THE FDA MAY NOT REGULATE TOBACCO PRODUCTS AS "DRUGS" OR AS "MEDICAL DEVICES"

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Professor Richard Merrill contends that the Federal Food, Drug, and Cosmetic Act does not grant the FDA regulatory authority over cigarettes and smokeless tobacco products. The fact that Congress did not expressly deny the FDA regulatory authority over tobacco cannot, Professor Merrill argues, be used to infer such authority. This inference is particularly inappropriate in the case of tobacco regulation, he maintains, because there is compelling evidence that Congress had no intention of delegating this authority to the FDA. He is unpersuaded that presidential approval legally sanctions the FDA's claim of authority by granting it a superficial political legitimacy. Finally, he reminds us of the FDA's own repeated denials of jurisdiction over tobacco products, and he recalls the numerous times that Congress passed legislation directed at tobacco without granting the FDA any role in its regulation.

Professor Merrill's Essay, like the other pieces in this volume, was written after the United States District Court for the Middle District of North Carolina decided Coyne Beahm v. FDA,[1] *but before a three judge panel of the United States Court of Appeals for the Fourth Circuit reversed that decision in* Brown & Williamson Tobacco Corp. v. FDA.[2] *In* Coyne Beahm, *the District Court held that the Federal*

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1. Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1393-1400 (M.D.N.C. 1997).
2. Brown & Williamson Tobacco Corp. v. FDA, Nos. 97-1604, 97-1581, 97-1606, 97-1614

Food, Drug, and Cosmetic Act authorized the FDA to regulate tobacco products, but not tobacco advertising. The Fourth Circuit rejected the District Court's jurisdictional ruling and invalidated the FDA's regulations in their entirety. The Clinton Administration has since requested an en banc *rehearing before the Fourth Circuit.*[3]

INTRODUCTION

In August 1996 the U.S. Food and Drug Administration (FDA) reversed its decades-old position and asserted jurisdiction over cigarettes and smokeless tobacco products[4] under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act").[5] Contending that these products are drug delivery devices,[6] and are thus subject to regulation as medical devices, the FDA promulgated comprehensive regulations governing their design, manufacture, distribution, sale, and, most notably, their advertising.[7] Thus, in a single dramatic step and without relying on any act of Congress that mentions tobacco, the FDA transformed the personal views of Commissioner David Kessler and President Clinton into federal law.[8] A major U.S. industry, which had not previously had dealings with the FDA, was suddenly subject to a brand new regulatory regime.

The announced goal of the FDA's scheme is to prevent the use of tobacco products by persons under eighteen.[9] Its principal

and 97-1605, 1998 WL 473320 (4th Cir. Aug. 14, 1998).

3. *See* Appellees' Petition for Rehearing, *Brown & Williamson* (No. 97-1604).

4. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897 (1997)) [hereinafter FDA Regulations].

5. 21 U.S.C. §§ 301-397 (1994 & Supp. II 1997).

6. *See* Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 45,208 (1996) [hereinafter FDA Jurisdictional Determination].

7. *See* 21 C.F.R. pt. 897 (1997).

8. *See* Ceci Connolly & John Mintz, *3 Unlikely Allies Built a Broad Anti-Tobacco Wave*, WASH. POST, Mar. 31, 1998, at A1 (detailing Kessler's antipathy toward the tobacco industry, and his role in convincing President Clinton of the political advantage of supporting the FDA's attempt to regulate tobacco products).

9. *See* 21 C.F.R. §§ 897.2, 897.14(a) (1997). The FDA estimated that "1 million youngsters become new smokers each year." FDA Regulations, *supra* note 4, at 44,573. The FDA predicted that its regulations would help achieve the goal of reducing underage tobacco use by one-half. *See id.* at 44,423. Regulations previously adopted by the Department of Health and Human Services which provide funding incentives to states to enforce their laws against sale to persons under eighteen should also help achieve that goal. *See id.* at 44,498 (citing the

instruments are a federal ban on the sale of tobacco products to persons under eighteen and a battery of Draconian restrictions on tobacco advertising. Among the latter are a ban on billboards within 1000 yards of any school,[10] a prohibition on the use of color or imagery in advertisements in publications with significant youth readership,[11] various restrictions on point-of-sale displays,[12] and prohibitions of branded merchandise (e.g., T-shirts) and tobacco brand sponsorship of concerts, exhibits, and sporting events, such as the Winston Cup racing series.[13] None of the FDA's advertising restrictions has become effective because a district court ruled that, while the FDA is not barred from regulating tobacco products, the FDCA does not give the Agency the authority to restrict their advertising.[14]

Professor Sunstein defends the FDA's legal authority to create, by agency rule, an entirely new regulatory program for tobacco products.[15] In this Essay, I challenge his defense of the FDA's action and summarize the grounds for the tobacco industry's challenge to the FDA's assertion of jurisdiction and to the specific requirements of its regulations. The arguments sketched here are set forth more fully in briefs filed in the case challenging the FDA's regulations that is now pending before the U.S. Court of Appeals for the Fourth Circuit.[16]

As would be expected, Professor Sunstein's defense of the FDA's assertion of jurisdiction over tobacco products is erudite and inventive. His treatment of the tobacco industry's contrary arguments—at least those with which he chooses to deal—is

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Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA] Reorganization Act of 1992, Pub. L. No. 102-391, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26 (1994))). However, even former FDA Commissioner Kessler now seems unconvinced that the FDA's regulations will significantly affect youth smoking. *See* Ceci Connolly & Sandra Torry, *Tobacco Bill Clears Senate Panel; $516 Billion Measure Hikes Fees, Restricts Ads, Limits Liability*, WASH. POST, Apr. 2, 1998, at A1.

10. *See* 21 C.F.R. § 897.30(b) (1997).

11. *See id.* at §§ 897.32(a), 897.32(a)(2).

12. *See id.* at §§ 897.30(a)(1), 897.30(a)(2).

13. *See id.* at § 897.34.

14. *See* Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1393-1400 (M.D.N.C. 1997).

15. *See* Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013 (1998).

16. [This appeal has since been decided *sub nom.* Brown & Williamson Tobacco Corp. v. FDA, Nos. 97-1604, 97-1581, 97-1606, 97-1614 and 97-1605, 1998 WL 473320 (4th Cir. Aug. 14, 1998). The Clinton Administration has requested a rehearing *en banc*. *See* Appellees' Petition for Rehearing, *Brown & Williamson* (No. 97-1604). –Eds.]

generally fair. His conclusion that these arguments are ultimately unconvincing is advanced with caution, for he acknowledges that a conscientious court could legitimately rule that the FDA lacks jurisdiction and declare the regulatory scheme it has adopted to be unauthorized.[17] Accordingly, as I said in remarks at the *Duke Law Journal*'s March 6 conference, I can agree with approximately forty-eight percent of Professor Sunstein's analysis.

In the end, however, I do not believe that a dispassionate court, mindful of established principles of statutory interpretation, can accept either the FDA's arguments or those advanced by Professor Sunstein in support of the Agency's position. In Part I, I focus on gaps in Professor Sunstein's explanation of the FDA's position and inconsistencies in the Agency's explanation of its regulations. In Part II, I highlight conflicts between its program for tobacco and the FDCA requirements for genuine medical devices. In Part III, I show how restricting advertising is incompatible with the FDA's role. In Part IV, I suggest why this audacious agency action fails even under *Chevron*[18] and the jurisprudence of agency deference.

I. FDA'S ASSERTION OF JURISDICTION REPUDIATES ITS HISTORICAL POLICY AND IGNORES CONGRESS'S SCHEME FOR CIGARETTES

Professor Sunstein's account of the background and rationale of the FDA's action is incomplete in critical respects. He suggests, for example, that the FDA's claim to jurisdiction relies in part on representations made by tobacco manufacturers—overtly or by implication—about the drug-like effects of their products. This is misleading. The true novelty of the FDA's contention that tobacco products are "*intended* to affect the structure or function of the body,"[19] and are thus within its regulatory jurisdiction, is that the Agency does *not* rely upon any representations made or implied by the makers of these products.[20] Historically, as the FDA has

17. *See* Sunstein, *supra* note 15, at 1015.

18. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

19. FDA Jurisdictional Determination, *supra* note 6, at 45,205 (emphasis added). *See also id.* ("[T]he Agency has determined that (1) cigarettes and smokeless tobacco 'affect the structure or any function of the body,' and (2) these effects on the structure and function of the body are 'intended' by the manufacturers.") (quoting 21 U.S.C. § 321(g)(1)(C) (1994)).

20. *See* Coyne Beahm v. FDA, 966 F. Supp. 1374, 1389 n.14 (M.D.N.C. 1997) ("FDA does not contend that tobacco manufacturers make any representations in connection with the sale of tobacco products. Therefore, if intended use can be established only by manufacturer

acknowledged, the "intended use" of an article—for purposes of the FDCA—has been determined by the claims made for it by the seller on the label, packaging, or in advertising.[21] The FDA has not claimed that any of the tobacco products to which its regulations would apply bear health claims that would justify their regulation.

Instead, the FDA has contended that "intended use" may be established by evidence that consumers overwhelmingly purchase an article for a given use that may then be attributed to the seller.[22] This theory, that consumers' intentions may be imputed to producers, has never been applied by any court to any product that the FDA sought to regulate.[23] A second theory, for which the FDA has not cited even dictum, is that the "intended use" of an article—for purposes of FDA jurisdiction—can be shown by statements of company employees in internal company documents.[24] In sum, the FDA's claim that tobacco products are within its jurisdiction is based on legal theories that are not supported by legal precedent.

It is not surprising that the FDA has attempted to give new meaning to the FDCA's "intended use" standard, for the Agency, over many decades, declared that the statute did not give it jurisdiction over ordinary tobacco products. Professor Sunstein acknowledges this,[25] but offers an incomplete history of the FDA's

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representations, tobacco products would not be subject to regulation pursuant to the FDCA.").

21. *See id*. at 1390.

22. The FDA's conclusion that tobacco products are "intended" to have drug effects is based, *inter alia*, on its finding that "[c]onsumers use cigarettes and smokeless tobacco products for pharmacological purposes, including sustaining their addiction to nicotine, mood alteration, and weight loss." FDA Jurisdictional Determination, *supra* note 6, at 44,630.

23. The FDA advanced this theory for the first time in *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (2d Cir. 1977), in support of its attempt to regulate vitamin supplements containing high levels of vitamins A and D as prescription drugs, rather than as foods. *See id.* at 329. The court acknowledged that evidence that a product was used "almost exclusively" for the treatment or prevention of disease might support the conclusion that it was intended for such drug uses, but held the evidence supporting the FDA's claim insufficient. *See id.* at 336. In *Action on Smoking and Health [ASH] v. Harris*, 655 F. 2d 236 (D.C. Cir. 1980), a tobacco case, the court upheld the FDA's conclusion that the petitioners, who sought to require the FDA to regulate cigarettes, had failed to assemble sufficient evidence that cigarettes were overwhelmingly used for their drug-like effects. *See id.* at 240. No case has held that the FDA is entitled to regulate a product, for which no health claims were made, as a "drug" solely on the basis of evidence of consumer use.

24. *See Coyne Beahm*, 966 F. Supp. at 1391 (noting that the FDA attempted to rely upon "internal manufacturer memoranda to establish intended use"). The District Court concluded that internal documents, showing only the subjective intent of manufacturers, could not be used as evidence of tobacco products' intended use. *See id*. at 1392.

25. *See* Sunstein, *supra* note 15, at 1023-24.

repeated denials of regulatory authority. For most of this century, until 1994, the FDA had told anyone who would listen—including, on several occasions, Congress—that it lacked authority to regulate ordinary tobacco products under the FDCA.[26] On two occasions the FDA specifically rejected petitions asking that it regulate cigarettes, first as drugs, and later as medical devices.[27] This was, the Agency said, because the sellers of those products did not make health claims that might bring the products within the "intended use" language of the Act.[28]

But FDA officials offered another reason for declining jurisdiction. The Agency's position was best explained by then-FDA Commissioner Charles Edwards in congressional testimony in 1972. This was seven years after Congress passed the first cigarette labeling law[29] and put aside legislation that would have given the FDA jurisdiction.[30] Dr. Edwards testified that if the FDA were to assert jurisdiction over cigarettes as "drugs" it would have to ban their sale because the FDCA does not permit the marketing of any drug whose safety and clinical effectiveness the Agency could not affirm.[31] In

26. *See id.* at 1381-82 (citing numerous instances of FDA denial of regulatory authority over tobacco).

27. *See* Letter from Donald Kennedy, Commissioner of Food and Drugs, to John F. Banzhaf, III, Executive Director and General Counsel, Action on Smoking and Health 4 (Dec. 5, 1977) (advising petitioner that "your request that FDA regulate cigarettes as a drug under the Act is denied") (on file with the *Duke Law Journal*); Letter from Mark Novitch, Deputy Commissioner of Food and Drugs, to John F. Banzhaf, III and Peter N. Georgiades, Action on Smoking and Health 1 (Nov. 25, 1980) (writing on behalf of Jere E. Goyan, Commissioner of Food and Drugs) (denying a request that the FDA regulate cigarettes as "devices," citing lack of jurisdiction) (on file with the *Duke Law Journal*). The D.C. Circuit upheld the agency's determination that it lacked authority to regulate cigarettes as drugs. *See ASH*, 655 F. 2d at 293. The FDA's refusal, on jurisdictional grounds, to regulate cigarettes as medical devices was not challenged in court. *See id.* at 237 n.4.

28. *See* Letter from Donald Kennedy, *supra* note 27, at 3 ("The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors."). *See also Cigarette Labeling and Advertising: Hearing Before the House Comm. on Interstate and Foreign Commerce on H.R. 2248*, 89th Cong. 193 (1965) [hereinafter *Hearings on H.R. 2248*] (testimony of Winton B. Rankin, Assistant Commissioner, FDA) ("The Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims.").

29. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994)).

30. *See* H.R. 2248, 89th Cong. (1965). Congress had earlier failed to pass other legislation that would have given the FDA jurisdiction over tobacco products. *See* H.R. 11280, 84th Cong. (1956); H.R. 5973, 88th Cong. (1963); S. 1682, 88th Cong. (1963).

31. *See Public Health Cigarette Amendments of 1971*: *Hearings Before the Commerce Subcomm. on S. 1454*, 92d Cong. 239 (1972) (statement of Charles Edwards, Comm'r, FDA).

short, according to the Commissioner, FDA jurisdiction over cigarettes would mean an end to their sale—a result so improbable that the conclusion that the FDCA did not apply was inescapable.

Dr. Edwards's observation, from which FDA officials have never until now dissented, explains another curious feature of the Agency's current position, a feature that Professor Sunstein mentions but does not explore. Indeed, his title obscures the point.[32] The FDA does *not* contend that cigarettes and smokeless tobacco products are "drugs," for that would mean, as Commissioner Edwards acknowledged, that they would have to be banned. To be sure, the Agency now says, tobacco products *contain* a drug, nicotine, but it quickly adds that tobacco products are medical "devices"—articles designed and constructed for the delivery of nicotine.[33] Then, claiming that it has discretion to regulate such "combination products" as drugs *or* as medical devices, the FDA determines it will regulate tobacco products as the latter.[34] The Agency apparently believes that this rebaptism allows it to escape the FDCA's requirement that all drugs be shown safe and effective. As I will explain later, this assertion is fundamentally mistaken, if not disingenuous.

Professor Sunstein observes that the FDA has not invariably declined to exercise jurisdiction over tobacco products, implying that the Agency's historical position has been one of equivocation rather than consistent denial. Two district court rulings from the 1950s supposedly provide evidence for this implication—the only evidence.[35] In each of the two cases the FDA sought the seizure of a brand of cigarettes for which the seller had made overt (and spurious) health claims in labeling and advertising.[36] The government

32. The title of his article is posed as a single question: *Is Tobacco a Drug?* Professor Sunstein does not address whether tobacco products are a "medical device" under 21 U.S.C. § 321(h) except to explain in a brief footnote that he "do[es] not discuss this provision, except to suggest that if the FDA is authorized to define tobacco products as a drug, it is almost certainly authorized to treat such products as 'combination products' subject to its device authority." *See* Sunstein, *supra* note 15, at 1015, n.8.

33. *See* FDA Jurisdictional Determination, *supra* note 6, at 45,205-07.

34. *See id.*

35. *See* United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959) (finding that "Trim Reducing-Aid Cigarettes" constituted a drug under 21 U.S.C.A. § 321(g)); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336, 339 (D.N.J. 1953) (finding that Fairfax Cigarettes fell within the statutory meaning of "drug").

36. *See 354 Bulk Cartons*, 178 F. Supp. at 848 (noting the packages were labeled "Trim Reducing-Aid Cigarettes"); *46 Cartons*, 113 F. Supp. at 337 (summarizing content of leaflets seized with cigarettes which described a "miracle vapor" that could reduce the frequency of respiratory diseases).

alleged that these claims made the products "drugs" under the FDCA, and in each case the trial court agreed.[37] The manufacturers of the cigarettes ceased making the claims and thereby escaped FDA jurisdiction. Neither trial court ruling was appealed. The FDA did not proceed to "regulate" the contents, labeling, or advertising of either brand of cigarettes. Nor, more importantly, did it ever attempt to regulate any other tobacco product.

These two cases thus reinforce the proposition that, under the FDCA, "intended use" is proved by the seller's claims. They do not represent any deviation from the FDA's repeatedly elaborated position that the FDCA gave it no jurisdiction over ordinary tobacco products.

Professor Sunstein repeats the FDA's argument that the Agency's prior refusals to regulate tobacco products reflected ignorance of the addictive properties of nicotine, and of the asserted efforts of manufacturers to manipulate the level of nicotine in their products. He argues, as does the FDA, that an agency is entitled to change its mind about a problem if the relevant facts change.[38] This argument, plausible as a general statement of the law, simply does not fit this case. First, if the pharmacological effects of nicotine are enough to give the FDA jurisdiction over tobacco products, the Agency had jurisdiction decades ago; these were not discovered recently. It is noteworthy that, before adopting its present regulations, the FDA had never suggested that these effects would make cigarettes "drugs." Second, even the addiction claim is not new. The citizen petition filed with the FDA by Action on Smoking and Health, the Agency's denial of which the D.C. Circuit upheld, specifically alleged that nicotine was addictive.[39] The FDA did not find this allegation sufficient to alter its conclusion that it lacked jurisdiction to regulate.[40] Third, any government agency that was paying attention had to know that cigarette manufacturers were in a position, within limits, to influence the amount of nicotine in their

37. *See 354 Bulk Cartons*, 178 F. Supp. at 851; *46 Cartons*, 113 F. Supp. at 339.

38. *See* Sunstein, *supra* note 15, at 1030. *See also* FDA Jurisdictional Determination, *supra* note 6, at 45,238-52.

39. *See* Citizen Petition, FDA Dkt. No. 77P-0185, at 8 (May 26, 1977) ("[N]icotine is not only a powerful drug; it is also a tremendously powerful addicting agent for many (perhaps the majority) of smokers.").

40. The FDA found the assertions made by the petitioners inadequate to justify regulation. *See* Action on Smoking and Health [ASH] v. Harris, 655 F. 2d 236, 240 (D.C. Cir. 1980).

products because for nearly thirty years they have been required, by law, to report that information to the federal government.[41] In short, the suggestion that the FDA is now entitled to exercise jurisdiction, when it could not before, because the facts have changed simply is not plausible.[42]

Professor Sunstein's account of congressional actions in this arena—from the adoption of the FDCA in 1938, through the passage of the Federal Cigarette Labeling and Advertising Act in 1965, to Congress's enactment of legislation specifically to combat youth smoking in 1992—is similarly incomplete. The full story is recounted in the briefs submitted by the tobacco manufacturers in the suit pending in the Fourth Circuit and is too long to repeat here.[43] However, the reader needs to be familiar with certain highlights to appreciate the force of the manufacturers' claim that Congress has effectively precluded the FDA's regulation of tobacco products.

There is no evidence that any member of the 1938 Congress, which passed the FDCA, believed that it could, or should, apply to ordinary tobacco products. It had long been understood that the Pure Food and Drug Act of 1906[44]—the predecessor to the FDCA—did not apply to tobacco.[45] Efforts in the 1920s to enact legislation giving

41. *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1332, 1335-1340 (1994)). The fact that federal law requires information about nicotine content is evidence that the manufacturers are able to control it, within limits, in package after package, since they obviously do not test each package, much less each cigarette.

42. Professor Sunstein cites the belated discovery of the dangers of the pesticide DDT as an example of his theory that new facts may give an agency authority to act that it did not previously possess. *See* Sunstein, *supra* note 15, at 1031. Those dangers supplied the basis for the Environmental Protection Agency's ban of the pesticide in 1970 even though for years it had gone unregulated. This example does not support Professor Sunstein's argument. DDT had been subject to federal regulation at least since the passage of the Federal Insecticide, Fungicide, and Rodenticide Act in 1947, Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified at 7 U.S.C. § 136 (1994)). For the product to be lawfully sold, it had to be registered with the U.S. Department of Agriculture, *see* 7 U.S.C. § 136a(a) (1994), which surrendered responsibility for administering the FIFRA to the EPA in 1970. In short, the USDA's and, later, the EPA's regulatory jurisdiction was never in dispute. How they exercised that jurisdiction was of course subject to change if the facts changed. In the present case, it is the existence—and not the exercise—of jurisdiction over tobacco products that is in dispute.

43. [This appeal has since been decided *sub nom.* Brown & Williamson Tobacco Corp. v. FDA, Nos. 97-1604, 97-1581, 97-1606, 97-1614 and 97-1605, 1998 WL 473320 (4th Cir. Aug. 14, 1998). The Clinton Administration has requested an *en banc* rehearing. *See* Appellees' Petition for Rehearing, *Brown & Williamson* (No. 97-1604). –Eds.]

44. Pub. L. No. 59-384, 34 Stat. 768, 769 (1906).

45. The FDA's predecessor agency took the position that the 1906 Act could not apply to cigarettes unless they were marketed as promoting health. *See* BUREAU OF CHEMISTRY, U.S.

the FDA jurisdiction over tobacco were predicated on this understanding, and failed.[46] On several occasions following the enactment of the 1938 statute, the FDA repeated its position that it did not have jurisdiction.[47] This position was made clear during congressional debate over what measures Congress should take in response to the 1964 Surgeon General's Report on Smoking and Health.[48] The FDA was apparently willing *to be given* jurisdiction, and legislation to do precisely that was under consideration at the same time as bills to assign regulatory responsibility elsewhere. Ultimately, the bill that became the first Federal Cigarette Labeling and Advertising Act[49] was passed and the bill to give the FDA authority was withdrawn.[50] Thereafter, when Congress periodically revisited the question of how tobacco products should be regulated and what federal agency should be responsible, the "FDA option" was frequently discussed and always dismissed.[51]

Thus, it is fair to summarize the 1965 compromise and later events as confirming a "deal" struck in Congress—a deal in which the FDA was excluded from any role in federal decisionmaking about the health effects of tobacco use. This understanding, reached in 1965 and never later altered, continued until the FDA unilaterally repudiated it in 1996.

In the meantime, Congress had not been inactive. Between 1965 and 1992 it enacted five statutes addressed specifically to the contents, advertising, or labeling of cigarettes and smokeless tobacco products.[52] In 1992, the specific concerns that later triggered the

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DEP'T OF AGRIC., SERVICE AND REGULATORY ANNOUNCEMENTS, 13, 21, 24 (Feb. 1914).

46. *See* Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1381 (M.D.N.C. 1997) (noting that "in 1929, legislation which would have amended the 1906 Act to cover tobacco products was introduced . . . but never passed" (citing S. 1468, 71st Cong. (1929))).

47. *See supra* note 26 and accompanying text.

48. *See Hearings on H.R. 2248*, *supra* note 28, at 193.

49. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994)).

50. *See* H.R. 2248, 89th Cong. (1965) (introducing legislation, which was eventually withdrawn, to place tobacco within regulatory jurisdiction of the FDA).

51. *See Coyne Beahm*, 966 F. Supp. at 1382 (stating that "numerous bills which would have expressly granted the FDA authority to regulate tobacco products" had been proposed, and noting that none of these bills passed).

52. *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1332, 1335-1340 (1994)) (extending public health protection with respect to cigarette smoking); Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. § 290aa-4(b) (1994)) (requiring Secretary of Health and Human Services to submit a report every three years to

FDA's intervention—the belief that many young people commence smoking before they are eighteen and the conclusion that state enforcement of age limits has been lax—led Congress to enact legislation to address this very problem. That legislation has two significant features, both of which are inconsistent with the program that the FDA has constructed. First, the 1992 Act claims only a small role for the federal government: it provides federal funds for the Department of Health and Human Services to distribute to states that adopt vigorous programs to combat youth smoking.[53] Second, it leaves the authority to design and enforce such programs where it has always rested—with the states.[54] Ironically, the FDA's substitute program, fashioned just three years later out of statutory provisions enacted in 1938[55] and 1976[56] that do not mention tobacco, not only subordinates the states to the federal government but automatically disrupts many of their efforts. This is because the medical device provisions of the FDCA, on which the FDA relies (to escape a ban), contain an automatic preemption of state requirements that differ from or add to those imposed by the FDA.[57]

In sum, a full account of the relevant legal and administrative history reveals that the FDA repeatedly asserted that the FDCA gave it no authority to regulate ordinary tobacco products; that it

Congress detailing research findings regarding addictive properties of tobacco and making recommendations for legislative and administrative action); Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified at 15 U.S.C. §§ 1331-1333, 1335a-1337 (1994)) (establishing a national program to increase the availability of information on the health consequences of smoking and changing labeling requirements for cigarettes); Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408 (1994)) (providing for public education regarding the health consequences of using smokeless tobacco products); ADAMHA Reorganization Act of 1992, Pub. L. No. 102-321, § 1926, 106 Stat. 323, 394-95 (codified at 42 U.S.C. § 300x-26 (1994)) (conditioning each state's receipt of federal mental health and substance abuse funds on the state's imposition of a minimum purchase age of eighteen for tobacco products).

53. 42 U.S.C. § 300x-26(b) (1994).

54. *See id.*

55. *See* Federal Food, Drug, and Cosmetic Act, Pub L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. II 1997)).

56. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. (1994)) (establishing the framework for device regulation).

57. *See* 21 U.S.C. § 360(k) (1994). Because the FDA's reliance on the device provisions of the FDCA automatically displaces state requirements for tobacco products that are different from or in addition to those the FDA has established, the agency has found it necessary to set up a system for accepting petitions for exemption from preemption—as the law allows—and for giving such petitions expedited treatment. *See* Exemptions From Federal Preemption of State and Local Medical Device Requirements, 21 C.F.R. § 808.20 (1998).

never previously attempted to regulate such products; and that Congress knew and approved of the FDA position. Moreover, instead of giving the FDA the authority that all agreed it lacked, Congress chose a very different approach—embodied in a series of tobacco-specific laws which imposed requirements unlike those the FDA has suddenly prescribed, and which left primary responsibility for addressing the problem of youth smoking to the states.

The FDA obviously has concluded that the program Congress has devised is deficient. The Agency's response is to substitute, by administrative fiat, a wholly new scheme while seeking to avoid Commissioner Edwards' prediction that regulation under the FDCA would necessitate a ban.[58] In defense of this scheme, the FDA relies on novel interpretations of the Act that conflict with what the Agency—and Dr. Kessler[59]—previously have said are the fundamental premises of that legislation.

In his argument, Professor Sunstein deals only with the first prong of the industry challenge to the FDA's authority—the prong which argues that, reading all of the relevant statutes in historical context, Congress has precluded the FDA from regulating ordinary tobacco products. Professor Sunstein offers the following observation (which I have edited, I hope not unfairly, for emphasis): It is, he wrote, "exceedingly likely . . . that the enacting *Congress did not intend to give the FDA power over tobacco*."[60] This is close to a concession that a contextual approach to interpreting the jurisdictional language of the FDCA should lead to invalidation of the FDA's regulations.

II. FDA'S REGULATIONS CONFLICT WITH THE FDCA'S REQUIREMENTS FOR GENUINE MEDICAL DEVICES

I want to address an issue with which Professor Sunstein does not deal, but which is central to any fair assessment of the FDA's claim of jurisdiction over tobacco products. Broadly speaking the issue is whether the FDA's assertion of jurisdiction and the specific requirements of its regulations can be reconciled with the language, structure, and history of the FDCA. My argument is not merely that the FDA's specific regulations should be held arbitrary or

58. *See supra* note 31 and accompanying text.

59. *See infra* note 68 and accompanying text.

60. *See* Sunstein, *supra* note 15, at 1029 (emphasis added).

inconsistent with legal authority under section 706 of the Administrative Procedure Act[61]—although this narrower claim is surely implicit in what follows. Rather, my argument is that if the FDA's regulations conflict with the structure and language of the FDCA, this is convincing evidence that Congress has not given the FDA authority to regulate tobacco at all. In other words, if the requirements of the FDCA, as written and as interpreted by the FDA, cannot be made to fit tobacco products as the FDA describes them, the inference is inescapable that the statute does not give the FDA jurisdiction to regulate them.

The industry briefs in the lawsuit challenging the regulations describe numerous collisions between what the FDA purports to require or permit for tobacco products and what the FDCA requires or permits for genuine medical devices. Some of the specific conflicts are arcane, but several are straightforward and do not require detailed familiarity with food and drug law.

A. Conflict with the FDCA's Requirement that All Devices be "Safe and Effective"

The most obvious conflict between what the FDCA requires and the FDA's scheme for tobacco is exposed by the Agency's lengthy indictment of the effects of tobacco use. The Agency repeatedly characterizes cigarettes and smokeless tobacco products as unsafe.[62] Furthermore, it entirely avoids addressing whether they are effective for any health-related use. Taken at face value, these findings would preclude the continued marketing of tobacco products if they were "drugs"—as Commissioner Edwards testified[63] and as other agency officials have since acknowledged.[64] To avoid this obviously

61. *See* Administrative Procedure Act § 706(2)(A), 5 U.S.C. § 706(2)(A) (1994) ("The reviewing court shall – . . . (2) hold unlawful and set aside agency action, findings, and conclusions found to be – (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . .").

62. *See, e.g.*, FDA Regulations, *supra* note 4, at 44,398 ("[T]obacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses."). In the preamble to its proposal, the agency contended that "tobacco products are responsible for more than 400,000 deaths each year . . . . Cigarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murders, suicides, illegal drugs, and fires combined." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (proposed Aug. 11, 1995).

63. *See supra* note 31 and accompanying text.

64. *See supra* note 26 and accompanying text.

unsustainable result, the FDA contends that tobacco products may also be regulated as medical "devices."[65] This gambit, however, does not avoid the dilemma for, as FDA officials themselves have often insisted, the FDCA also forbids the marketing of any *device* that is not safe and effective for its intended use.[66]

The same year that the FDA adopted its tobacco regulations, the Deputy Commissioner of the FDA, William Schultz, told Congress (perhaps in a careless lapse) that: "A fundamental precept of drug *and device* regulation in this country is that these products must be proven safe and effective before they can be sold."[67] Four years earlier, in a defense of the FDA's action terminating the sale of silicone breast implants, Commissioner David Kessler wrote in the *New England Journal of Medicine*:

> The 1976 Medical Device Amendments . . . require that medical devices be shown by their manufacturers to be safe and effective before they may be distributed and used . . . [T]he law requires a positive demonstration of safety—and the burden of proof rests squarely with the manufacturer.[68]

This statement was, of course, made before the FDA decided that tobacco products were "medical devices."

B. Conflict with the FDCA's Prohibition of Devices Found to be"Dangerous to Health"

The FDCA's demand that any marketed device be safe is confirmed by section 502(j), which prohibits the marketing of any device that is "dangerous to health when used in the . . . manner . . . suggested in the labeling thereof."[69] The FDA has expressly found that "cigarettes and smokeless tobacco are dangerous products" when used as intended.[70] Congress itself so found in 1970, when, while affirmatively permitting the continued sale of cigarettes, it required

65. *See* FDA Jurisdictional Determination, *supra* note 6, at 45,208.

66. *See* Medical Device Amendments of 1976 §§ 513-515, 520, 21 U.S.C. §§ 360c-360e, 360j (1994).

67. *More Information For Better Patient Care: Hearing on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 83 (1996) (statement of William B. Schultz, Deputy Comm'r for Policy, FDA) (emphasis added).

68. David A. Kessler, *The Basis of the FDA's Decision on Breast Implants*, 326 NEW ENG. J. MED. 1713, 1713 (1992).

69. FDCA § 502(j), 21 U.S.C. § 352(j) (1994).

70. FDA Regulations, *supra* note 4, at 44,420.

them to be labeled as "dangerous to your health."[71] The FDA has not explained how the continued sale of tobacco products can be reconciled with this statutory provision, given its own findings about the hazards of tobacco use. Section 502(j) is clearly an impediment to the FDA's scheme, but apparently one the Agency considers so inconsequential—or so awkward—that it does not even address it.

C. Conflict with the FDCA's Exclusion of Chemical Agents from the Category of "Devices"

Another internal conflict exposes the FDA's willingness to distort the FDCA so that it may exert jurisdiction over tobacco products without having to ban their continued sale. The FDA contends that it may regulate tobacco products as medical devices even though they also are, or contain, "drugs" under the FDCA.[72] That is, the FDA takes the position that a product may fall within both regulatory categories. For some products this is true, but it is not true for products that achieve their intended effects through chemical action rather than by physical action (as, for example, a heart valve does). The FDCA definition of "device" specifically excludes products that achieve their intended effect through chemical action.[73] Whatever may be the effects on the body of nicotine (and other ingredients of cigarettes), they are achieved by chemical action. Such a product—if subject to FDA regulation at all—is a drug. But this conclusion would, obviously, imperil the FDA's scheme.[74]

D. Conflict with the FDCA's Labeling Requirements

Section 502(f)(2) of the FDCA provides that a device is misbranded—which means it may not be sold—if it fails to bear

71. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 4, 84 Stat. 87, 88 (1970) (codified as amended at 15 U.S.C. § 1333 (1994)) (requiring that cigarette packages bear one of several approved warning labels).

72. *See* FDA Jurisdictional Determination, *supra* note 6, at 45,207-08.

73. *See* 21 U.S.C. § 321(h)(3) (1994).

74. The FDA attempts to reconcile its resort to the device provisions of the Act with the statutory definition by claiming that tobacco products, as "drug delivery" systems, achieve their intended effect by mechanical and not chemical means. Their intended effect, according to the agency, is to get nicotine into the body. *See* FDA Jurisdictional Determination, *supra* note 6, at 45,205-18. Curiously, the FDA's legal theory does not seem to square with its assertions about the addictive properties of nicotine and the effects of tobacco, which, if true, would clearly be "chemical" in nature.

"adequate warnings against use . . . by children."[75] The statute permits no exceptions to this requirement. The FDA's attempt to regulate tobacco products is premised on its conclusion that they are now, but should not be, available to or used by persons under eighteen.[76] It would seem strange, if not outright inconsistent, for the Agency nonetheless to conclude that the current congressionally mandated warnings *are* "adequate" to protect against use by children. Yet, to avoid the conclusion that these label warnings—which the Agency realizes that it may not alter—do not satisfy the FDCA, the FDA has done precisely this. Congress's requirements for tobacco products, which the FDA manifestly considers insufficient, are, in this single instance, declared to be "adequate" under the FDCA.

The FDA itself once admitted that the FDCA does not "provide authority suitable to the regulation of cigarettes."[77] The FDA's tobacco regulations demonstrate the accuracy of this statement. The Agency contends that cigarettes are dangerous; the FDCA requires proof that any device be safe and effective. The FDA is determined to avoid banning cigarettes; yet the FDCA forbids the marketing of any device (or drug) that has the effects the FDA attributes to cigarettes. The FDA must find statutory support for its Draconian controls over tobacco advertising; but the FDCA does not authorize the FDA to impose such restrictions on the advertising of *any* device.[78] The FDA rejects the regulatory scheme for tobacco products that Congress has fashioned in other statutes, and substitutes a scheme of its own.

III. SECTION 360J(E) DOES NOT AUTHORIZE FDA TO REGULATE TOBACCO ADVERTISING

There is one other square conflict between what the FDA seeks to require of sellers of tobacco products and what the FDCA allows it

75. *See* 21 U.S.C. § 352(f)(2) (1994).

76. *See* Medical Devices: Cigarettes and Smokeless Tobacco, 21 C.F.R. §§ 897.2, 897.14(a) (1997).

77. Letter from Mark Novitch, *supra* note 27, at 3. Apparently the Senate supporters of the "global settlement" legislation sponsored by Senator John McCain have come to the same conclusion. The version of the McCain bill that garnered very strong committee support before the recent Easter recess would do what no statute has done before: give the FDA explicit jurisdiction to regulate tobacco products. It would not, however, as the FDA has attempted to do, shoehorn tobacco into provisions designed for medical products, but instead would add a brand new, tobacco-specific title to the FDCA. *See 11th-Hour Deal by White House, McCain Led to FDA Tobacco Plan*, FDA WEEK, Apr. 3, 1998, at 1, 10-12.

78. *See infra* text accompanying notes 81-91.

to require of producers of genuine medical devices. This conflict goes to the heart of the FDA's regulatory program, which consists mainly of restrictions on the advertising and promotion of tobacco products.[79] The goal of the FDA's regulations is to blunt the supposed appeal of tobacco products to young people by controlling how their sellers can advertise them.[80] Without their restrictions on tobacco advertising, the FDA's regulations are an empty shell.

The FDA's conviction that tobacco advertising must be curtailed provides a further explanation for its determination to regulate tobacco products as medical devices. If tobacco products were to be regulated as drugs under the FDCA, no one—not even the FDA—would contend that the Agency had authority to regulate their advertising. This is because the statute gives the FDA authority only over advertising of *prescription* drugs.[81] The Agency obviously has no wish to convert tobacco products into prescription drugs. It apparently hoped that the device provisions of the FDCA would provide the authority that the drug provisions fail to provide. This decision, however, cannot be explained on the ground that the device provisions specifically authorize the kind of advertising restrictions that the FDA seeks to impose, for they obviously do not. Sections 502(q) and 502(r) of the FDCA do allow the FDA to enforce certain limits on the advertising of what are called "restricted" devices,[82] but the FDA's restrictions on tobacco advertising bear no resemblance to such limits, and the Agency does not rely on section 502(q) or section 502(r) to support them.

Instead, the FDA relies on section 520(e) of the Act, which permits the Agency to restrict the "sale, distribution, or use" of specific devices if necessary to provide assurance that they will be safe and effective in use.[83] This provision is the counterpart to the section of the Act that allows the FDA to restrict drugs to

79. *See supra* notes 9-13 and accompanying text.

80. *See* FDA Regulations, *supra* note 4, at 44,465 ("The purpose of the advertising regulations is to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people."); Medical Devices: Cigarettes and Smokeless Tobacco, 21 C.F.R. §§ 897.30, 897.32, 897.34 (1997) (establishing regulations governing tobacco product advertising).

81. *See* 21 U.S.C. § 352(n) (1994).

82. *See* 21 U.S.C. § 352(q) (1994) (granting authority where false or misleading advertising is used in promotion of restricted devices); 21 U.S.C. § 352(r) (1994) (granting authority where requisite accompanying statements are omitted from advertising or other descriptive matter).

83. 21 U.S.C. § 360j(e) (1994).

prescription status.[84] But section 520(e) does not—just as section 503(b) does not—give the FDA authority to impose any restrictions on advertising. Section 520(e) does not mention "advertising" (or "promotion" for that matter), while sections 502(q) and 502(r)—enacted at very the same time—do.[85] Nor does the legislative history of section 520(e) contain any hint that the draftsmen believed it would be a source of authority to regulate or limit advertising.

Confirmation that section 520(e) does not give the FDA authority to regulate (much less virtually ban) advertising is provided by the history of the FDA and the FDCA. The original 1938 Act gave the FDA no authority to regulate advertising for *any* product within its jurisdiction.[86] This was no accident. A critical element of the legislative compromise that allowed the passage of the 1938 Act was the understanding that the FDA would not have authority to regulate the advertising of food, drugs, devices, or cosmetics.[87] Rather, that authority was delegated to the Federal Trade Commission in the contemporaneous Wheeler-Lea Amendments to the Federal Trade Commission Act.[88]

In short, the FDA had no advertising authority whatever under the original FDCA. Congress later modified this state of affairs on two occasions. In 1962, it gave the FDA the aforementioned authority to regulate advertisements for prescription drugs.[89] And in 1976, as part of the Medical Device Amendments[90] to the FDCA, the FDA was given the authority to enforce the specific limits on advertisements for restricted devices that appear in sections 502(q) and 502(r).[91]

84. *See* 21 U.S.C. § 321(n) (1994).

85. *Compare* 21 U.S.C. § 360j(e) (1994) (permitting the FDA to limit the "sale, distribution, or use" of restricted devices), *with* 21 U.S.C. § 352(r) (1994) (permitting the FDA to limit "advertising" of certain restricted devices in certain specified situations).

86. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 10,440 (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. II 1997)).

87. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 13-14 (1939).

88. *See* CHARLES JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL 145-46 (circa 1975); Cavers, *supra* note 87, at 13-14.

89. *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. § 321(n) (1994)).

90. Pub. L. No. 94-295, 90 Stat. 539 (1976).

91. *See* 21 U.S.C. § 352(q) (1994) (granting authority to prohibit false or misleading advertising for restricted devices); 21 U.S.C. § 352(r) (1994) (granting authority where required accompanying statements are omitted from advertising or other descriptive matter).

issue of jurisdiction. The FDA is attempting to impose a brand new regulatory regime—encompassing product composition, labeling, manufacture, and sale, as well as advertising—on an industry that has never before been subject to its control. By contrast, in *Chevron* itself the Supreme Court faced a question of how—and not whether—the Clean Air Act applied to certain sources of air emissions.[98] The EPA's conclusion that within-plant modifications should not be regulated under the provisions of the Act applicable to new sources did not mean that such plants fell outside the Act's jurisdiction.[99]

Furthermore, even if the Supreme Court were to rule—as it has not done yet—that deference should be given to an agency's interpretation of its own jurisdiction, a strong argument can be made that problematic assertions of jurisdiction should be more closely scrutinized than decisions that jurisdiction is lacking. This point is particularly salient in the present context, where the FDA's sudden assertion of jurisdiction occurs after several decades of denial and against a background of careful congressional attention to the boundaries of federal authority over tobacco.

It is not surprising, therefore, that Professor Sunstein acknowledges that the application of *Chevron* here is subject to doubt. In an important earlier article, he wrote:

> Does an agency have the authority to decide on its own jurisdiction? *Chevron* does not say. At least if the distinction between jurisdictional and nonjurisdictional determinations could be easily and sharply drawn, it would be tempting to say that *Chevron* is inapplicable to the former. If, for example, the Federal Communications Commission ("FCC") is deciding whether it has the power to regulate cable television, or the NLRB whether it can regulate independent contractors, one might think that the rule of deference ought not to apply. In Anglo-American law, those limited by law are generally not empowered to decide on the meaning of the limitation.[100]

98. *See Chevron*, 467 U.S. at 840-42.

99. The Court's conclusion that in-plant modifications did not require "new source" review, *see id.* at 866, might have meant that responsibility for regulating any emissions would be vested, in the first instance at least, with the states under EPA-approved implementation plans.

100. Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2097 (1990) (citations omitted).

Continuing, Professor Sunstein stated:

> Because congressional instructions are crucial here, courts should probably refuse to defer to agency decisions with respect to issues of jurisdiction—again, if we assume that the distinction between jurisdictional and nonjurisdictional questions is easily administrable. The principal reason is that Congress would be unlikely to want agencies to have the authority to decide on the extent of their own powers. To accord such power to agencies would be to allow them to be judges in their own cause, in which they are of course susceptible to bias.[101]

If a court were to follow this wise guidance, it should ignore Professor Sunstein's present argument and review the question of the FDA jurisdiction over tobacco products *de novo*.

But let us assume, *arguendo*, that *Chevron* provides the framework for evaluating the FDA's claim to jurisdiction. The district court, agreeing that *Chevron* did govern,[102] generally followed the FDA's reasoning—until it came to the Agency's claim to regulate the advertising for tobacco products.[103] However, the district court misinterpreted the Supreme Court's instructions and consequently awarded the FDA more deference than the case would justify. It assumed that the issue of FDA jurisdiction was resolved once it found that the FDCA's definitions were broad enough to encompass tobacco products and confirmed that the Act did not elsewhere expressly exclude them.[104] This reasoning would justify upholding the FDA regulation of any body-affecting product that Congress has not expressly excluded from the Act—including, for example, firearms,[105] performance-enhancing athletic wear, and exercise equipment.

The Supreme Court provided guidance to help courts avoid such counterintuitive conclusions. In *Chevron* itself it instructed that, in determining whether Congress has spoken directly to the issue raised by an agency's interpretation, a court should employ the traditional tools of statutory interpretation.[106] These include, of course, the text of a statute, but they also include its structure, the context of its

101. *Id*. at 2099.

102. *See* Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1379-80 (M.D.N.C. 1997).

103. *See id*. at 1397-1400.

104. *See id*. at 1380-81.

105. Could firearms be a "device" for delivering bullets?

106. *See* Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 n.9 (1984).

passage, its legislative history, its relationship with other relevant laws, and the degree to which its provisions "fit" the subject matter. The FDA's defense of its claim to jurisdiction, like Professor Sunstein's reprise, subordinates or ignores these other sources of interpretative guidance.

CONCLUSION

Professor Sunstein's approach combines literalism with a theory of political accountability deduced from the Supreme Court's opinion in the *Chevron* case. His argument, as I understand it, goes something like this: The FDCA definition of "drug" is broad enough to apply to tobacco since tobacco is not expressly excluded and the statutory language does not limit the kinds of evidence the FDA might rely upon to establish the "intended use" of an article. Yet the language does not say that tobacco *is* covered. Thus, the argument apparently continues, since Congress has not spoken directly to the question of whether the FDA may regulate tobacco under the FDCA, the Agency's assertion that the statute may apply should be accorded deference. Furthermore, and on this Professor Sunstein is quite explicit, it is appropriate that the FDA be given deference because the Agency acted with presidential approval, possibly at presidential direction, and thus its action can claim political legitimacy.[107] This claim is stronger, apparently, than the repeated actions of Congress which are, Professor Sunstein asserts, difficult to decipher and premised on incomplete understandings of the effects of tobacco and of the knowledge of those who market it.[108]

In the end, Professor Sunstein's argument is a claim of legislative authorization in only the very broadest sense. At bottom, it is a claim that, in the absence of express congressional prohibition, an administrative agency is entitled to extend federal authority into a new arena and to construct an entire regulatory program for an industry that has never before been subject to its jurisdiction. This is a remarkable claim, one that is not supported by the *Chevron* case, or any other precedent.

As I hinted at the beginning of this Essay, the reader will discern many points on which Professor Sunstein and I agree. His account of the history of the FDA's treatment of tobacco, although incomplete,

107. *See* Sunstein, *supra* note 15, at 1056-57.

108. *See id.* at 1049.

is generally fair. His acknowledgment that the Congress which enacted the law on which the FDA relies did not intend to give the Agency jurisdiction over tobacco is my conclusion too. And we also agree that the FDA's regulations are designed to implement the personal convictions of Commissioner Kessler and, critically, President Clinton. For Professor Sunstein, however, this characterization is not merely descriptive; it is the legitimating feature of the regulations.

Apparently the FDA agrees. In a recent article, William Schultz, FDA Deputy Commissioner for Policy and the primary architect of the Agency's tobacco regulations, offered the following account:

> In February 1994, an agency that had not been actively involved in the tobacco issue presented a new opportunity for tobacco regulation. In responding to a petition by a tobacco control group, Dr. David Kessler . . . announced that the FDA would investigate whether nicotine in tobacco products was a drug[109] that could be regulated by the FDA. *That was an historic decision because it provided an opportunity for taking decisive action on tobacco without requiring action by Congress.*[110]

In the final analysis the controversy over the FDA's tobacco regulations is a debate about the allocation of policymaking power within the national government. Is it for Congress to decide whether and how the national government should deal with the health effects of tobacco use and the access of children to tobacco products, or is this a subject for unilateral presidential choice? Congress did not give the FDA jurisdiction over tobacco products. It did not expect the FDA to claim that it has jurisdiction. And on the several occasions when Congress considered its options, it made conscious decisions to deal with the subject in other ways, through different instruments.

Acceptance of Professor Sunstein's defense of the FDA's authority to regulate tobacco would transform administrative law. The legitimacy of the American regulatory state rests on the premise that the power to enact national policy into law belongs to Congress. To be sure, the power to execute congressional policy, including the power to make subordinate choices contemplated by legislative framework, may rest with administrators. But the FDA's assertion of jurisdiction over tobacco and its substitution of a new regulatory

109. The reader will note the surprising omission of any reference to the term, or category, "device."

110. William B. Schultz, 18 PACE L. REV. 27, 28-29 (1997) (emphasis added).

program for one that Congress has enacted specifically for tobacco surpass the broadest limits on delegated authority ever recognized by U.S. courts.