expanding its jurisdiction may be necessary. In the absence of

182. See Warner, *supra* note 180, at 136 (reporting that a proposal for phasing out nicotine across the board has been criticized on the ground that it could lead to compensatory smoking).

183. *Id.* at 115-16.

184. Philip Morris, *supra* note 13.

185. *Id.* The preemption provision denies the FDA such authority at the present moment. See *supra* text accompanying note 90.

186. Such staged cigarettes would, of course, require testing to ensure effectiveness. See Page, *supra* note 138, at 16-19, 33-36 (discussing the regulatory status and testing standards for cessation products sold as drugs). Accurately determining, in the light of smoker behavior, the overall consequences of new products on public health involves confronting questions that are unanswered and, perhaps, unanswerable. See Warner, *supra* note 180, at 136 (noting that some questions are "possibly not subject to definitive answers"); see also KESSLER, *supra* note 3, at 236-37 (noting with respect to a denicotinized cigarette called Next that while some users found it helpful in quitting, most merely compensated by smoking more cigarettes, and eventually abandoned Next entirely).

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such legislation, however, the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.* arguably allows the Agency to assert control over reduced-risk products on the basis of its existing authority with respect to disease prevention claims. The failure of the FDA's ambitious jurisdictional claim need not hamper tobacco reform; it only forces such reform to pursue the more defined goals of reducing risk and encouraging cessation.