An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco

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AN EXERCISE IN ADMINISTRATIVE CREATIVITY: THE FDA'S ASSERTION OF JURISDICTION OVER TOBACCO

The Food and Drug Administration (FDA) is the administrative agency charged with safeguarding the nation's food and drug supply. Like other executive branch agencies, the FDA executes its mission pursuant to statutory authority provided by Congress. The Federal Food, Drug, and

1. The FDA, in various organizational frameworks, has regulated the nation's food and drug supply since 1906, the year that Congress enacted the Federal Food and Drugs Act. Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, repealed in part by Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 9, § 902(a), 52 Stat. 1040, 1059 (1938); Michael Brannon, Organizing and Reorganizing FDA, in FOOD AND DRUG LAW 113, 115 (Food and Drug Law Inst. ed., 1991). The FDA finds its roots in the Bureau of Chemistry, the Department of Agriculture Agency responsible for enforcing the Federal Food and Drugs Act of 1906. Id. Since the FDA's initial organization, it has grown from an agency with a few hundred employees to an agency with approximately 7000 employees, and has survived nine major reorganizations. Id. Today, the Agency is a part of the United States Department of Health and Human Services. Id. at 113; see infra notes 18-25 and accompanying text (discussing historical aspects of the FDA’s jurisdiction to regulate drugs and medical devices).

Major expansions of the FDA’s regulatory authority tend to follow outrageous industry practices, public health tragedies, or significant scientific advances. Food industry practices that led to the Federal Food and Drugs Act of 1906, for example, often resulted in unsafe or unintended food additives. See C.C. Regier, The Struggle for Federal Food and Drugs Legislation, 1 LAW & CONTEMP. PROBS. 3, 7-8 (1933) (describing sausages and hamburger steak that contained boracic acid in amounts approaching five to ten times that of a typical medical dosage). The Federal Food, Drug, and Cosmetic Act of 1938 languished in Congress for four years until 1937, when a tragedy involving the drug Elixir Sulfanilamide claimed at least 73 lives. David F. Cavers, The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions, 6 LAW & CONTEMP. PROBS. 2, 20 (1939). After the Elixir Sulfanilamide tragedy, which animal testing or even a review of the scientific literature could have prevented, Congress granted the FDA authority to approve new drugs. See id. at 20, 40. Finally, expansions of the FDA’s authority often follow significant scientific advances. In enacting the Medical Device Amendments of 1976, for instance, Congress intended to increase the FDA’s authority to regulate the “increasing number of sophisticated, critically important medical devices [that] are being developed and used in the United States.” S. REP. No. 33, 94th Cong., 2d Sess. 2 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1071.

2. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)). Although the FDCA is the basis for much of the FDA’s modern regulatory framework, the FDA enforces other statutes. See 21 C.F.R. § 5.10(a) (1995) (delegating authority to the Commissioner of Food and Drugs to enforce certain statutory functions vested in the Secretary of Health and Human Services);
Cosmetic Act (FDCA or the Act) grants the FDA jurisdiction to regulate foods, drugs, medical devices, and cosmetics.3

Before the FDA may subject a product to its extensive regulatory controls, it first must determine that the product properly falls within its jurisdiction.4 This jurisdictional determination requires the FDA to interpret the definitional provisions of the FDCA.5 Because the FDA

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4. See Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1376 (9th Cir. 1983) (explaining that the FDA has “primary jurisdiction” to determine a product’s drug status). But see Premo Pharmaceutical Labs., Inc. v. United States, 629 F.2d 795, 801 (2d Cir. 1980) (holding that federal district courts and the FDA have concurrent jurisdiction in interpreting the “new drug” definition). The FDA’s authority to determine a product’s FDCA status, prior to judicial review, illustrates the doctrine of primary jurisdiction. United States v. Alcon Labs., 636 F.2d 876, 888-89 (1st Cir. 1981), cert. denied, 451 U.S. 1017 (1981); see Peter B. Hutt & Richard A. Merrill, Food and Drug Law 1276-83 (2d ed. 1991) (providing an overview of the primary jurisdiction doctrine): James T. O'Reilly, 1 Food and Drug Administration § 13.04, at 13-22 (2d ed. 1995) (stating that the Premo case closely represents legislative intent). The doctrine of primary jurisdiction serves three important purposes. Alcon Labs., 636 F.2d at 888-89. First, the doctrine helps to “coordinate administrative and judicial machinery.” Id. at 888 (quoting Mashpee Tribe v. New Seabury Corp., 592 F.2d 575, 580 (1st Cir.), cert. denied, 444 U.S. 866 (1979). Second, it facilitates uniform regulation, because one administrative agency is likely to be more consistent than multiple reviewing courts. Id. Third, it takes advantage of an administrative agency’s technical expertise, such as the FDA’s command of constantly evolving technologies and scientific principles. Id. at 889.

In this Comment, the term “jurisdiction” refers to the FDA’s authority to make the initial determination that the FDCA applies to a particular product. Additionally, the term refers to the FDA’s authority to categorize a product that is obviously inside the FDA’s ambit. See Gary E. Gammerman, Note, Intended Use and Medical Devices: Distinguishing Nonmedical “Devices” from Medical “Devices” Under 21 U.S.C. § 321(h), 61 Geo. Wash. L. Rev. 806, 808 n.13 (1993) (explaining that most FDCA litigation involves product categorization within the Act rather than the Act’s initial application to the product at issue).

5. See 21 U.S.C. § 321 (1994) (providing definitions); see also infra notes 26-99 and accompanying text (reviewing legislative and judicial interpretations of the FDCA’s drug and device definitions).
possesses broad powers, the Agency's assertion of jurisdiction often is disputed vigorously.\footnote{6}{See 21 U.S.C. § 332 (1994) (injunctions); id. § 334 (seizures of foods, drugs, and cosmetics); id. § 334(g) (detention orders for devices upon inspection and reasonable belief of adulteration or misbranding); id. §§ 372-374 (inspections); id. § 375 (publicity of judgments, decrees, and court orders rendered under the Act); id. §§ 381-382 (imports and exports); see also Scott Bass, Enforcement Powers of the Food and Drug Administration, in Food and Drug Law, supra note 1, at 61, 67 (noting that the FDCA is unusual because it permits both criminal and civil penalties for the same violations).}

In its most controversial action in years, the FDA recently added to the tobacco industry's miseries\footnote{7}{See Estee Lauder, Inc. v. FDA, 727 F. Supp. 1, 7 (D.D.C. 1989) (holding that a lawsuit challenging FDA drug jurisdiction asserted by regulatory letter was not ripe for judicial review). Manufacturers may challenge an FDA jurisdictional determination by seeking a declaratory judgment. See id. at 1 (seeking such judgment). A declaratory judgment, however, is not an available remedy until the FDA has taken a final agency position, and the manufacturer has exhausted its administrative remedies. 21 C.F.R. § 10.45(d)(1)(i) (1995); see generally 1 O'Reilly, supra note 4, §§ 7.01-.15 (describing civil actions involving FDA enforcement).} by asserting jurisdiction over nicotine-containing cigarettes and smokeless tobacco.\footnote{8}{See Irene Scharf, Breathe Deeply: The Tort of Smokers' Battery, 32 Hous. L. Rev. 615, 616-22 (1995) (summarizing developments affecting the tobacco industry). The United States Supreme Court recently held that federal tobacco legislation did not preempt all state common law claims brought against tobacco companies. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517-20 (1992). Disgruntled former smokers, who are often terminally ill, have sought millions of dollars in damages in unprecedented class action suits against the tobacco industry. See Castano v. American Tobacco Co., 870 F. Supp. 1425, 1434 (E.D. La. 1994) (refusing to dismiss a class action lawsuit on behalf of all persons addicted to nicotine), class certification granted, in part, 160 F.R.D. 544 (E.D. La. 1995). Additionally, at least five states have attempted to hold the tobacco industry liable for Medicaid costs that are linked to tobacco-related illnesses. See Frank Phillips, State Lawsuit Seeks $1 [Billion] from Tobacco Industry, BOSTON GLOBE, Dec. 20, 1995, at 25 (reporting lawsuits linked to Medicaid costs in five states). Concerned about the health effects of environmental tobacco smoke, some states have enacted strict bans on smoking in public places. See Md. Code Ann., Health-Gen. § 24-205 (Supp. 1995) (restricting smoking in hospitals, nursing homes, health clinics, and physician offices); id. § 24-501 to 505 (restricting smoking in retail establishments); see also Philip J. Hilts, States Adopt Stringent Smoking Bans, N.Y. Times, July 22, 1994, at A12 (discussing smoking bans in Maryland and California). Not to be excluded, many businesses have prohibited smoking also, including McDonald's. See Christopher J. Farley, The Butt Stops Here, Time, Apr. 18, 1994, at 58 (noting that McDonald's, the restaurant chain, banned smoking in its 1400 company-owned restaurants). Smoking is forbidden even in the White House. Id. at 60. 9. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (1995) (to be codified at 21 C.F.R. pts. 801, 803, 804, 897) (proposed Aug. 11, 1995) [hereinafter Proposed Regulations]; Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453 (1995) [hereinafter Analysis Regarding Agency Jurisdiction]; see, e.g., Ann Devroy & John Schwartz, FDA Given Power for Cigarette Rules, WASH. POST, Aug. 10, 1995, at A1; Michael K. Frisby & Hilary Stout, Clinton to Declare Nicotine in Cigarettes a Drug that Can}
products\textsuperscript{10} do not fall within the Act's reach.\textsuperscript{11} Despite this precedent, the Agency asserted that recent developments have brought tobacco products within the statutory definitions of "drugs" and "medical devices."\textsuperscript{12} Accordingly, the FDA has proposed regulatory measures addressing what the Agency considers to be the root of the nation's tobacco problem: tobacco use by persons under eighteen years of age.\textsuperscript{13}

The FDA's desire to regulate tobacco products is understandable. Tobacco products, which have been associated with cancer, cardiovascular disease, pulmonary disease, and other disorders,\textsuperscript{14} are said to cause more than 400,000 deaths each year.\textsuperscript{15} Nevertheless, the FDA's authority to


Not surprisingly, six tobacco manufacturers are challenging the FDA's proposed regulations. Coyne Beahm, Inc. v. United States FDA, No. 2:95CV00691 (M.D.N.C. filed Aug. 10, 1995). In their original complaint for declaratory and injunctive relief, the manufacturers—Coyne Beam, Inc., Brown & Williamson Tobacco Corp., Liggett Group, Inc., Lorillard Tobacco Co., Philip Morris Inc., and R.J. Reynolds Tobacco Co.—claim that the FDA's assertion of jurisdiction over tobacco violates the Federal Cigarette Labeling and Advertising Act, the FDCA, the Administrative Procedure Act, and the guarantees of free speech and due process in the United States Constitution. Id. at 2. This Comment focuses upon the FDA's statutory authority to regulate tobacco products; it does not address the complex first amendment and due process issues.

10. For the purpose of this Comment, the term "tobacco products" includes only nicotine-containing cigarettes and smokeless tobacco. The FDA's assertion of jurisdiction over tobacco products does not include cigars or pipe tobacco. See Analysis Regarding Agency Jurisdiction, \textsuperscript{supra} note 9, at 41,463-64 (concluding, without reference to cigars or pipe tobacco, that cigarettes and smokeless tobacco products fall within the FDCA's definitions of drug and device).

11. See Action on Smoking and Health v. Harris, 655 F.2d 236, 237 (D.C. Cir. 1980) (upholding the FDA's refusal to assert jurisdiction over cigarettes).

12. Analysis Regarding Agency Jurisdiction, \textsuperscript{supra} note 9, at 41,482 n.5. The FDA relied on three recent developments to justify a departure from its position that it lacked the jurisdiction to regulate tobacco products. Id. at 41,482. First, the FDA asserted that since it last evaluated its position, the Surgeon General of the United States and many major public health organizations have concluded that nicotine is addictive. Id. at 41,482 n.5. Second, the FDA exercised jurisdiction over alternative nicotine delivery systems, such as nicotine gums and transdermal patches. Id. at 41,482-83 n.5. Third, the FDA asserted that it has uncovered evidence indicating that the tobacco industry recognized nicotine's addictive properties and acted to facilitate the use of nicotine as an addictive drug. Id. at 41,483 n.5. Significantly, the FDA relied upon tobacco industry statements and research related to the manipulation of nicotine levels in cigarettes. Id. at 41,491-520.

13. Proposed Regulations, \textsuperscript{supra} note 9, at 41,314; see text accompanying infra notes 193-200 (describing proposed regulations).


regulate tobacco is questionable.\textsuperscript{16} After continuously denying its authority to regulate tobacco, is the FDA now in a position to assert tobacco jurisdiction? Attempting to answer this question in the affirmative, the FDA—an Agency with a rich history of interpreting the FDCA creatively—has advanced an interpretation of the Act’s definitional provisions beyond well-established boundaries.\textsuperscript{17}

This Comment examines whether the FDA’s assertion of jurisdiction over tobacco exceeds the Agency’s statutory authority to regulate drugs and medical devices. Focusing on the statutory definitions of “drugs” and “devices,” this Comment first reviews the plain language, legislative history, and judicial constructions of the FDCA’s definitional provisions. Next, this Comment surveys federal tobacco regulation, including the FDA’s limited role in regulating tobacco products. This Comment then analyzes the FDA’s current jurisdictional determination, finding a significant departure from existing FDCA standards. This Comment argues that Congress did not intend the FDA to regulate tobacco products as “drugs” or “medical devices,” absent certain public representations by tobacco manufacturers. This Comment further argues that the FDA’s jurisdictional determination is manifestly contrary to the Act’s organization and purpose. This Comment concludes that only Congress can provide a regulatory framework to deal with the health consequences of tobacco use.

I. Development of the FDA’s Drug and Device Jurisdiction

Comprehensive federal authority to regulate drugs and medical devices is a relatively new development.\textsuperscript{18} It was not until 1906 that Congress passed the Federal Food and Drugs Act (1906 Act), the first major legislative effort to provide a comprehensive scheme for federal regulation of illegal drugs, suicides, and fires combined. INSTITUTE OF MEDICINE, GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTH 3 (Barbara S. Lynch & Richard J. Bonnie eds., 1994) [hereinafter GROWING UP TOBACCO FREE].

16. See infra notes 290-300 and accompanying text (concluding that the FDA should regulate tobacco products only with an explicit authorization from Congress).

17. See infra notes 201-46 and accompanying text (analyzing the FDA’s jurisdictional determination).

18. See HUTT & MERRILL, supra note 4, at 6-10 (discussing 19th century state laws and scattered federal enactments regulating food and drugs); see also supra note 1 and accompanying text (discussing the origin of the FDA). See generally Wallace F. Janssen, America’s First Food and Drug Laws, 30 FOOD DRUG COSM. L.J. 665 (1975).
food and drugs. Although revolutionary at the time of its enactment, the 1906 Act’s reach was limited; rapidly emerging technologies soon revealed its many deficiencies. Thus, in 1933, New Deal reformers began the difficult and controversial task of amending the nation’s premiere food and drug statute. The five years of vigorous debate that followed culminated in the passage of the FDCA, the FDA’s enabling act and the basis for much of the Agency’s modern regulatory framework.


20. See Joel E. Hoffman, The Food and Drug Administration’s Administrative Procedures, in Food and Drug Law, supra note 1, at 1, 2 (discussing concerns that the 1906 Act would authorize federal intrusion into purely local activities such as food processing and drug manufacturing). See generally James H. Young, Pure Food: Securing the Federal Food and Drugs Act of 1906 (1989) (detailing six decades of relevant history preceding the enactment of the 1906 Act).

21. See Charles O. Jackson, Food and Drug Legislation in the New Deal 4-15 (1970) (detailing abusive industry practices that were beyond the reach of the 1906 Act); Hoffman, supra note 20, at 4 (noting that many regarded the 1906 Act as a failure). One notable weakness of the 1906 Act was its failure to provide for the regulation of false advertising. Jackson, supra, at 5. For example, one vendor promoted a product labeled “Crazy Crystals” as a cure for colitis, diabetes, and other diseases. Id. at 6. Because the crystals were actually a simple cathartic that became dangerous with repeated use, the FDA seized shipments of the product. Id. The vendor, however, was able to avoid federal regulation by shifting the claims from labeling to other forms of advertising. Id. One such testimonial advertisement boasted that “Crazy Crystals Pulled Me Out of the Grave.” Id. In addition to its failure to control false advertising, the 1906 Act also failed to reach cosmetics, medical devices, and drugs intended to affect the structure or function of the body. H.R. Rep. No. 2139, 75th Cong., 3d Sess. 2, reprinted in 6 A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 301 (1979) [hereinafter Legislative History]. Further, the 1906 Act did not require premarket testing of new drugs for safety. Id.

22. The FDCA was considered and enacted during the “New Deal.” Jackson, supra note 21, at 201-21. The New Deal, spanning the years 1933 to 1938, was characterized by numerous legislative and executive actions designed to deal with domestic matters, specifically the Great Depression. Id. at 201; see also Hoffman, supra note 20, at 5-11 (positing that Congress’ distrust of New Deal administrators was one reason for the five-year debate over the FDCA).

23. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)). An enabling statute, the foundation upon which an administrative agency is built, limits an agency’s power, so that acts exceeding the scope of the statute are invalid. See BLACK’S LAW DICTIONARY 526 (6th ed. 1990) (defining the term “enabling statute” as “any statute enabling . . . agencies to do what before they could not”). The FDCA is the FDA’s enabling statute. See 21 U.S.C. § 371(a) (1994) (providing authority to the FDA to promulgate regulations for the efficient enforcement of the Act); Bass, supra note 6, at 61 (providing an overview of the FDA’s statutory authorities and enforcement powers). In the FDCA, Congress limited the FDA’s power to act in several ways. First, the FDCA defines the categories of products that the FDA may properly regulate. See 21 U.S.C. § 321(f), (g), (h), (i) (1994) (defining “food,” “drug,” “device,” and “cosmetic”). Second, the FDCA outlines the prohibited acts that trigger FDA enforcement authority. Id. § 331. Third, the FDCA enumerates the FDA’s enforce-
FDCA delineates the scope of the FDA's drug and device jurisdiction and directs the FDA to ensure that drugs and medical devices are reasonably safe and effective.

A. The FDA's Drug Jurisdiction: The Impact of the "Structure or any Function" Clause

Through its extensive FDCA authorities, the FDA approves new drugs, seizes adulterated drugs, and seeks injunctions, civil penalties, and criminal sanctions for violations of the Act. Not surprisingly, vendors frequently dispute whether a given product is a "drug" within the meaning of the FDCA. See 21 U.S.C. § 321(g) (1994) (defining "drug"); id. § 321(h) (defining "device"); Stephen Weitzman, Drug, Device, Cosmetic?—Part I, 24 FOOD & DRUG L.J. 226, 230-47 (1969) (delineating, by history, the boundaries and overlap of the FDCA's definitional provisions).

The FDCA prohibits the marketing of new drugs without FDA approval, id. § 355 (1994) (requiring new drugs to meet safety and efficacy standards); id. § 360(c)(2) (requiring devices to meet safety and efficacy standards). The traditional route to obtaining FDA approval of a drug involves three major stages. Id. at 514-15. In the first stage, preclinical testing, a member of the pharmaceutical industry examines a compound's chemistry, pharmacology, and toxicology to determine its potential usefulness in humans. Id. at 514-15. Second, to gain permission to conduct clinical studies in humans, the drug's sponsor submits the preclinical research data to the FDA in a "Claimed Exemption for an Investigational New Drug" (IND). Id. at 515. If approved, the IND application permits the sponsor to proceed to clinical testing of the drug's safety and efficacy in human volunteers. Id. at 514, 516. After three phases of clinical studies, involving healthy subjects and potentially thousands of patients with the disease or condition that the drug is designed to treat, a drug's sponsor may choose to file a new drug application (NDA). See id. at 516 (noting that only ten percent of drugs obtaining the IND status will have sufficient merit to warrant a NDA). In the third and final stage of the drug approval process, the FDA evaluates the NDA, which presents both summaries and raw data relating to the drug's safety and efficacy. Id. at 519. If the drug gains FDA approval, the FDA releases a "summary of the basis of approval" to the public, id. at 531-32, and imposes various postapproval requirements, such as reports of adverse drug reactions, id. at 537.


25. 21 U.S.C. § 355 (1994) (requiring new drugs to meet safety and efficacy standards); id. § 360(c)(2) (requiring devices to meet safety and efficacy standards).

26. Id. § 355; see HUTT & MERRILL, supra note 4, at 513-37 (providing a comprehensive overview of the drug approval process and related considerations); 1 O'REILLY, supra note 4, § 13.11-.19 (same). The FDCA defines a "new drug" as "[a]ny drug... the composition of which... is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1) (1994). Except for an extremely narrow class of "grandfathered drugs," all substances the FDA deems to be "drugs" are also "new drugs" subject to the FDA's approval process. See 1 O'REILLY, supra note 4, § 13.06, at 13-34 (noting the heavy burden of proof required to obtain grandfather status).

The FDCA prohibits the marketing of new drugs without FDA approval, id. § 355(a), a process that takes about seven to thirteen years to complete. HUTT & MERRILL, supra note 4, at 514. The traditional route to obtaining FDA approval of a drug involves three major stages. Id. In the first stage, preclinical testing, a member of the pharmaceutical industry examines a compound's chemistry, pharmacology, and toxicology to determine its potential usefulness in humans. Id. at 514-15. Second, to gain permission to conduct clinical studies in humans, the drug's sponsor submits the preclinical research data to the FDA in a "Claimed Exemption for an Investigational New Drug" (IND). Id. at 515. If approved, the IND application permits the sponsor to proceed to clinical testing of the drug's safety and efficacy in human volunteers. Id. at 514, 516. After three phases of clinical studies, involving healthy subjects and potentially thousands of patients with the disease or condition that the drug is designed to treat, a drug's sponsor may choose to file a new drug application (NDA). See id. at 516 (noting that only ten percent of drugs obtaining the IND status will have sufficient merit to warrant a NDA). In the third and final stage of the drug approval process, the FDA evaluates the NDA, which presents both summaries and raw data relating to the drug's safety and efficacy. Id. at 519. If the drug gains FDA approval, the FDA releases a "summary of the basis of approval" to the public, id. at 531-32, and imposes various postapproval requirements, such as reports of adverse drug reactions, id. at 537.
meaning of the FDCA, and thus subject to FDA jurisdiction. 29 Of the four categories of drugs recognized by the FDCA, 30 21 U.S.C. § 321(g)(1)(C) defines the category that is perhaps most open to creative interpretation: "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 31

The drafters of § 321(g)(1)(C) intended to expand the definition of "drug" to bring within the FDA's jurisdiction products that had escaped regulation under the 1906 Act. 32 Concerned about fraudulent weight control products, 33 the drafters found the 1906 Act's definition of "drug" incomplete because it did not extend beyond products intended to affect

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29. See Hutt & Merrill, supra note 4, at 380 (noting that the product classification issue is frequently litigated); O'Reilly, supra note 4, § 13.03, at 13-8 (opining that the drug definition "may be the most litigated definition in the whole realm of [FDA] regulation").

30. The FDCA provides four definitions of the term "drug":
(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary ... and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).


Despite the specific statutory language in § 321(g)(1), courts have found a product's listing in the United States Pharmacopoeia undeterminative of its drug status. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 336-38 (2d Cir. 1977) (refusing to find that vitamins A and D were drugs despite listings in the United States Pharmacopoeia and the National Formulary). Because the 1890 edition of the United States Homoeopathic Pharmacopoeia included nicotine, this portion of the drug definition is of some interest to the tobacco issue. Health Consequences of Smoking: Nicotine Addiction: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong., 2d Sess. 149 n.6 (1988) (statement of Gregory N. Connolly, D.M.D., M.P.H.) (citing a 1984 Report of the Surgeon General). Apparently, nicotine deliberately was deleted from the Pharmacopoeia to gain votes in favor of the 1906 Act from tobacco states' legislators. Id. at 158. As the Pharmacopoeia and National Formulary are largely ignored in the drug classification process, however, nicotine's original listing is merely interesting tobacco trivia.


32. See H.R. Rep. No. 2139, supra note 21, at 3, reprinted in 6 LEGISLATIVE HISTORY, supra note 21, at 302. The Committee on Interstate and Foreign Commerce described the expanded drug definition:

The definition of drug is expanded to include articles used in the diagnosis of disease, and articles other than food intended to affect the structure or any function of the body of man or other animals. These expansions are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law.

Id.

33. See S. Rep. No. 361, 74th Cong., 1st Sess. 3, reprinted in 3 LEGISLATIVE HISTORY, supra note 21, at 662 (noting that some obesity cures were worthless and others dangerous to health); Ruth DeForest Lamb, American Chamber of Horrors: The Truth
The drafters thus invoked the "structure or any function" language to extend FDA jurisdiction to products intended to affect physiological conditions, such as obesity. From the beginning, the definition of drug turned on the vendor's intent; that is, whether a particular vendor intended its product to affect the structure or any function of the body.

For the most part, courts interpreting § 321(g)(1)(C) have approved expansions of the FDA's drug jurisdiction. In United States v. An Article . . . Sudden Change, the United States Court of Appeals for the Second Circuit held that a clear liquid lotion was a "drug" within the meaning of

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34. Federal Food and Drugs Act, Pub. L. No. 59-384, ch. 3915, § 6, 34 Stat. 768, 769 (repealed in part by Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 9, § 902(a), 52 Stat. 1040, 1059 (1938). The definition of "drug" in the 1906 Act included "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.” Id.

35. See H.R. REP. No. 2139, supra note 21, at 2, reprinted in 6 LEGISLATIVE HISTORY, supra note 21, at 301 (explaining that the FDCA would reach drugs intended to affect body weight). The Committee Report explained that “[d]rugs intended for . . . remedying underweight or overweight or for otherwise affecting bodily structure or function are subjected to regulation.” Id.

36. In discussing the standard of intent under the FDCA, this Comment uses the terms “vendor” and “manufacturer” interchangeably.

37. S. REP. No. 361, supra note 33, at 4, reprinted in 3 LEGISLATIVE HISTORY, supra note 21, at 663. The legislative history links the "intended use" determination to the manufacturer’s representations, including labeling and advertising, in connection with the sale of the product. Id.; see also Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338-39 (7th Cir. 1983) (holding that jurisdiction is established by the vendor’s intended use, not the product’s composition).

38. See, e.g., United States v. Storage Spaces Designated Nos. “8” & “49”, 777 F.2d 1363, 1366 (9th Cir. 1985) (holding that product advertisements suggesting that the product was similar to cocaine established statutory intent), cert. denied, 479 U.S. 1086 (1987); Schweiker, 713 F.2d at 339 (holding that a starch blocker intended to prevent the absorption of calories from starch foods was a § 321(g)(1)(C) drug); United States v. An Article . . . "Line Away Temporary Wrinkle Smoother, Coty", 415 F.2d 369, 372 (3d Cir. 1969) (holding that promotional materials depicting a product as an "amazing protein lotion" made in a "pharmaceutical laboratory" established statutory intent); United States v. Kasz Enters., Inc., 855 F. Supp. 534, 540 (D.R.I.) (holding that hair care products intended to make hair thicker were drugs because hair growth is a bodily function), amended on other grounds, 862 F. Supp. 717 (D.R.I. 1994); United States v. Undetermined Quantities of "Cal-Ban 3000", 776 F. Supp. 249, 255 (E.D.N.C. 1991) (holding that a product marketed as a weight reduction aid was a drug). But see United States v. An Article . . . "Magic Secret", 331 F. Supp. 912, 917 (D. Md. 1971) (holding that a vendor's claim that its lotion was a "pure protein" resulting in an "astringent sensation" did not establish an intent to affect the structure or any function of the body).

39. 409 F.2d 734 (2d Cir. 1969).
the FDCA. The manufacturer's advertisements in *Sudden Change* claimed that the lotion, comprising mostly distilled water and bovine albumin, provided a "face lift without surgery." Invoking the rule that the manufacturer's intended use determines the product's status as a drug under the FDCA, the Second Circuit noted that any relevant source, including the product label, advertising, and promotional materials may determine intended use. Further, to guide its evaluation of product claims, the Second Circuit applied a standard to determine whether "the ignorant, the unthinking, and the credulous" individual would believe that the product would affect a bodily structure or function. Reasoning that the vendor's references to "face lift" and "surgery" implied that the lotion could affect the structure of the body beyond merely altering an individual's appearance temporarily, the court concluded that the lotion was a drug under § 321(g)(1)(C).

The *Sudden Change* court, relying in part on the manufacturer's claim of a "face lift without surgery," focused on intent to affect the structure of the body. Similarly, in *United States v. Undetermined Quantities . . . "Pets Smellfree"*, the United States Court of Appeals for the Tenth Circuit focused on the manufacturer's intent to affect a function of the body—digestion. Advertisements for Pets Smellfree, a food additive for animals, claimed that the product would eliminate pet odors related to feces, urine, gas, and bad breath. Because Pets Smellfree purported to reduce intestinal bacteria, thus affecting the function of digestion, the Tenth Circuit concluded that Pets Smellfree was a drug under § 321(g)(1)(C).

Although a literal reading of the FDCA's "structure or any function" language would permit or even compel FDA jurisdiction over numerous articles, some courts have read this language narrowly. In one notable

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40. *Id.* at 742.
41. *Id.* at 737. The claims accompanying the lotion were essential to its drug status. *Id.* at 739. Consequently, the court explained that the lotion would cease to be a drug within the meaning of § 321(g)(1)(C) once the manufacturer retracted the promotional claims. *Id.* at 742.
42. *Id.* at 739.
43. *Id.* at 740 (quoting *Florence Mfg. Co. v. J.C. Dowd & Co.*, 178 F. 73, 75 (2d Cir 1910)).
44. *Id.* at 742.
45. *Id.* at 741.
46. 22 F.3d 235 (10th Cir. 1994).
47. *Id.* at 240.
48. *Id.* at 236. The Tenth Circuit noted that normal intestinal bacteria cause such pet odors, and Pets Smellfree reduced odors by reducing the number of bacteria in the animal's digestive system and oral cavities. *Id.* at 240.
49. *Id.*
In the case, *Action on Smoking and Health v. Harris*, the District of Columbia Circuit deferred to the FDA's refusal to assert jurisdiction over cigarettes as a § 321(g)(1)(C) drug. In *Action on Smoking and Health*, fourteen organizations and individuals filed a citizen's petition requesting that the FDA assert jurisdiction over cigarettes. When the FDA refused to assert jurisdiction, a citizen group, Action on Smoking and Health, brought suit to compel the FDA to assert jurisdiction. In evaluating the FDA's inaction, the court first examined whether cigarette vendors possessed the statutory intent. Because the record completely lacked evidence of the vendors' intent, the court concluded that *Action on Smoking and Health* failed to meet its burden of proving that tobacco vendors intended cigarettes to affect the "structure or any function" of the body. Further, the court rejected as overly broad a literal interpre-

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50. 655 F.2d 236 (D.C. Cir. 1980).
51. *Id.* at 237-38 (stating "the [FDA's] construction and application of [§ 321(g)(1)(C)] is entitled to substantial deference"). The District of Columbia Circuit did not address the issue of cigarettes as "medical devices" under the FDCA. *Id.* at 237 n.4.
52. *See* Administrative Procedure Act, 5 U.S.C. § 553(e) (1994) (providing that the public may petition administrative agencies to adopt or to alter rules); 1 O'REILLY, supra note 4, § 4.16, at 4-46 to 4-49 (providing an overview of the citizen's petition under the FDCA). While anyone may petition the FDA to issue, amend, or repeal regulations, the FDCA also provides for petitions under particular circumstances. *See* 21 U.S.C. § 348(b) (1994) (food additives); *id.* § 355(b)(1) (new drug applications); *id.* § 371(e) (miscellaneous provisions); *id.* § 376 (seafood inspections). Further, parties wishing to file lawsuits demanding FDA action on a particular subject must file the appropriate petition first. 21 C.F.R. § 10.45(a)-(c) (1995); *see* 1 O'REILLY, supra note 4, § 4.16, at 4-47.
53. *Action on Smoking and Health*, 655 F.2d at 237.
54. *Id.* The FDA argued successfully that agency jurisdiction must be predicated upon the vendor's representations about the product. *Id.* at 239-41. Absent health claims from cigarette vendors, the FDA consistently had refused to assert regulatory jurisdiction over cigarettes. *Id.* at 239. Further, the Agency asserted that FDA jurisdiction could not be based upon evidence of a serious health hazard. *Id.*
55. *Id.* at 238-41.
56. *Id.* at 239. The court noted that *Action on Smoking and Health* had failed to produce subjective evidence regarding the intent of cigarette vendors, such as vendor claims. *Id.* Additionally, the citizens' group had failed to produce objective evidence of vendor intent, such as labeling, promotional materials, and advertising. *Id.*
57. *Id.* at 240. *Action on Smoking and Health* argued that consumers use cigarettes to affect a structure or function of the body, and that such consumer use established the requisite vendor intent. *Id.* at 239. The court rejected this argument, but left open the possibility that consumer use alone could establish vendor intent. *Id.* For consumer use to be a relevant source for determining vendor intent, the evidence would have to be strong enough to justify an inference that the vendor intended the particular consumer use. *Id.* Although *Action on Smoking and Health* did not meet this "substantial showing," the court concluded that evidence that consumers use cigarettes "nearly exclusively" to affect a bodily structure or function would establish the requisite vendor intent. *Id.* at 239-40. Thus, a successful showing of the "nearly exclusively" standard of consumer use would render cigarettes a drug under the FDCA. *Id.* at 240.
tation of the "structure or any function" language.\textsuperscript{58} Given this narrow reading, § 321(g)(1)(C) will not apply where a product is intended to affect an insignificant or remote physical function of the body.\textsuperscript{59}

B. \textit{From Rags to Riches: The FDA's Medical Device Jurisdiction}

1. \textit{The Drug-Device Distinction and its Influence on the Scope of Regulation}

Although the 1906 Act did not authorize the regulation of devices,\textsuperscript{60} fraudulently promoted or "quack" devices became an increasingly com-

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\textsuperscript{58} \textit{Action on Smoking and Health}, 655 F.2d at 240. The District of Columbia Circuit clearly limited the reach of § 321(g)(1)(C):

Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article "intended to affect the functions of the body of man" . . . .

Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be. \textit{Id.} (quoting \textit{FTC v. Liggett \& Myers Tobacco Co.}, 108 F. Supp. 573, 576 (S.D.N.Y. 1952), \textit{aff'd}, 203 F.2d 955 (2d Cir. 1953)).

\textsuperscript{59} \textit{See E.R. Squibb and Sons, Inc. v. Bowen}, 870 F.2d 678, 682-83 (D.C. Cir. 1989) (confining the "structure or function" definitions to products that claim literally to change the physical structure of the body or to alter its basic functions).

\textsuperscript{60} \textit{H.R. REP. No. 2139, supra} note 21, at 3, \textit{reprinted in 6 LEGISLATIVE HISTORY}, supra note 21, at 302; \textit{see Weitzman, supra} note 24, at 230-46 (reviewing the legislative history of the FDCA definitional provisions). \textit{See generally} Peter B. Hutt, \textit{A History of
mon problem in the 1930s. Thus, when Congress enacted the FDCA, early drafts attempted to bring devices within the statutory definition of "drug." Colorful debates on the Senate floor revealed the controversial nature of this approach. Senator Clark, an outspoken critic of the expansive definition, contended that by classifying a mechanical device, such as a shoulder brace, as a drug, Congress would be enacting bad legislation. In response to these criticisms, Senator Copeland proposed an amendment containing a separate, although parallel, definition of device; Congress later approved this amendment without further debate. The debate between Senator Clark and Senator Copeland foreshadowed, however, the confusion that would continue to cloud the drug-device distinction.


61. See Lamb, supra note 33, at 132 (exposing fraudulent devices of the 1930s). Ineffective and dangerous devices thrived under the 1906 Act. Id. Fraudulent devices marketed during that period included nose straighteners, eyeball exercisers, whistles for developing weak lungs, height-stretching machines, and heated rubber applicators marketed as cures for prostate gland disorders. Id.


63. See 79 Cong. Rec. 4840-51 (1935), reprinted in 3 Legislative History, supra note 21, at 796-807 (setting forth a 1935 debate between Senators Copeland and Clark regarding the device definition in S. 5).

64. 79 Cong. Rec. 4841, reprinted in 3 Legislative History, supra note 21, at 797. Senator Clark criticized the definition as a "palpable absurdity" that was irreconcilable with the common meaning of the term device. Id. In Senator Clark's view, the effect of the illogical definition was "the same thing as if the Congress of the United States should attempt to say by law that calling a sheep's tail a leg would make it a leg." Id.

65. See Weitzman, supra note 24, at 237-38 (noting that the committee's revision of the device definition was in part a result of Senator Clark's objections). Under the FDCA, the terms "drug" and "device" are defined in a parallel manner:

The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (1994); see id. § 321(g)(1) (defining the term "drug").

66. See infra notes 67-99 and accompanying text (discussing major developments in the FDA's device jurisdiction).
Technological advancements in the 1960s resulted in many products that fell into a legal grey area between "drugs" and "devices." Because the FDA's authority to regulate drugs was significantly broader than its authority to regulate devices, the FDA used this legal grey area to classify many products with device characteristics as "drugs." This FDA practice of stretching the drug definition led to two influential decisions: AMP, Inc. v. Gardner and United States v. An Article of Drug... Bacto-Unidisk. In AMP, the United States Court of Appeals for the Second Circuit held that surgical blood vessel loops and clamps, products intended to reconnect severed blood vessels, were drugs and not devices. In making this seemingly awkward ruling, the Second Circuit noted first that, except for the FDA's premarket approval authority over drugs, the distinction between "drugs" and "devices" was insignificant. Accordingly, the court reasoned that products should be classified with reference to Congress' purpose in enacting the premarket approval provisions of the Act: the prevention of inadequately tested medical products from entering interstate commerce. Despite the obvious mechanical nature of these products, the Second Circuit found that they presented many of the same threats to public health as "drugs" and thus should be regulated as drugs.

67. See S. REP. NO. 33, supra note 1, at 17, reprinted in 1976 U.S.C.C.A.N. 1070, 1087 (noting the confusion surrounding the definitions of "drugs" and "devices"). Examples of sophisticated products that did not fall neatly into either the drug or the device category included implants and in vitro diagnostic products. Id. The Medical Device Amendments of 1976 added such products to the definition of "device," thus clarifying a confusing issue. Id.

68. Prior to 1976, the premarket approval power was the most significant difference separating the FDA's drug authorities from the device authorities. Rodney R. Munsey & Howard M. Holstein, Medical Device Regulation, In Transition, in FOOD AND DRUG LAW, supra note 1, at 371, 372. The lack of advance approval power forced the FDA to control devices through post facto regulation, namely by bringing enforcement actions in court. Id. The Medical Device Amendments of 1976 provided premarket approval authority for devices as well as drugs to remedy this power imbalance. Compare 21 U.S.C. § 355 (1994) (authority to approve new drugs) with 21 U.S.C § 360e (1994) (authority to approve new devices).

69. See Hoffman, supra note 20, at 28-29 (detailing FDA's history of obtaining increased authority through reinterpretation of definitional provisions.)

70. 389 F.2d 825 (2d Cir.), cert. denied, 393 U.S. 825 (1968).


72. AMP, 389 F.2d at 830.

73. Id. at 829 (relying on legislative history).

74. Id.

75. Id. at 830. The Second Circuit limited "devices" to items Congress intended expressly to regulate as devices. Id.
Similarly, in *Bacto-Unidisk*, the United States Supreme Court held that a paper disc containing antibiotics was a § 321(g)(1)(B) drug.\(^7^6\) Chief Justice Warren, writing for the majority, noted the 1935 Senate floor debate concerning the scope of the term "drug," and found that the distinction between drugs and devices was semantical.\(^7^7\) Relying on this semantical distinction, coupled with the FDCA's remedial purpose, the *Bacto-Unidisk* Court read the definition of "drug" broadly, and upheld the FDA's contention that the cardboard disks were classified properly as "drugs" under the Act.\(^7^8\) Commentators criticized *AMP* and *Bacto-Unidisk* sharply as "judicial legislation,"\(^7^9\) and both decisions helped to bring about the Medical Device Amendments of 1976.\(^8^0\)


The Medical Device Amendments of 1976 ushered in the modern era of medical device regulation.\(^8^1\) This legislation represented a compromise between the regulated industry, the FDA, and Congress: the regulated industry wanted clarified regulations that would not stifle development;\(^8^2\) the FDA wanted expanded regulatory powers without resorting to illogical interpretations of FDCA definitions;\(^8^3\) and Congress

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77. *Id.* at 797-98. The Court listed several products for which a drug classification would have been absurd, and concluded that Congress added a separate device definition merely to avoid incongruous results. *Id.* at 796. For example, the legislative history listed the following products as demonstrative of the potential absurdity of a single definition: shoulder braces, crutches, radium belts, electrical devices, bathroom weight scales, and hospital air conditioners. *Id.*
78. *Id.* at 799-800.
79. See Vincent A. Kleinfeld, *Surgical Implants: Drugs or Devices, and New Device Legislation*, 23 Food Drug Cosm. L.J. 510, 518 (1968) (stating that the *AMP* court based its product classification on policy and not legal justifications, and that the products at issue were "clearly devices"); Joseph R. Radzius, *Medical Devices and Judicial Legislation*, 27 Food Drug Cosm. L.J. 639, 642-43 (1972) (citing *AMP* as an "excellent example of judicial legislation"); Stephen Weitzman, *Drug, Device, Cosmetic?—Part II*, 24 Food Drug Cosm. L.J. 320, 341 (1969) (examining *AMP* and *Bacto-Unidisk* and concluding that "[n]o doubt there may be concern for better consumer protection, but it is for Congress, not the courts, to legislate").
81. 1 O'REILLY, *supra* note 4, § 18.01, at 18-1 to 18-2.
82. *Id.* at 18-7 n.42.
83. *Id.* at 18-6 to 18-7.
wanted to ensure public safety and product development while preventing excessive expansion of the FDA's device jurisdiction.\textsuperscript{84} The Medical Device Amendments, an extremely complex piece of legislation, effected two significant changes in the FDA's device jurisdiction.\textsuperscript{85} First, the Amendments clarified the definition of “device,” carefully distinguishing “device” from “drug.”\textsuperscript{86} Second, even if a product properly is regulated as a device, the Amendments required the FDA to classify the device into one of three groups, each of which is subject to varying regulatory authority.\textsuperscript{87} The classification requirement epitomized

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\item \textsuperscript{84} Id. at 18-7. Congress repeatedly has expressed concern about the FDA's ability to expand its jurisdiction arbitrarily. 79 CONG. REC., supra note 63, at 4841, reprinted in \textit{Legislative History}, supra note 21, at 797 (statement of Sen. Clark). Prior to the passage of the FDCA, Senator Clark of Missouri opined that “[t]he language . . . in the bill is broad enough to cover any device of which the [FDA] chooses to take jurisdiction.” Id. A similar concern surfaced during the debate preceding the Medical Device Amendments of 1976, when one representative remarked that “this classification of devices pretty well includes everything, or well nigh everything in creation.” 122 CONG. REC. 5851 (1976) (statement of Rep. Collins). The Medical Device Amendments, however, reflected these concerns about the FDA's regulatory zeal: “[T]his body quite understandably is suspicious of regulatory legislation. But there need be no concern over this conference report. It has been carefully designed so that the least regulation necessary to assure safety and effectiveness will be applied to devices.” 122 CONG. REC. 13,778 (1976) (statement of Rep. Rogers, Chairman of the Health and Environment Subcommittee). Thus, Congress designed the Amendments specifically to authorize FDA regulation in proportion to the public health risk. \textit{See infra} note 88 and accompanying text (discussing the medical device classification system, the framework that allows the FDA to vary the extent of regulation in proportion to the risk presented to the public health).
\item \textsuperscript{85} A complete discussion of the Medical Device Amendments is beyond the scope of this Comment. For more detailed information, see generally \textit{The Food and Drug Law Institute, An Analytical Legislative History of the Medical Device Amendments of 1976} (Daniel F. O'Keefe, Jr. & Robert A. Spiegel eds., 1976) (organizing the legislative history according to specific subsections of the Amendments); Munsey & Holstein, supra note 68 (setting forth the history of the Amendments and the resulting regulatory schemes).
\item \textsuperscript{86} Medical Device Amendments of 1976, Pub. L. No. 94-295, § 3(a), 90 Stat. 539, 575 (codified as amended at 21 U.S.C. § 321(h) (1994)). Retaining much of the drug-device distinction first promulgated in 1976, the FDCA currently provides two important distinctions between drugs and devices. 21 U.S.C. § 321(h)(3). First, unlike a drug, a device cannot “achieve its primary intended purposes through chemical action within or on the body.” Id. Second, a device must not be “dependent upon being metabolized for the achievement of its primary intended purposes.” Id. The Medical Device Amendments provided mutually exclusive definitions of “drug” and “device”; however, the Safe Medical Device Act of 1990 eliminated this distinction by recognizing drug-device combination products. Safe Medical Devices Act of 1990, § 16, 104 Stat. 4511, 4526; \textit{see infra} notes 92-93 and accompanying text (describing the FDA's authority to regulate products as drug-device combinations).
\item \textsuperscript{87} Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540-41 (codified as amended in scattered sections of 21 U.S.C.). The Amendments designated the groups as Class I, General Controls; Class II, Performance Standards; and Class III, Premarket Approval. \textit{Id}.
the spirit of the legislation, which sought to correlate the amount of device regulation with the health risks and benefits of each device.88 Although the regulated industry, Congress, and the FDA supported the Medical Device Amendments enthusiastically, the law's complexity caused implementation problems.89 In response, Congress enacted the Safe Medical Devices Act of 1990 (SMDA).90 The SMDA, known primarily for strengthening and streamlining the Medical Device Amendments, also affected the FDA's device jurisdiction.91 In the SMDA, Congress recognized drug-device combination products for the first time.92 Thus, after 1990, the FDA enjoyed increased flexibility in regulating products with characteristics of both drugs and devices, such as pre-filled syringes or surgical scrub brushes impregnated with antimicrobial agents.93

88. Munsey & Holstein, supra note 68, at 378. The device classification system also is known as the “tiered system of regulation.” Id. Class I devices require the least amount of regulation to ensure safety and effectiveness; thus, the general FDCA controls relating to the prevention of adulteration, misbranding, and similar concerns will suffice. 21 U.S.C. § 360c(a)(1)(A) (1994). Examples of Class I devices include cholesterol testing systems, 21 C.F.R. § 862.1175 (1995), microscopes, id. § 864.3600, and some surgical instruments, such as forceps, id. § 870.4500. For Class II devices, the general FDCA controls will not ensure safety and effectiveness. 21 U.S.C. § 360c(a)(1)(B) (1994). Rather, the FDA must establish performance standards, with the help of independent advisory panels, to protect the public health adequately. Id. § 360c(b)(1). Devices in Class II include portable oxygen generators, 21 C.F.R. § 868.5440 (1995), and blood gas monitors used in open heart surgeries, id. § 870.4330. Finally, Class III devices are those that present the most significant risks to public health. 21 U.S.C. § 360c(a)(1)(C) (1994). For these devices, the FDA requires premarket approval. Id. Class III devices include life-support systems, 21 C.F.R. § 860.93 (1995), and certain cancer detection tests, id. § 866.6010.


91. See id. § 16, 104 Stat. at 4526 (affecting the FDA’s device jurisdiction by allowing combination devices and by clarifying the device definition); see also infra note 93 (discussing the jurisdictional disputes concerning combination devices that have arisen within the FDA).

92. § 16, 104 Stat. at 4526. The FDA’s regulations define “combination product” as a “product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.” 21 C.F.R. § 3.2(e)(1) (1995). The FDA’s current tobacco analysis classifies cigarettes and smokeless tobacco as “combination products.” See infra notes 180-86 and accompanying text (describing the FDA’s classification of tobacco products).

93. See FDA, INTERCENTER AGREEMENT BETWEEN THE CENTER FOR DRUG EVALUATION AND RESEARCH AND THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (Oct. 31, 1991), reprinted in 3 Food & Drug L. Rep. (FDLI) No. 2, at supp. 44 (Feb. 1992) (outlining possible regulatory schemes) [hereinafter INTERCENTER AGREEMENT]. Within the FDA, specialized offices or “Centers,” such as the Center for Drug Evaluation and

Relatively few federal courts have interpreted the "structure or any function" language of § 321(h)(3). Moreover, the few decisions that do exist provide little interpretive guidance beyond merely stating the features needed to render the product a "device" under § 321(h)(3). Nevertheless, one case demonstrates the breadth of this language aptly: *United States v. 23 Articles [... Time to Sleep]*.95

In *Time to Sleep*, the United States Court of Appeals for the Second Circuit held that a phonograph record promoted as a cure for insomnia was a device within the meaning of § 321(h)(3).96 As a preliminary matter, the Second Circuit found that a phonograph record, consistent with the statutory language, was a contrivance.97 The Second Circuit noted...
that expert testimony unanimously indicated that sleep is a function of the body.\textsuperscript{98} Relying on this expert testimony, the Second Circuit concluded that the record fell within the statutory definition of "device" because it was intended to affect sleep, a function of the body.\textsuperscript{99}

C. Judicial Review of FDA Decisions

Disputes about FDA jurisdiction frequently lead to judicial review of FDA interpretations of the FDCA. Throughout decisions reviewing the Agency's interpretations, two themes persist: the need to construe remedial legislation broadly,\textsuperscript{100} and the applicability of the framework the Supreme Court established in \textit{Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.}\textsuperscript{101}

1. Remedial Legislation

The FDCA is an example of remedial legislation.\textsuperscript{102} Congress designed the Act specifically to authorize the FDA to promulgate regulations in
the public interest. \(^{103}\) Not surprisingly, the Agency’s mission to protect the public health entitles FDA decisions to a considerable amount of judicial deference. \(^{104}\) Such deference often results in broad readings of FDCA provisions, including product definitions. \(^{105}\) Accordingly, despite occasional setbacks, \(^{106}\) the Agency is a tremendously successful litigant. \(^{107}\)

\(^{103}\) See S. REP. No. 361, supra note 33, at 2, reprinted in 3 LEGISLATIVE HISTORY, supra note 21, at 661 (explaining that the FDCA was intended “to safeguard the public health and to promote honesty and fair dealing”).

\(^{104}\) See Nancy L. Buc & Deborah F. Neipris, The Food and Drug Administration and the Supreme Court, in FOOD AND DRUG LAW, supra note 1, at 93, 94 (noting that the United States Supreme Court has been hospitable to expansive applications of the Act); see also Community Nutrition Inst., 476 U.S. at 981-82 (allowing the FDA to decide whether to set tolerance levels for certain harmful substances in foods); Heckler v. Chaney, 470 U.S. 821, 837-38 (1985) (holding that the FDA’s refusal to undertake an enforcement action was unreviewable); United States v. Generix Drug Corp., 460 U.S. 453, 459 (1983) (upholding an FDA interpretation that the term “drug” included inactive as well as active ingredients); United States v. Rutherford, 442 U.S. 544, 553-54, 559 (1979) (refusing to enjoin the FDA from imposing safety and efficacy requirements on a drug intended for use with terminal patients); United States v. Park, 421 U.S. 658, 676 (1975) (interpreting the Act to impose a duty to prevent, as well as remedy, violations); United States v. An Article of Drug... Bacto-Unidisk, 394 U.S. 784, 791-92 (1969) (deferring to the FDA’s determination that a cardboard disk containing antibiotics was a “drug”); Kordel v. United States, 335 U.S. 345, 349 (1948) (extending “labeling” to include any materials used in distribution and sale, despite lack of physical connection to product); United States v. Walsh, 331 U.S. 432, 438 (1947) (allowing the FDCA to reach an intrastate shipment of goods, provided that the recipient engaged in interstate commerce); United States v. Dotterweich, 320 U.S. 277, 281-82 (1943) (approving a rule of strict criminal liability for corporate officers). In Dotterweich, Justice Frankfurter, writing for the majority, justified a broad reading by reference to the Act’s purpose to protect the consumer:

The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

\(^{105}\) Id. at 280.

\(^{106}\) See Bacto-Unidisk, 394 U.S. at 798. In Bacto-Unidisk, Chief Justice Warren, writing for the majority, gave the FDCA a broad reading: “[W]e must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health.” Id.

\(^{107}\) See, e.g., National Nutritional Foods Ass’n v. Mathews, 557 F.2d 325, 336 (2d Cir. 1977) (rejecting the FDA’s attempt to classify high dosage vitamins as drugs); United States v. An Article of Drug... “OVA II”, 414 F. Supp. 660, 664-65 (D.N.J. 1975) (refusing to defer to the FDA’s classification of a home pregnancy test as a “drug”), aff’d without op., 535 F.2d 1248 (3d Cir. 1976); United States v. An Article of Drug... “Helene Curtis Magic Secret”, 331 F. Supp. 912, 917 (D. Md. 1971) (holding that a lotion was not a drug despite its advertisements).

\(^{107}\) See 1 O’REILLY, supra note 4, § 7.01, at 7-2 (noting that litigants opposing the FDA are at “an extreme disadvantage”); see also supra notes 104-05 (discussing judicial deference and the resulting broad readings of the Act).
2. The Chevron Framework

The most significant guidance for courts reviewing an agency's interpretation of its organic statute is the framework the Court announced in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*108 In *Chevron*, the United States Supreme Court reviewed the Environmental Protection Agency's (EPA) interpretation of the term "stationary source" in the Clean Air Act Amendments of 1977.109 The EPA construed the term broadly, permitting states to treat pollution-emitting devices within one industrial grouping as one source of pollution, as opposed to requiring states to treat each individual device as one source.110 The Court held that the EPA's interpretation of the term was a permissible construction of the statute.111

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109. *Chevron*, 467 U.S. at 839-40. Justice Stevens, writing for the majority, noted that in the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (Amendments), Congress attempted to improve the nation's air quality by imposing strict requirements on states that did not attain defined air quality goals. Id. The legislation required those "nonattainment" states to meet stringent conditions prior to adding or modifying a "stationary source", which is a pollution-emitting device. Id. at 840. The EPA permitted the nonattainment states to adopt a plantwide definition of "stationary source," thus treating pollution-emitting devices within one industrial grouping as one source of pollution. Id. Under the EPA regulations, an existing plant was able to add or modify equipment without meeting the stringent standards that the Amendments imposed, so long as the alteration did not increase the plant's total emissions. Id. The National Resources Defense Council asserted that the EPA based its regulations on an impermissible interpretation of the term "stationary source," and challenged the EPA regulations. Id. at 840-41.

110. Id. at 840.

111. Id. at 866.
In order to analyze the EPA's interpretation of the statute, the Court adopted a two-pronged standard for judicial review of an agency's construction of its enabling statute.\textsuperscript{112} First, a reviewing court must ask "whether Congress has directly spoken to the precise question at issue."\textsuperscript{113} If congressional intent is clear, the court need not address the second prong; the court and the agency must defer to Congress' unambiguously expressed intent.\textsuperscript{114} However, if congressional intent is ambiguous, the court must confront the second prong of the \textit{Chevron} analysis: whether the agency's construction of the statute is permissible.\textsuperscript{115} Under the second prong of the \textit{Chevron} framework, an agency's construction of its enabling statute is "permissible" so long as the construction is a "reasonable" interpretation of the statutory language.\textsuperscript{116} Thus, the \textit{Chevron} framework, or at least the second prong, affords maximum deference to an agency's interpretation of its enabling statute.\textsuperscript{117}

\section{The Intricate Web of Federal Tobacco Regulation}

\subsection{Federal Regulatory Schemes for Tobacco Advertising and Labeling}

Several federal agencies subject tobacco, at all stages of production, to considerable regulation. The Bureau of Alcohol, Tobacco, and Firearms

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\begin{enumerate}
\item Id. at 842-43. \textit{But see} Thomas W. Merrill, \textit{Judicial Deference to Executive Precedent}, 101 \textit{Yale L.J.} 969, 976 (1992) (asserting that the \textit{Chevron} Court may have believed its two-pronged test did not deviate from Supreme Court precedent, but merely restated the prior law).
\item \textit{Chevron}, 467 U.S. at 842.
\item Id. at 842-43.
\item Id. at 843.
\item Id. at 843-44. \textit{Chevron} and its progeny provide little guidance for determining when agency interpretations will be "reasonable." Sunstein, \textit{supra} note 108, at 2104. Indeed, Professor Merrill notes that most of the cases rejecting the agency's interpretation have turned on \textit{Chevron}'s first prong, whether Congress has spoken on the precise question at issue. \textit{See} Merrill, \textit{supra} note 112, at 980-93 (providing and describing data regarding Supreme Court cases that have addressed whether deference should be afforded to an administrative interpretation of a statute). Nevertheless, the "reasonable" standard probably is similar to the well-known "arbitrary or capricious" standard. Sunstein, \textit{supra} note 108, at 2105; \textit{cf.} \textit{Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.}, 463 U.S. 29, 43 (1983) (indicating that "an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended [the agency] to consider").
\item \textit{Chevron}, 467 U.S. at 842-44.
\end{enumerate}
\end{footnotesize}
(ATF),\textsuperscript{118} the FDA,\textsuperscript{119} the Federal Trade Commission (FTC),\textsuperscript{120} the Internal Revenue Service (IRS),\textsuperscript{121} and the Department of Agriculture\textsuperscript{122} all play current or potential regulatory roles. Congress announced the regulatory schemes most relevant to the FDA's assertion of jurisdiction over tobacco, however, in two relatively recent enactments: the Federal Cigarette Labeling and Advertising Act (FCLAA)\textsuperscript{123} and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA).\textsuperscript{124} Significantly, neither the FCLAA nor the CSTHEA provides a regulatory role for the FDA.\textsuperscript{125}

In the FCLAA, Congress purported to "establish a comprehensive Federal Program to deal with cigarette labeling and advertising" as they pertain to the relationship between smoking and health.\textsuperscript{126} The statute sets forth two explicit purposes for federal involvement. First, the FCLAA attests to Congress' intent to keep the public informed of the

\textsuperscript{118} See 27 C.F.R. \S\S 270.61-.76 (1995) (authorizing the Bureau of Alcohol, Tobacco, and Firearms to qualify tobacco manufacturers and to regulate the process of manufacturing tobacco products).

\textsuperscript{119} See United States v. 354 Bulk Cartons ..., Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959) (holding that a vendor's cigarettes were "drugs" within the meaning of the FDCA because the vendor's claims demonstrated that the product was intended to affect bodily structure); United States v. 46 Cartons ... Fairfax Cigarettes, 113 F. Supp. 336, 339 (D.N.J. 1953) (holding that a vendor's cigarettes were drugs within the meaning of the FDCA because the vendor's claims implied that use of the product would prevent or mitigate disease).

\textsuperscript{120} See 15 U.S.C. \S 1333(c) (1994) (requiring the Federal Trade Commission to approve the arrangement and timely rotation of warning statements on cigarette labels).

\textsuperscript{121} See 26 U.S.C. \S 5701(b) (1994) (authorizing the Internal Revenue Service to impose taxes upon domestic and imported cigarettes).

\textsuperscript{122} See 7 U.S.C. \S\S 1312-1313 (1994) (authorizing the United States Department of Agriculture to set production quotas and price levels for the tobacco leaf).


\textsuperscript{125} See text accompanying infra notes 126-35 (describing the FCLAA and the CSTHEA). \textit{But cf.} Proposed Regulations, \textit{supra} note 9, at 41,352-53 (asserting that neither the FCLAA nor the CSTHEA preempts FDA regulation of tobacco).

\textsuperscript{126} 15 U.S.C. \S 1331 (1994). The significant health hazards that cigarettes posed prompted Congress to consider and enact the FCLAA. See H.R. REP. No. 449, 89th Cong., 1st Sess. 2-3 (1965), \textit{reprinted in} 1965 U.S.C.C.A.N. 2350, 2351-52 (discussing the Surgeon General's recommendation for remedial action to deal with health problems related to cigarette smoking). Because the cigarette issue is multi-faceted, Congress unambiguously reserved the right to fashion an appropriate remedy. See H.R. REP. No. 449, \textit{supra}, \textit{reprinted in} 1965 U.S.C.C.A.N. at 2351-52 (stating that remedial action regarding cigarette smoking is Congress's responsibility). Congress cited the need to examine all aspects of the issue, including the broad implications for public health, health research, the tobacco raising and manufacturing industries, and the television, radio, and publishing industries. \textit{Id.}
health hazards related to cigarette smoking.\textsuperscript{127} Second, the statute declares Congress' intent to protect the national economy by avoiding "diverse, nonuniform, and confusing" regulations addressed at any relationship between smoking and health.\textsuperscript{128} The statutory scheme achieves these purposes by requiring warning notices on cigarette advertisements and labels,\textsuperscript{129} and by prohibiting television and radio advertising of cigarettes.\textsuperscript{130} In addition, the statutory scheme requires the Secretary of Health and Human Services and the FTC to submit annual reports concerning smoking-related health and advertising issues to Congress.\textsuperscript{131}

The CSTHEA's regulatory framework for smokeless tobacco products bears many similarities to the FCLAA's regulatory framework for cigarettes. Like the FCLAA, the CSTHEA requires warning notices\textsuperscript{132} and prohibits television and radio advertising.\textsuperscript{133} The CSTHEA also requires the Secretary of Health and Human Services to submit reports to Congress on the health effects of smokeless tobacco products.\textsuperscript{134} Finally, the

\begin{footnotes}
\item[128] Id. § 1331(2)(B).
\item[129] Id. § 1333. The FCLAA requires cigarette manufacturers to rotate four warning statements on the labels of cigarette packages. Id. § 1333(a)(1). The required warnings are bold and specific:

\begin{quote}
SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.
\end{quote}

Id.
\item[130] Id. § 1335.
\item[131] Id. § 1337(b)(1). The FCLAA requires the Secretary of Health and Human Services to submit an annual report to Congress discussing current information concerning the health consequences of smoking. Id. § 1337(a)(1). In addition, the FTC must submit an annual report detailing current advertising and promotional practices of cigarette manufacturers. Id. § 1337(b)(1). Moreover, both the Secretary of HHS and the FTC are required to recommend legislation, if appropriate. Id. § 1337(a)(2), (b)(2).
\item[132] Id. § 4402. Manufacturers must display one of three warnings on packages of smokeless tobacco products: "WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER; WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS; AND WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES." Id. § 4402(a)(1).
\item[133] Id. § 4402(f).
\item[134] Id. § 4403(b). The CSTHEA directs manufacturers of smokeless tobacco to submit to the Secretary a list of product ingredients on a yearly basis. Id. § 4403(a). Using these lists, and any other information pertinent to the public interest, the Secretary keeps Congress informed of the smokeless tobacco issue with regular reports. Id. § 4403(b).
\end{footnotes}
CSTHEA provides for public education programs and research on the relationship between smokeless tobacco and health.\footnote{135}

\section*{B. The Dubious Relationship Between the FDA and Tobacco}

\subsection*{1. Cigarettes as Drugs: The Role of Tobacco Vendors' Claims}

Although tobacco products are popularly classified as drugs,\footnote{136} neither the text of the FDCA nor its legislative history mentions tobacco or tobacco products.\footnote{137} Indeed, most legislation concerning tobacco use focuses upon tobacco's health consequences, not its potential status as a drug.\footnote{138} Nevertheless, in two instances, the FDA relied on marketing representations to bring cigarettes within the statutory definition of "drug."

In United States v. 46 Cartons . . . Fairfax Cigarettes,\footnote{139} promotional materials suggested that a particular brand of cigarettes would decrease a smoker's odds of contracting colds and other respiratory infections.\footnote{140}
The United States District Court for the District of New Jersey, distinguishing claims of respiratory benefits from claims of smoking enjoyment, ruled that the cigarettes were drugs within § 321(g)(1)(B) of the FDCA because those marketing representations demonstrated an intent to mitigate, cure, or prevent disease. Similarly, in United States v. 354 Bulk Cartons... Trim Reducing-Aid Cigarettes, the same court examined advertising claims that a particular brand of cigarettes suppressed appetite and reduced weight. Consistent with § 321(g)(1)(C), the court found ample evidence to demonstrate an intent to affect the "structure or any function" of the body: the marketing claims demonstrated an intent to affect body weight, and the cigarettes purported to contain tartaric acid, an appetite suppressant. The court thus held that the marketing claims brought the specific brand of cigarettes within the purview of § 321(g)(1)(C).

In addition to evaluating drug jurisdiction based on a cigarette vendor's express health claims, the FDA also has analyzed the issue underlying the current controversy: whether cigarettes, irrespective of vendor claims, are drugs within the FDCA. In the late 1970s, the public interest group Action on Smoking and Health requested the FDA to assert jurisdiction over nicotine-containing cigarettes as drugs or devices within the meaning of § 321(g) and (h). The FDA refused the petition, contend-
ing that it would assert jurisdiction over cigarettes only when the vendor or manufacturer asserted health claims related to the cigarettes. In a subsequent challenge to the FDA's determination, Action on Smoking and Health v. Harris, the United States Court of Appeals for the District of Columbia upheld the FDA's refusal to assert jurisdiction. Deferring to the FDA's decision, the District of Columbia Circuit construed the "structure or any function" language of § 321(g)(1)(C) narrowly. Further, the court cited congressional acquiescence to the FDA's lack of jurisdiction over tobacco to support the Agency's inaction. Although Action on Smoking and Health was decided in 1980, congressional acquiescence remains a significant issue; Congress has considered and rejected several attempts to amend the FDCA to include cigarettes within the FDA's drug jurisdiction.

149. Id.
150. 655 F.2d 236 (D.C. Cir. 1980).
151. Id. at 242-43.
152. Id. at 239-41; see supra notes 50-59 and accompanying text (describing the impact of Action on Smoking and Health on the FDA's drug jurisdiction).
153. Id. at 241-42 (citations omitted). In its thorough discussion of congressional acquiescence, the District of Columbia Circuit found first that the FDA had advised Congress repeatedly of the Agency's inability to assert jurisdiction over cigarettes unaccompanied by vendor health claims. See id. at 241 (citing congressional hearings and statements by former FDA Commissioners). The court examined next an analogous situation involving the Consumer Product Safety Commission (CSPC), and embraced "the wisdom of judicial deference to administrative interpretations of statutes that have been consistently communicated to the legislative branch." Id. at 241-42. The CSPC issue began with the FDA's determination that it could not regulate cigarettes under the Federal Hazardous Substances Act (FHSA). Id. at 241. Subsequently, Congress amended the FHSA, transferring the FDA's jurisdiction under the FHSA to the CPSC. Id. A public interest group filed suit against the CPSC in an attempt to compel the Agency to assert jurisdiction over "high tar" cigarettes. Id. The District Court for the District of Columbia held that the CPSC possessed jurisdiction, and Congress reacted within two months. Id. at 241-42. In less than one year, Congress eliminated the CPSC's jurisdiction over "high tar" cigarettes. Id. at 242.

Standing alone, Action on Smoking and Health is not dispositive of the current issue regarding the FDA's attempt to regulate tobacco products. First, Action on Smoking and Health did not address whether the FDA could regulate cigarettes as medical devices. Id. at 237 n.4. Second, the opinion expressly recognized that the FDA is not "irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch." Id. at 242 n.10. Rather, an agency may revise its interpretations, so long as it provides a "reasoned explanation for its action." Id. Nonetheless, the FDA's current analysis of jurisdiction constitutes a severe departure from FDCA jurisprudence, and is problematic in many respects. See infra notes 201-46 and accompanying text (scrutinizing the FDA's jurisdictional analysis). In addition, the FDA's new interpretation leads to inconsistent results under the FDCA. See infra notes 271-89 and accompanying text (demonstrating that the FDA's interpretation is contrary to the FDCA).

2. The FDA’s New Analysis of Jurisdiction Over Tobacco

On August 11, 1995, the FDA signaled a major change in its interpretation of the FDCA by asserting jurisdiction over cigarettes and smokeless tobacco. Rather than executing the traditional enforcement action as a means to assert jurisdiction, the FDA chose instead to effect jurisdiction by way of notice and comment rulemaking. Consequently, the FDA published a sixty-four page legal analysis of its jurisdiction over cigarettes and smokeless tobacco products in the Federal Register. The Agency’s legal analysis addressed three main issues: (1) the pharmacological effects that allegedly bring tobacco products within the statutory language of § 321(g)(1)(C) and (h)(3); (2) the appropriate standard of vendor intent; and (3) the proposed classification of tobacco products under the FDCA.

Addressing the effects of tobacco products on the body, the FDA suggested first that Congress intended an expansive reading of § 321(g)(1)(C) and its parallel provision for devices, § 321(h)(3). With that foundation, the Agency asserted that both sections reach products that are not intended for therapeutic uses. Further, the FDA argued, both sections encompass products that have, or that vendors promote as

H.R. 3294, 100th Cong., 1st Sess. 1 (1987) (same); see infra notes 254-61 and accompanying text (discussing the failed FDCA amendments).

155. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,463-66; see supra note 12 (explaining the Agency’s rationale for its change of position on the tobacco issue).

156. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,455. Traditional enforcement actions, including injunctions, seizures, and criminal sanctions, allow the FDA to assert jurisdiction over individual products and manufacturers. See Bass, supra note 6, at 62-64 (reviewing the historical development of FDA’s enforcement powers). Notice and Comment Rulemaking, on the other hand, is more efficient because it allows the FDA to promulgate regulations applicable to an entire industry. See Peter B. Hutt, The Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act, 28 FOOD DRUG COSM. L.J. 177, 183 (1973) (contending that case-by-case enforcement is an inadequate regulatory approach); see also 1 O’REILLY, supra note 4, § 4.01, at 4-1 to 4-7 (introducing classifications of FDA regulations). Congress authorized the FDA to promulgate regulations for the “efficient enforcement” of the FDCA, a broad standard. 21 U.S.C. § 371(a) (1994).

157. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,462-526.

158. See infra notes 159-90 and accompanying text (summarizing the FDA’s analysis of its jurisdiction over tobacco products).

159. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,467 (citing H.R. REP. No. 2139, supra note 21, at 3).

160. Id.; see United States v. Undetermined Quantities of “Cal-Ban 3000”, 776 F. Supp. 249, 253 (E.D.N.C. 1991) (stating that “the term ‘drug’ should be interpreted broadly and not limited to products that are commonly known as drugs”). But cf. Gamerman, supra note 4, at 809 (arguing that therapeutic intent is an essential predicate to FDA device jurisdiction, but that such term has not been defined adequately).
having, pharmacological or physiological effects.\footnote{161} The FDA concluded that cigarettes and smokeless tobacco products affect the structure and function of the body.\footnote{162} Specifically, the FDA determined that the nicotine in these tobacco products exerts a pharmacological effect on the central nervous system, particularly the brain.\footnote{163}

The FDA continued its legal analysis by examining the appropriate standard of vendor intent.\footnote{164} According to the Agency's analysis, vendor intent should be evaluated against an objective standard\footnote{165} that is, whether a reasonable person would believe that the vendor intended the product to affect the structure or any function of the body.\footnote{166} The FDA also argued that the standard of objective intent embraced the notion of foreseeability, allowing an inquiry into whether the vendor could foresee that consumers would use a product for pharmacological purposes.\footnote{167} The FDA maintained that it may base a finding of objective intent on the

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\footnote{161}{Analysis Regarding Agency Jurisdiction, \textit{supra} note 9, at 41,470. The FDA cited cocaine as an example of a substance that falls within the drug definition because it produces psychoactive effects, thus affecting the structure or function of the body. \textit{Id.} at 41,469-70. The FDA's assertion, however, ignores the fact that Congress declared cocaine's drug status unambiguously. See 21 U.S.C. § 802(17)(D) (1994) (providing that the term "narcotic drug" includes cocaine). Congress has not expressed any similar intent for tobacco products, although it did reserve the exclusive right to remedy the public health consequences resulting from tobacco use. See \textit{H.R. REP. No. 449, supra} note 126, at 2-3, \textit{reprinted in} 1965 \textit{U.S.C.C.A.N.} at 2351-52 (discussing the scope of the tobacco problem in light of the FCLAA).}

\footnote{162}{Analysis Regarding Agency Jurisdiction, \textit{supra} note 9, at 41,470.}

\footnote{163}{\textit{Id.} The FDA contends, in scattered sections of the Federal Register, that nicotine affects the structure and function of the body in several ways. First, the FDA maintains that nicotine is addictive, and that there is a pharmacologic basis to the addiction. \textit{Id.} at 41,470, 41,483-88, 41,540-41. Nicotine attaches to receptors in the brain, thus stimulating the release of dopamine, a brain chemical that helps to produce pleasurable feelings. \textit{Id.} at 41,535-36. Second, the FDA notes that nicotine produces psychoactive effects, which electroencephalographic (EEG) analysis apparently confirmed, by alternatively stimulating and depressing mood. \textit{Id.} at 41,488, 41,536, 41,632-33. Finally, the FDA contends that nicotine affects the structure of the body because it affects body weight. \textit{Id.} at 41,489, 41,580. The FDA's use of the term "pharmacologic effects" is tautological; "pharmacologic" simply refers to the study of drugs. See \textit{DORLAND'S MEDICAL DICTIONARY} 1000 (26th ed. 1985) (defining pharmacology as "the science that deals with the origin, nature, chemistry, effects, and uses of drugs").}

\footnote{164}{Analysis Regarding Agency Jurisdiction, \textit{supra} note 9, at 41,471. As the Second Circuit noted, "[t]he vendors' intent in selling the product to the public is the key element in this statutory definition." \textit{National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333 (2d Cir. 1977) (construing 21 U.S.C. § 321(g)(1)(B)).}}

\footnote{165}{Analysis Regarding Agency Jurisdiction, \textit{supra} note 9, at 41,472.}

\footnote{166}{\textit{Id.} at 41,471, 41,474. A subjective standard of vendor intent, on the other hand, would consider the vendor's actual state of mind. \textit{Id.} at 41,472-73. The FDA argued that a subjective intent standard would limit the relevant evidence to express representations, promotional claims, and similar indications. \textit{Id.} at 41,473.}

\footnote{167}{\textit{Id.}}
Having stressed its authority to determine objective intent by the totality of the relevant evidence, the FDA asserted next that certain types of evidence, even when considered alone, are sufficient to establish objective intent.\textsuperscript{169} As an example, the FDA claimed that a product may be a drug merely because it contains a pharmacologically active ingredient.\textsuperscript{170} Accordingly, even in the absence of explicit drug claims, the presence of the pharmacologically active ingredient is determinative of objective intent and thus, the product’s drug status.\textsuperscript{171} Additionally, the FDA claimed that it could establish objective intent solely by evidence of consumer use of the product.\textsuperscript{172} Thus, the FDA argued, mere evidence showing consumer use to be almost exclusively for pharmacological purposes would be sufficient to establish the requisite vendor intent.\textsuperscript{173}

After laying the foundation for its interpretation of objective intent, the FDA applied its interpretation to tobacco products.\textsuperscript{174} According to the FDA, tobacco vendors possess the statutory intent to affect the structure or function of the body because a reasonable tobacco vendor can foresee nicotine’s pharmacological effects—addictive properties, psychoactive or mood alterations, and impact on weight control.\textsuperscript{175} In addition, the FDA claimed that consumers use tobacco “nearly exclusively for pharmacological purposes,” thus independently establishing the requisite vendor intent.\textsuperscript{176} Finally, the FDA pointed to tobacco industry

\textsuperscript{168} Id. at 41,473-74. The FDA has promulgated regulations adopting an objective standard of vendor intent. 21 C.F.R. § 201.128 (1995) (drugs); id. § 801.4 (devices).

\textsuperscript{169} Analysis Regarding Agency Jurisdiction, supra note 9, at 41,475-81; see text accompanying infra notes 170-73.

\textsuperscript{170} Analysis Regarding Agency Jurisdiction, supra note 9, at 41,475-76.

\textsuperscript{171} Id.

\textsuperscript{172} Id. at 41,479-80; see supra note 57 (discussing the showing required to demonstrate objective intent by consumer use alone).

\textsuperscript{173} Analysis Regarding Agency Jurisdiction, supra note 9, at 41,579-80.

\textsuperscript{174} See id. at 41,482-520.

\textsuperscript{175} Id. at 41,483-90. Nicotine’s effects on the structure and function of the body are foreseeable, the FDA reasoned, because the effects have been so well documented in scientific literature. Id. at 41,483.

\textsuperscript{176} Id. at 41,490-91. The FDA cited statistics to demonstrate that consumers use tobacco products regularly and compulsively. Id. at 41,486. According to the FDA, 87% of cigarette smokers use cigarettes daily; only 3% of smokers who attempt to quit achieve long-term success; clinical studies have demonstrated that between 75% and 90% of frequent smokers are addicted; likewise, more than one-third of smokeless tobacco users are addicted. Id. at 41,486-87. Alternatively, the FDA argued that, even if the evidence of consumer use were not sufficient to establish vendor intent, the totality of the FDA’s evidence demonstrates the requisite intent. Id. at 41,490-91.
research, documents, and statements of key personnel to support its findings of vendor intent.\(^{177}\)

Under the FDA’s analysis, the tobacco industry research, documents, and personnel statements demonstrated vendor intent in two important respects. First, the evidence confirmed that tobacco vendors know that nicotine affects bodily structure and functions, and that consumers use tobacco products for precisely these purposes.\(^{178}\) Second, the evidence confirmed that tobacco vendors act to facilitate this use of tobacco products, namely through manipulating nicotine levels in cigarettes and smokeless tobacco.\(^{179}\)

\(^{177}\) Id. at 41,491-520. To support its jurisdictional determination, the FDA has amassed hundreds of tobacco-related studies, industry documents, and statements. Id. at 41,492. The FDA, however, did not present evidence to implicate every tobacco manufacturer in the United States. Id. at 41,525. Nonetheless, the Agency contends that its evidence applies to the entire tobacco industry because it implicates over 95% of the United States tobacco market. Id.

\(^{178}\) Id. at 41,492-504. Comparing the tobacco industry to the pharmaceutical industry, the FDA cited studies, which the tobacco industry funded and conducted, to illustrate that tobacco manufacturers know that nicotine affects the structure and function of the body. Id. at 41,496, 41,499. Most of the studies the FDA cited explored the role of nicotine in the human body. See, e.g., id. at 41,493 (nicotine’s addictive properties); id. at 41,495, 41,497 n.11, 41,499 (nicotine’s psychoactive effects, including effects on performance and cognition); id. at 41,496 (nicotine absorption and delivery to brain). Significantly, the FDA cited statements by industry personnel, including scientists, executives, and even an attorney, who stated: “[w]e are, then, in the business of selling nicotine, an addictive drug.” Id. at 41,494 (quoting the general counsel to the Brown and Williamson Tobacco Corporation).

The FDA also asserted that the evidence demonstrated the tobacco industry’s knowledge that consumers use tobacco as a drug. Id. at 41,499-504. This evidence consists mostly of documents and statements, such as one statement by a Philip Morris official:

Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshalled to support this argument:

1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine.

2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.

3) Despite many low nicotine brand entries in the market place, none of them have captured a substantial segment of the market.

Id. at 41,500 (alteration in original) (emphasis omitted) (quoting William Dunn, Jr., a Philip Morris executive).

\(^{179}\) Id. at 41,504. The FDA contended that many of the tobacco industry’s technologies and practices demonstrate an intent to affect the structure and function of the body. Id. at 41,504-05. Specifically, the FDA maintained that the following tobacco industry practices demonstrate the requisite intent: (1) developing high-nicotine tobacco plants through genetic engineering; (2) blending different types of tobacco leaves to attain higher levels of nicotine; (3) fortifying tobacco products with nicotine powders and other derivatives; and (4) adding chemicals, such as ammonia, to increase the amount of nicotine delivered to the smoker. Id. at 41,507, 41,509-11. According to the FDA, these industry practices are successful because the level of nicotine is extremely consistent from cigarette to cigarette. Id. at 41,509.
The FDA ended its legal analysis of jurisdiction over tobacco products by concluding that cigarettes and smokeless tobacco products appropriately are regulated as devices under the FDCA. Specifically, the Agency concluded that cigarettes and smokeless tobacco are devices because they constitute drug delivery systems. Under this analysis, regulating a cigarette as a device is consistent with the statutory definition in that the cigarette “does not achieve its primary intended purposes through chemical action, [and] is not dependent upon being metabolized for the achievement of its primary intended purposes.”

Rather, according to the FDA, the cigarette’s primary purpose is to deliver nicotine to the tobacco user. Further, the user does not metabolize the cigarette, but discards it after use. Similarly, the device element of smokeless tobacco is the tobacco itself, which delivers nicotine to the user by way of absorption through the cheek tissue; after the nicotine is absorbed, the user removes the tobacco from the mouth. Like the cigarette, the smokeless tobacco product’s primary purpose is to deliver nicotine to the user.

Although the FDA claimed jurisdiction to regulate tobacco products as drugs, devices, or both, the Agency concluded that regulation pursuant to its device authorities was the most appropriate option. Conceding that regulation pursuant to the FDCA’s drug authorities might cause tobacco

180. Id. at 41,521-23; see supra notes 67-99 and accompanying text (outlining the FDA’s device jurisdiction).

181. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,521-23. The FDA regulates as devices several contrivances containing drugs, also known as drug delivery systems. Id. Examples of such drug delivery systems include pre-filled syringes, transdermal patches, and metered-dose inhalers. Id. at 41,521. The FDA found that “a cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream.” Id. at 41,522.

182. Id. at 41,522 (quoting 21 U.S.C. § 321(h) (1994)).

183. Id. The FDA noted that on average, a cigarette delivers approximately 1.0 mg of nicotine to the lungs when inhaled. Id.

184. Id.

185. Id. at 41,522-23. The FDA analogized smokeless tobacco to “infusion devices or transdermal patches that deliver a controlled continuous amount of nicotine to the cheek tissue for absorption into the bloodstream.” Id.

186. Id. Specifically, the FDA stated that “[t]he primary purpose of the tobacco is to provide a palpable vehicle that allows nicotine to be extracted from the tobacco by the user’s saliva so that it may be absorbed into the body.” Id. at 41,523.

187. Id. at 41,523-24. The FDCA’s provisions for the regulation of combination products allow the FDA to regulate some products as drugs, devices, or both. See 21 U.S.C. § 353(g)(1) (1994) (allowing combination products to be regulated under the FDCA); see also supra notes 91-93 and accompanying text (explaining the FDA’s authority to regulate combination products).
products to be removed from the marketplace, the FDA expressed concern over the detrimental effect that such a drastic remedy would have on the millions of Americans currently addicted to tobacco. The FDCA's flexible device authorities permit a staged, multi-tiered approach to meeting the statutory requirements of safety and effectiveness; therefore, the FDA concluded, it should regulate cigarettes and smokeless tobacco as devices.

### 3. Proposed Regulations to Curtail Tobacco Use

After completing the legal analysis and justification for its jurisdiction over tobacco, the FDA proposed a regulatory solution. Relying on statistical evidence indicating that nearly all tobacco users begin smoking or using smokeless tobacco at a young age, the FDA limited its regulatory focus to one major goal: reducing the number of people under eighteen years of age who become addicted to nicotine through cigarette and smokeless tobacco use.

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188. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,523-24. The FDA's Commissioner, Dr. David Kessler, stated that "I am convinced that [a] finding [of safety and effectiveness] would not be made by this agency and that therefore [cigarettes] could not be approved as a new drug." Justice Department to Investigate Allegations of Nicotine Manipulation, 3 Health L. Rep. (BNA) No. 12, at 372 (Mar. 24, 1994) (quoting Dr. Kessler's testimony before the House Appropriations Committee's Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies on March 16, 1994). Similarly, the Institute of Medicine concluded that "an inevitable effect of classifying nicotine-containing tobacco products as 'drugs' would be to ban them." GROWING UP TOBACCO FREE, supra note 15, at 235.

189. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,523-24. The FDA stated that currently, over 40 million Americans are addicted to cigarettes and smokeless tobacco products. Id. at 41,524.

190. Id. at 41,524.

191. See Proposed Rules, supra note 9, at 41,314, 41,316 n.9 (citing a 1994 Surgeon General's Report). This Surgeon General's Report described one study that found that 88% of all smokers had tried their first cigarette by age 18. PREVENTING TOBACCO USE AMONG YOUNG PEOPLE, supra note 136, at 65-67.

192. See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,785-87 (describing regulatory objectives). The FDA found that "addiction to nicotine-containing tobacco products is, first and foremost, a pediatric disease." Id. at 41,786. Thus, the Agency concluded, "FDA regulatory action should be based on a youth-centered strategy that is intended to reduce the risk that future generations of Americans will become dependent on nicotine without prohibiting access to these products by adults." Id.
The proposed regulatory framework imposes numerous restrictions on tobacco vendors. Briefly, the FDA would prohibit vending machine sales, self-service displays, mail-order sales, and “other ‘impersonal’ modes” of selling tobacco products. The proposed regulations also prohibit any item or service, whether complimentary or for profit, from bearing the brand name of any cigarette or smokeless tobacco product. Similarly, the proposed regulations disallow the brand-name sponsorship of any sporting or cultural event. The FDA would limit billboard advertising to black text on a white background, and require all advertisements to state that tobacco products are “Nicotine-Delivery Device[s].” Finally, the regulations would require tobacco vendors to establish a national public educational program to discourage persons under eighteen years of age from using tobacco products.

193. The regulatory framework was proposed pursuant to the Act’s restricted device authorities. See 21 U.S.C. § 360j(e) (1994) (providing general authority to regulate restricted devices); id. § 352(r) (providing authority to regulate advertising of restricted devices). Restricted devices establish yet another subdivision of the general device category. See supra note 88 and accompanying text (describing the classification system for devices). If the FDA determines that it cannot otherwise reasonably assure a device’s safety and effectiveness, the FDCA permits the Agency to restrict the sale, distribution, or use of that potentially harmful device. 21 U.S.C. § 360j(e); 21 C.F.R. § 807.3(i) (1995). Generally, the Agency’s restricted device authorities are similar to its prescription drug authorities. See Hutt & Merrill, supra note 4, at 786-87 (comparing restricted devices to prescription drugs). Indeed, most restrictions the FDA has imposed involved only a requirement that the device be sold by prescription. Munsey & Holstein, supra note 68, at 394-95.

The FDA and the FTC share responsibilities for regulating medical device advertising: the FDA has jurisdiction to regulate advertising of restricted devices, while the FTC regulates advertising for all other devices. Munsey & Holstein, supra note 68, at 394. Congress expressly created this split of authority in the Medical Device Amendments. See S. Rep. No. 33, supra note 1, at 17, reprinted in 1976 U.S.C.C.A.N. at 1086 (providing that the Federal Trade Commission Act is inapplicable to the advertising of restricted devices). In delegating restricted device advertising to the FDA, Congress declared that the authority “is more properly vested in the agency most knowledgeable about the area and the one that is truly charged with matters affecting public health and thus assuring the safety and efficacy of medical devices.” Id. Interestingly, the FDA has rarely used its authority to regulate advertising of restricted devices. See Hutt & Merrill, supra note 4, at 787 (noting that the FDA has not used its authority to regulate labeling and advertising of restricted devices, except to condition approval of certain devices).

194. Proposed Regulations, supra note 9, at 41,372-75.
195. Id. at 41,374.
196. Id. This prohibition would not apply to the actual cigarette or smokeless tobacco product. Id.
197. Id. at 41,375. Teams in sponsored events, however, could wear labeling that identified the cigarette or smokeless tobacco product. Id. at 41,374.
198. Id. at 41,374. The FDA explained that “text-only” advertising is less attractive to young people, yet it preserves the advertiser’s ability to convey useful information about tobacco products to adults. Id. at 41,335-36.
199. Id. at 41,374.
200. Id.
III. The FDA’s Analysis of Jurisdiction: Smoke and Mirrors

The FDA’s assertion of jurisdiction over tobacco products is a noble effort to address a significant health problem. On many points, the FDA’s analysis is correct. Nevertheless, when considered in its totality, the jurisdictional analysis constitutes a significant departure from the legislative intent and judicial interpretations of the FDCA.

A. Cigarettes and Smokeless Tobacco as Affecting the “Structure or any Function” of the Body

In its legal analysis, the FDA asserted that tobacco products have pharmacological effects and lead to addiction, thereby affecting the “structure or any function” of the body. On this isolated assertion, the FDA’s analysis comports with FDCA precedent. It is true that Congress intended an expansive reading of the FDCA’s “structure or any function” language. It also is true that this language reaches products intended for nonmedical uses. Indeed, the courts have complied with this legislative intent, finding that even the process of hair growth is a function of the body. Thus, the FDA has a rational basis for asserting that nico-

201. See infra notes 203-08, 214-15 and accompanying text (discussing the FDA’s findings that tobacco products affect the structure or function of the body and that vendor intent is determined by an objective standard).
202. See infra notes 209-35 and accompanying text (examining the FDA’s proposed standard of objective intent).
203. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,467-70; see supra notes 162-63 and accompanying text (describing the structures and functions affected by tobacco products).
205. See supra notes 32-35 and accompanying text (discussing the legislative intent to expand the definition of “drug”).
206. See E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 682 (D.C. Cir. 1989) (construing the “structure or any function” language to contemplate a physiologic rather than a therapeutic effect).
207. Kasz Enters., 855 F. Supp. at 540; see supra note 204 (citing cases construing the “structure or any function” language to reach products without therapeutic uses).
tine, with its effects on the brain, affects the structure and function of the body.\textsuperscript{208} Mere effects on a bodily structure or function, however, do not determine a product's drug status.\textsuperscript{209} Throughout its analysis, the FDA subtly understates the importance of the vendor's intent, a key element of the drug definition.\textsuperscript{210} Evidence of the actual effects of tobacco products is relevant only to the extent that it is probative of the vendor's intent.\textsuperscript{211} By creating a definition that turns upon the vendor's intent, the drafters of the FDCA sought to strike a balance between consumer protection and legitimate business interests.\textsuperscript{212} Allowing FDA jurisdiction over drugs and devices when the vendor's representations, in connection with the sale of the product, demonstrate an intent to market a product that will affect the structure or any function of the body achieves this balance.\textsuperscript{213}

\textsuperscript{208} The FDA probably devoted a section of its legal analysis to the "structure or any function" language, among other reasons, to overcome any argument that cigarettes merely stimulate the senses. See Action on Smoking and Health v. Harris, 655 F.2d 236, 240 (D.C. Cir. 1980) (implying that cigarettes affect the structure or function of the body remotely because they stimulate the senses); see also supra note 58 (quoting the Action on Smoking and Health court's decision to limit the reach of § 321(g)(1)(C)).

\textsuperscript{209} See supra notes 37-44 and accompanying text (discussing intended use, the true determinant of a product's drug status under the FDCA).

\textsuperscript{210} See, e.g., Analysis Regarding Agency Jurisdiction, supra note 9, at 41,471 (describing intent in terms of foreseeable consequences); id. at 41,475 (stating that the mere presence of pharmacologically active ingredients demonstrates intent); id. at 41,477 (describing intent in terms of consumer use alone).

\textsuperscript{211} See, e.g., Action on Smoking and Health, 655 F.2d at 238-39 (stating that the "crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent"); National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333 (2d Cir. 1977) (recognizing that the "vendors' intent in selling the product to the public is the key element in this statutory definition"); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Ill. 1991) (noting that, in the context of food additives, intended use under the FDCA is determined according to an objective standard), aff'd, 984 F.2d 814 (7th Cir. 1993).

\textsuperscript{212} See S. Rep. No. 361, supra note 33, at 4, reprinted in 3 Legislative History, supra note 21, at 663. The legislative history demonstrates the drafters' desire to allow a vendor to retain some control over a product's status under the Act:

The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.

\textit{Id.}

\textsuperscript{213} See Action on Smoking and Health, 655 F.2d at 238-39 (quoting legislative history emphasizing the importance of the vendor's representations); S. Rep. No. 361, supra note 33, at 4, reprinted in 3 Legislative History, supra note 21, at 663. In Action on Smoking and Health, the court explored the legislative history, and found that in doubtful cases of Agency jurisdiction, the FDA would focus upon a vendor's representations. Action on Smoking and Health, 655 F.2d at 238.
B. Pure Puffery: The FDA's New Standard of Objective Intent

Perhaps, from the FDA's perspective, the jurisdictional analysis espoused an ideal standard of objective intent. To be sure, the FDA concluded correctly that objective intent is the appropriate standard. Nonetheless, the Agency's interpretation of that standard would expand the concept far beyond Congress' intent, as construed in over fifty years of judicial precedent.

Most significantly, the Agency's adoption of a foreseeable use standard constitutes a severe departure from FDCA precedent. Under the FDCA's legislative history, the foreseeable use of a product as a drug or device is not a basis for inferring statutory intent. On the contrary, the legislative history explicitly connects a product's drug or device status to intended use as demonstrated by the vendor's representations. Further, it is doubtful that any court construing the FDCA has ever relied on foreseeable use as a component of objective intent. Even the FDA's regulations describing the objective intent standard fail to mention foreseeable use as indicative of the statutory intent.

To support its foreseeable use standard, the FDA was forced to turn to cases construing the Federal Hazardous Substances Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Courts examining

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214. See supra notes 38-44 and accompanying text (examining objective intent standard as applied in Sudden Change).
215. See infra notes 216-46 and accompanying text (arguing that the FDA's current analysis departs from legislative intent).
216. See infra notes 217-25 and accompanying text (arguing that the FDA's foreseeable use standard departs from legislative intent).
217. See S. Rep. No. 361, supra note 33, at 4, reprinted in 3 Legislative History, supra note 21, at 663 (describing intended use by reference to a vendor's representations of the product, but not foreseeable uses); cf. Analysis Regarding Agency Jurisdiction, supra note 9, at 41,471-73 (discussing the foreseeable use standard without specific reference to the FDCA's legislative history).
219. See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,472-482 (discussing the foreseeable use standard without reference to judicial constructions of FDCA); National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977) (defining objective intent by reference to labeling, promotional materials, advertising, and any other relevant source, but not foreseeable product uses).
220. See 21 C.F.R. § 201.128 (1995) (describing the objective intent standard for drugs as embracing labeling claims, advertisements, oral or written vendor statements, and actual use of product); id. § 801.4 (discussing the identical objective intent standard in the context of medical devices).
222. 7 U.S.C. §§ 136-136g (1994); see Analysis Regarding Agency Jurisdiction, supra note 9, at 41,471, 41,476-79 (citing cases exploring the intent element in the FDCA and other federal enactments); United States v. Focht, 882 F.2d 55 (3d Cir. 1989) (construing
vendor intent under these federal statutes lack extensive legislative history and judicial precedent to guide their inquiries.\footnote{223} In stark contrast, courts examining vendor intent under the FDCA may turn to volumes of legislative history and judicial precedent.\footnote{224} Because the standard of objective vendor intent under the FDCA is so well developed, the FDA's resort to cases interpreting other federal statutes is improper.\footnote{225}


In \textit{Focht}, the court faced an issue of first impression: whether the language "intended to produce," in regulations promulgated pursuant to the Federal Hazardous Substances Act (FHSA), should be interpreted according to a subjective or an objective standard. \textit{Focht}, 882 F.2d at 57-58. Relying on the FHSA's remedial purpose, the court concluded that the language "clearly contemplates[d] an objective seller standard." \textit{Id.} at 58. The court rejected a subjective standard, reasoning that such a standard would frustrate the statutory purpose. \textit{Id.} at 59. Under a subjective standard, for instance, a seller could demonstrate a good faith belief that it did not intend the use in question. See \textit{Id.} at 61 (citing \textit{Baby Rattles}, 614 F. Supp. at 232).

Similarly, in \textit{Baby Rattles}, the court considered whether the language "intended to be used by children" in the FHSA should be interpreted according to a subjective or an objective test. \textit{Baby Rattles}, 614 F. Supp. at 230-32. Like the \textit{Focht} court, the \textit{Baby Rattles} court looked to the FHSA's remedial purpose, and concluded that the "only rational interpretation of the word 'intended' in the statute calls for an objective test." \textit{Id.} at 231. The court expressed its objective test in terms of "whether a reasonable person would believe that the object is a toy or article intended for use by children." \textit{Id.}

In \textit{N. Jonas \& Co.}, the court considered whether a vendor's product was a "pesticide" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). \textit{N. Jonas \& Co.}, 666 F.2d at 830. Examining the statutory definition of pesticide, the court concluded that the language "intended for preventing, destroying, repelling, or mitigating any pest" necessitated an objective standard. \textit{Id.} at 831-33 (quoting 40 C.F.R. § 162.4). Further, the court defined this objective standard in terms of the reasonable consumer, and concluded that "the company intends those uses to which the reasonable consumer will put its products." \textit{Id.} at 833.

In all three cases—\textit{Focht}, \textit{Baby Rattles}, and \textit{N. Jonas}—the courts lacked judicial precedent defining an objective intent standard. See \textit{Focht}, 882 F.2d at 60 n.10 (citing only \textit{Baby Rattles} in support); \textit{N. Jonas \& Co.}, 666 F.2d at 833 (citing cases construing the FDCA); \textit{Baby Rattles}, 614 F. Supp. at 231-32 (relying on statutory language alone). Courts examining the objective intent standard under the FDCA, on the other hand, may rely on extensive legislative history and years of judicial precedents. See \textit{National Nutritional Foods Ass'n v. United States FDA}, 504 F.2d 761, 789 (2d Cir. 1974) (describing the objective intent determination), \textit{cert. denied}, 420 U.S. 946 (1975).

\footnote{223} See supra note 222 (describing cases construing the FHSA and the FIFRA).

\footnote{224} See supra notes 18-99 and accompanying text (discussing the legislative history and judicial constructions of the FDCA's definitional provisions).

\footnote{225} See supra notes 38-59 and accompanying text (describing the objective intent standard in the context of 21 U.S.C. § 321(g)(1)(C) (1994)). The FDA's argument, in relying on \textit{Focht}, \textit{N. Jonas \& Co.}, and \textit{Baby Rattles}, assumed that there is only one type of objective intent standard. See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,472-79 (combining cases defining the FDCA version of objective intent with cases defining objective intent in light of the FHSA and the FIFRA). The objective intent standard under
A second problem with the Agency's interpretation of the objective intent standard involves the proper weight to be accorded to evidence of consumer use of tobacco products. Although consumer use is relevant to the issue of intent, courts have afforded the FDA limited discretion to infer vendor intent based solely on consumer use. To allow such an inference, the FDA would have to meet the substantial burden of proving that consumers use tobacco "nearly exclusively" for drug purposes. In the case of cigarettes and tobacco, however, consumer use alone cannot support an inference of the requisite vendor intent. Consumers do not use tobacco products "nearly exclusively" for drug purposes because too many other purposes exist, including taste and social image.

the FDCA, however, must be read against the statute's legislative history connecting intended use with a vendor's representations or other circumstances surrounding the sale of the product. S. REP. NO. 361, supra note 33, at 4, reprinted in 3 LEGISLATIVE HISTORY, supra note 21, at 663; see Weitzman, supra note 24, at 230 (asserting that courts interpreting the FDCA's definitional provisions must fully consider the legislative history).

The FDA's resort to the cases construing the FHSA and the FIFRA is improper for yet another reason. Two of the three cases—N. Jonas & Co. and Baby Rattles—expressly adopted a reasonable person standard. N. Jonas & Co., 666 F.2d at 832; Baby Rattles, 614 F. Supp. at 231. The reasonable person standard directly conflicts with the well-accepted FDCA principle that the term "drug" should include items not commonly thought of as drugs. E.g., United States v. Undetermined Quantities of "Cal-Ban 3000", 776 F. Supp. 249, 253 (E.D.N.C. 1991). This principle reflects a major purpose of the Act—to protect the unwary consumer. United States v. Dotterweich, 320 U.S. 277, 280 (1943).

226. See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,479-81 (arguing that the objective intent of tobacco manufacturers to affect the structure or function of the body may be adduced by consumer use alone); see supra note 57 (discussing evidence of consumer use as a basis for inferring the statutory intent).

227. See, e.g., Action on Smoking and Health v. Harris, 655 F.2d 236, 239-40 (D.C. Cir. 1980) (refusing to find that cigarettes are drugs based solely on the presented evidence of consumer use); National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334-36 (2d Cir. 1977) (refusing to find that high dosage vitamin supplements were drugs based solely on evidence of consumer use); Millet, Pit & Seed Co. v. United States, 436 F. Supp. 84, 89 n.4 (E.D. Tenn. 1977) (refusing to find that apricot kernels sold as dietary supplements were drugs based upon consumer use), vacated without op. sub nom., United States v. Article of Food & Drug, 627 F.2d 1093 (6th Cir. 1980).

228. Action on Smoking and Health, 655 F.2d at 240.

229. Id.

230. See Simon Chapman, Smokers: Why Do They Start—and Continue?, 16 WORLD HEALTH F. 1, 2-6 (1995) (describing motives for smoking). According to Dr. Chapman, new smokers often use cigarettes to demonstrate adulthood, rebellion, affluence, fashion and style, hospitality, friendship, and social class norms. Id. at 2-4. Regarding experienced smokers, Dr. Chapman emphasized the pleasurable aspects of smoking: "Perhaps the most underemphasized yet obvious reason why many smokers continue to smoke is that they derive pleasure from both the pharmacological effects of smoking and the social rituals that surround the act. The psychopharmacology of nicotine has been studied extensively, but not the pleasure involved." Id. at 6 (emphasis added). But see Analysis Regarding Agency Jurisdiction, supra note 9, at 41,563-68 (asserting that other motives for smoking are secondary to usage for drug purposes); id. at 41,772-78 (asserting that tobacco vendors know that other motives for smoking are secondary to usage for drug purposes).
The FDA further argued that intended use may be inferred merely from the presence of a pharmacologically active ingredient.\textsuperscript{231} While this proposition sounds reasonable in the abstract, the FDCA does not permit such an inference.\textsuperscript{232} To the contrary, courts repeatedly have ruled that a product's actual composition is irrelevant to the drug or device determination.\textsuperscript{233} Even so, the FDA bolsters its assertion by referring to past enforcement actions in which it asserted jurisdiction over products solely on the basis of the product's composition.\textsuperscript{234} This evidence may answer an accusation of inconsistency, but it does not necessarily show that the Agency is acting within its statutory grant of authority.\textsuperscript{235}

\textsuperscript{231} Analysis Regarding Agency Jurisdiction, supra note 9, at 41,475-76.

\textsuperscript{232} See infra notes 233-34 and accompanying text (arguing that a product's content does not determine its drug status). The FDA's jurisdiction to regulate drugs and devices would be nearly limitless if the Agency were able to infer intended use solely from a product's composition or effects on the body. Under such a scheme, products with multiple potential uses suddenly could be regulated as "drugs" or "medical devices." For example, an electrostatic air cleaner that emits ozone arguably affects the "structure or any function of the body." See Hutt \& Merrill, supra note 4, at 749 (describing the intended use determination). The FDA, however, properly has concluded that "electrostatic air cleaners are not inherently medical devices"; such products have numerous uses. Id. (quoting Letter from R.M. Cooper, FDA Chief Counsel, to S. Lemberg, CPSC Assistant General Counsel (May 14, 1979)). The proper intended use determination, which considers the circumstances surrounding the sale, thus prevents arbitrary expansions of the FDA's authority.

\textsuperscript{233} See, e.g., United States v. Undetermined Quantities . . . "Pets Smellfree", 22 F.3d 235, 239 (10th Cir. 1994) (holding that an additive was a drug despite its actual composition); United States v. An Article . . . Sudden Change, 409 F.2d 734, 742 (2d Cir. 1969) (holding that a clear liquid lotion was a drug regardless of actual ingredients); United States v. Kasz Enters., Inc., 855 F. Supp. 534, 539 (D.R.I.) (holding that a hair product was a drug regardless of its physical properties), amended on other grounds, 862 F. Supp. 717 (D.R.I. 1994). In Kasz, the court concluded that "[w]hether or not a product is a drug . . . depends not on the physical properties of the product or what effect the product has on humans but rather on the intended uses or effects of the product." Id.

\textsuperscript{234} See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,527-31 (listing examples of products the FDA regulated based on the product's composition, consumer use of the product, or the product's effect on the body).

\textsuperscript{235} The products subjected to past enforcement actions are either distinguishable from tobacco products, or were not the subject of judicial review. See id. (listing 11 examples of products regulated as drugs or devices, two of which were subject to judicial review). Judicial review, however, remains an important check on administrative interpretations. See Sunstein, supra note 108, at 2086 (suggesting that the Administrative Procedure Act recognized a need for judicial review of administrative actions).

One enforcement action discussed in the Analysis of Agency Jurisdiction involved "caine" or imitation cocaine, and was the subject of judicial review in the United States Court of Appeals for the Ninth Circuit. See United States v. Storage Spaces Designated Nos. "8" & "49", 777 F.2d 1363, 1366-67 (9th Cir. 1985) (holding that an imitation cocaine product was a "drug" under the FDCA), cert. denied, 479 U.S. 1086 (1987); Analysis of Agency Jurisdiction, supra note 9, at 41,527-28 (discussing imitation cocaine as support for the FDA's assertion of tobacco jurisdiction). In Storage Spaces, the Ninth Circuit considered whether products labelled as "incense" were drugs under the FDCA. Storage Spaces,
C. Defying Logic: Cigarettes and Tobacco Leaves as Medical Devices

The FDA's characterization of cigarettes and tobacco leaves as medical devices is one of many examples of the Agency's ability to interpret its enabling act creatively.\(^2\)\(^3\)\(^6\) To be sure, the vast majority of products the FDA regulates as medical devices are clearly within the Agency's jurisdiction.\(^2\)\(^3\)\(^7\) Nonetheless, the Agency has a history of jurisdictional determinations that are questionable at best.\(^2\)\(^3\)\(^8\) The tobacco analysis is one such determination.\(^2\)\(^3\)\(^9\)

In practical effect, the FDA's unusual treatment of its tobacco jurisdiction is somewhat akin to the controversy that gave rise to the AMP and Bacto-Unidisk decisions.\(^2\)\(^4\)\(^0\) In those cases, the FDA found its device authorities insufficient to regulate the products at issue properly.\(^2\)\(^4\)\(^1\) Rather than settle for less regulation, the FDA chose to categorize the products—blood vessel loops, surgical clamps, and a paper disk—as drugs.\(^2\)\(^4\)\(^2\) These unusually broad classifications were one reason that prompted

777 F.2d at 1366-67. In finding that the products were "drugs," the Ninth Circuit emphasized that the FDA did not rely on the actual composition or use of the products. Id. at 1367. Rather, the FDA produced promotional flyers entitled "Cocaine," and other similar vendor representations to demonstrate the vendor's intent to market the products as drugs. Id. at 1366. Thus, while the FDA asserted that the products actually contained drug ingredients, drug jurisdiction properly was based on the circumstances surrounding the sale of the incense products. Id. at 1366-67. In its assertion of jurisdiction over tobacco, on the other hand, the FDA's evidence focused upon the actual composition of tobacco products, the effects of tobacco products on the body, and internal statements by individual tobacco vendors. See supra notes 155-90 and accompanying text (discussing the FDA's analysis of its tobacco jurisdiction).

236. See infra notes 240-43 and accompanying text (comparing the FDA's classification of tobacco products as medical devices to previous unreasonably broad product classifications).

237. See generally 1 O'REILLY, supra note 4, § 18.02 (discussing device definitions and providing examples of products regulated as medical devices).

238. See Hoffman, supra note 20, at 28-30 (noting the FDA's ability to expand its jurisdiction arbitrarily through reinterpretation of the FDCA's definitional provisions); see also infra notes 240-42 (discussing AMP and Bacto-Unidisk as examples of questionable jurisdictional determinations).

239. See infra notes 271-89 and accompanying text (arguing that the FDA's jurisdictional analysis is manifestly contrary to the FDCA).


241. See supra note 68 and accompanying text (discussing the FDA's desire for premarket approval authority over medical devices).

Congress to intervene and enact the Medical Device Amendments.\footnote{243} Similarly, Congress is certain to debate the issue of the FDA’s tobacco jurisdiction.\footnote{244} Indeed, as little as five weeks after the FDA’s jurisdictional announcement, Senator Wendell Ford (D-Ky) introduced the Tobacco Products Control Act of 1995, a bill that explicitly prohibits FDA jurisdiction over tobacco.\footnote{245} Regardless of the final legislative outcome, congressional attention is the appropriate response to the FDA’s characterization of tobacco leaves and cigarettes as medical devices.\footnote{246}

IV. A REASONABLE INTERPRETATION OF THE FDCA OR JUST BLOWING SMOKE?

The FDA’s assertion of jurisdiction over tobacco products is controversial because the Agency’s action conflicts with the deeply rooted concept that the executive branch should not define the limitations of the law that it is entrusted to administer.\footnote{247} Granted, Congress has delegated a considerable amount of authority to the FDA, and that authority includes the initial determination of a product’s status as a “drug” or “device.”\footnote{248} Nonetheless, it sometimes is necessary to examine whether the FDA has crossed the sometimes hazy line between executing the intent of Congress and exceeding the scope of delegated authority.\footnote{249} Such an examination begins with the \textit{Chevron} analysis.\footnote{250}

\footnote{243. See supra notes 67-69 and accompanying text (discussing the “legal grey area” between drugs and devices and the role it played in the Medical Device Amendments).


\footnote{245. S. 1262, 104th Cong., 1st Sess. § 906 (1995). Section 906 states that “[n]othing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products.” \textit{Id}.

\footnote{246. See Stephen Weitzman, supra note 79, at 336-41 (concluding that congressional intervention was warranted following the \textit{Bacto-Unidisk} and \textit{AMP} decisions).

\footnote{247. See Sunstein, supra note 108, at 2077 (setting forth constitutional considerations that administrative interpretations of enabling acts implicate).

\footnote{248. See supra note 4 (discussing the primary jurisdiction doctrine).


\footnote{250. \textit{Id}. At least one commentator has speculated as to whether \textit{Chevron} deference should apply to an administrative agency’s determination of its own jurisdiction. See Sunstein, supra note 108, at 2097 (questioning whether \textit{Chevron} deference should apply when an administrative agency seeks to extend its jurisdiction to a broad area of regulation); see also Adams Fruit Co. v. Barrett, 494 U.S. 638, 650 (1990) (holding that the Migrant and Seasonal Agricultural Worker Protection Act did not empower the Secretary of Labor to determine the scope of remedies available under the Act). Compare \textit{Dole} v. United Steelworkers of America, 494 U.S. 26, 53 (1990) (White, J., dissenting) (arguing that \textit{Chevron} deference applies to an agency’s interpretation that affects its jurisdiction) \textit{and} Mississippi
A. Congress Has Spoken on the Issue of the FDA's Jurisdiction Over Tobacco

In the first step of the *Chevron* analysis, a reviewing court must determine whether Congress has "directly spoken to the precise question at issue." In two respects, congressional intent regarding the FDA's jurisdiction to regulate tobacco products is clear. First, Congress has refused to pass proposed amendments that would have expressly brought tobacco within the FDA's jurisdiction. Second, Congress enacted a comprehensive regulatory framework designed to address the relationship between smoking and health.

Over the years, several bills have been introduced for the purpose of extending FDA jurisdiction to tobacco products; all have failed. Interestingly, most of the failed bills were strikingly similar to the FDA's current legal analysis and regulatory proposals. For example, most of the attempted amendments created a separate chapter for tobacco products, rather than allowing the FDA to regulate tobacco pursuant to its drug authorities. Both the drafters of the failed amendments and the FDA recognized that regulation pursuant to FDCA drug authorities would...

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251. *Chevron*, 467 U.S. at 842.

252. See, e.g., S. 2298, 102d Cong., 2d Sess. (1992) (attempting to amend the FDCA to grant the FDA express jurisdiction over tobacco products); H.R. 4350, 102 Cong., 2d Sess. (1992) (providing the House version of S. 2298); S. 769, 101st Cong., 1st Sess. (1989) (attempting to amend the FDCA to grant the FDA express jurisdiction over tobacco products); H.R. 1494, 101st Cong., 1st Sess. (1989) (providing the House version of S. 769); H.R. 3294, 100th Cong., 1st Sess. (1987) (attempting to amend the FDCA to grant the FDA express jurisdiction over tobacco products).


254. See supra note 252 (listing unenacted amendments to FDCA).

255. See H.R. 4350, 102d Cong., 2d Sess. (1992) (attempting to amend the FDCA to grant the FDA express jurisdiction over tobacco products). Significantly, both the proposed amendments and the FDA's current analysis incorporated findings that nicotine is a harmful and addictive drug. *Id.* § 2(5); Analysis Regarding Agency Jurisdiction, *supra* note 9, at 41,470.

256. E.g., H.R. 4350, 102d Cong., 2d Sess. § 2(11), (1992) (creating a separate chapter for tobacco products in a proposed amendment to the FDCA).
compel the banning of tobacco products—a politically undesirable solution. Further, most of the failed amendments attempted to prevent tobacco use by young people, and most contained provisions severely restricting the promotion of tobacco products as a means to this end.

Admittedly, it is risky to assign interpretive weight to failed amendments. Congress refuses to pass bills for many reasons, some of which may be substantively unrelated to the bills at issue. In addition, committee reports, the most reliable indicia of congressional intent, did not accompany the failed bills. Consequently, the other preferable evidence demonstrating that Congress has spoken on the issue of FDA tobacco jurisdiction—the current regulatory framework dealing with the relationship between tobacco and health—is an essential piece of the puzzle in determining congressional intent.

In two major enactments designed to deal with the relationship between tobacco and health, the FCLAA and the CSTHEA, Congress intended to establish a comprehensive federal program, thus preempting FDA jurisdiction over tobacco. First, the plain language of both stat-

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257. See id. In the findings section of H.R. 4350, Congress recognized that "creation of a separate chapter for tobacco under the [FDCA] assures the most effective means of regulating the product without the product being banned." Id.


259. See GEORGE A. COSTELLO, CONGRESSIONAL RESEARCH SERVICE, SOURCES OF LEGISLATIVE HISTORY AS AIDS TO STATUTORY CONSTRUCTION 53 (1989) (stating that congressional inaction is not necessarily entitled to interpretational weight).

260. Id.

261. See George A. Costello, Average Voting Members and Other "Benign Fictions": The Relative Reliability of Committee Reports, Floor Debates, and Other Sources of Legislative History, 1990 DUKE L.J. 39, 42-43 (finding that the United States Supreme Court relies upon committee reports more frequently than other forms of legislative history). It is not surprising that the unenacted bills lacked committee explanation; committee reports usually are generated only when bills are reported to the Senate or House floor for action. ABNER J. MIKVA & ERIC LANE, LEGISLATIVE PROCESS 217-18 (1995).


264. See 15 U.S.C. § 1331 (1994) (stating the purpose of the FCLAA); id. § 1334 (preempting federal and state action regarding statements on cigarette packages); id. § 4406(a) (preempting federal action regarding statements on any package or advertisement of a smokeless tobacco product); cf. Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5, 12-13, 17 (1976) (noting, in a jurisdictional conflict between the BATF and the FDA, that the Federal Alcohol Administration Act is special legislation designed to deal with the alcoholic beverage industry, and holding that the BATF has exclusive jurisdiction to regulate the labeling of alcoholic beverages).
utes carves out specific roles for the FTC. Indeed, both statutes purport neither to expand nor to limit the FTC's jurisdiction with respect to the false or misleading advertising of cigarettes. If Congress had so desired, it could have made a similar statement relating to FDA jurisdiction; the fact that it did not do so suggests that Congress did not believe that tobacco products fell within FDA jurisdiction. Second, the legislative history of both statutes demonstrates that Congress focused on the problem of tobacco use by young people, and intended the regulatory framework to address that problem. Finally, both statutes reveal that Congress intended to avoid the undesirable effects of diverse, nonuniform, and confusing federal regulations. The FDA's proposed regulations would frustrate this explicit congressional intent.

B. An Unreasonable Interpretation

If congressional intent regarding FDA jurisdiction over tobacco is unambiguous, any judicial inquiry must end. Even if reasonable minds could differ, however, as to whether Congress has spoken on this issue, the FDA's jurisdictional determination could not survive judicial review under the second step of the Chevron framework. In other words, the FDA's decision to assert jurisdiction over tobacco is not based on a permissible construction of the statute.

By creating statutory definitions of "drug" and "device," Congress expressly delegated authority to the FDA to interpret those provisions

265. See id. § 1336 (providing authority for the FTC in the FCLAA); id. § 4407 (requiring reports from HHS and the FTC in the CSTHEA); see also supra notes 118-35 and accompanying text (discussing roles of several federal agencies in tobacco regulation).

266. 15 U.S.C. § 1336 (1994) (providing the FTC's authority under the FCLAA); id. § 4404(c) (providing the FTC's authority under the CSTHEA).

267. See Action on Smoking and Health v. Harris, 655 F.2d 236, 241-43 (D.C. Cir. 1980) (citing congressional acquiescence to the lack of FDA tobacco jurisdiction as a basis for upholding the FDA's refusal to regulate cigarettes as drugs).


269. 15 U.S.C. § 1331(2)(B) (1994); see id. § 4406(a) (expressly preempting federal efforts to require statements on cigarette packages).

270. See supra notes 193-200 and accompanying text (describing proposed regulations for tobacco products).


272. See id. (setting forth Chevron's second step).

273. See id. at 843-44.
through the regulatory process. Under *Chevron*'s second step, courts must uphold such regulations unless they are "arbitrary, capricious, or manifestly contrary to the statute." The FDA's determination that tobacco products properly are regulated as medical devices must fail, however, because it is manifestly contrary to the FDCA. Simply put, the FDA's determination will require the Agency to depart from its statutory mandate, leading to results that conflict with the FDCA's new drug authorities and safety and efficacy requirements.

First, the FDA's proposal failed to regulate nicotine as a drug, illustrating one contrary outcome of the FDA's jurisdictional analysis. The bulk of over 600 pages of evidence and analysis is dedicated to detailing the delivery mechanisms and dangers of nicotine. Furthermore, nicotine is essential to the FDA's finding of statutory intent to affect the structure or any function of the body. The FDA even concluded that nicotine is a "drug." Despite the attention the FDA gave to nicotine's drug status, however, the Agency still chose to regulate tobacco products pursuant to the Act's device authorities. In effect, the Agency has contended that it may declare a product a "drug," but then choose the statutory provisions that best suit its regulatory preferences. Because the

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274. *See* *Chevron*, 467 U.S. at 843-45 (discussing the congressional practice of leaving statutory "gaps" for an administrative agency to fill).

275. *See id.* at 844 (explaining that a regulation will not be given controlling weight if it is manifestly contrary to the enabling statute).

276. *See infra* notes 278-89 and accompanying text (explaining why the FDA's current tobacco analysis is manifestly contrary to the structure of the FDCA).

277. *See infra* notes 278-89 and accompanying text.

278. *See* Analysis Regarding Agency Jurisdiction, *supra* note 9, at 41,521-25 (concluding that nicotine is a "drug," but maintaining that regulation of nicotine is discretionary); *id.* at 41,523 (choosing to regulate tobacco products as medical devices).

279. *See id.* at 41,453-87 (presenting a legal analysis of tobacco jurisdiction and formal findings regarding tobacco products); *id.* apps. (comprising 312 pages of background materials in a separate volume to supplement the federal register documents).

280. *Id.* at 41,521; *see id.* at 41,467-70 (describing the effects of tobacco on the structure and function of the body solely by reference to nicotine).

281. *Id.* at 41,523.

282. *Id.* Undoubtedly, the FDA wished to avoid regulating nicotine as a drug because that would lead to the removal of nicotine from the market. *See* 21 U.S.C. § 355 (1994) (requiring FDA to remove new drugs from the market unless such drugs are safe and effective); Analysis Regarding Agency Jurisdiction, *supra* note 9, at 41,523-24 (acknowledging that regulation of nicotine as a drug could lead to its prohibition).

283. Granted, the FDA has a great deal of discretion in choosing its regulatory techniques. *See supra* notes 102-07 and accompanying text (noting that the FDA's mission to protect the public health entitles it to a considerable amount of judicial deference). Nonetheless, the FDA abused its discretion when it attempted to issue regulations that contradict its quintessential mission—to assure the safety and efficacy of drugs and devices. *See supra* notes 25-26 and accompanying text (discussing the safety and efficacy requirements). The FDA's proposed tobacco regulations do not attempt to ensure the safety or efficacy of
FDA contended that nicotine is the root of the tobacco problem, a logical regulatory scheme would classify nicotine as a "new drug" subject to the FDA's approval power.\footnote{284}

The second contrary result of the FDA's proposal, involving the safety and efficacy requirement, is closely related to the first. A major purpose of the FDCA is to ensure that drugs and medical devices are safe and effective for their intended uses.\footnote{285} Furthermore, the FDCA requires the tobacco products. Rather, the proposed regulations intend to decrease the number of tobacco users. See Analysis Regarding Agency Jurisdiction, supra note 9, at 41,785-87 (providing regulatory objectives). While this noble goal certainly is related to the public health, the safety and efficacy requirements demonstrate that it is not the sort of situation that Congress intended the FDCA to address. See supra notes 25-26 and accompanying text. Thus, assuming that the FDA sustained its burden of proving vendor intent, a significant assumption, the natural result of FDA tobacco jurisdiction would be an examination of tobacco's safety and efficacy under the Act's new drug authorities. See 21 U.S.C. \S\ 355 (1994) (describing the approval process for new drugs); id. \S\ 321(p) (defining the term "new drug" to include drugs "not generally recognized . . . as safe and effective").

An example illustrates the point. The FDA recently asserted jurisdiction to regulate over-the-counter (OTC) products labelled as smoking deterrents. 21 C.F.R. \S\ 310.544(a) (1995). In its regulations, the FDA first noted that products claiming to "stop or reduce the cigarette urge" were drugs. Id. Second, the FDA declared that such products often contain cloves, coriander, ginger, licorice root extract, and other commonly available ingredients. Id. Nonetheless, the FDA concluded that the lack of data regarding the safety and efficacy of such ingredients for OTC uses indicated that OTC smoking deterrent products containing these ingredients were not "generally recognized as safe and effective." Id. Consequently, OTC smoking deterrent products containing these common ingredients would violate the FDCA, absent an approved new drug application. Id. \S\ 310.544(b). The Agency's cautious handling of ginger, cloves, and other spices advertised as smoking deterrents demonstrates the appropriate regulatory approach under the FDCA: the FDA connected the product's drug status to the vendor's claimed intent to affect a structure or function of the body, and the Agency attempted to ensure the product's safety and effectiveness.

\footnote{284} See supra note 26 (describing the FDA's new drug authority). This result also would be consistent with the SMDA, which provides that a combination product's status should be determined by its "primary mode of action." 21 U.S.C. \S\ 353(g)(1) (1994); see supra note 93 (describing the SMDA and the FDA's Intercenter Agreement regarding combination products). Additionally, classification of nicotine as a "new drug" would be more consistent with the FCLAA, the CSTHEA, and the FDCA's restricted device authorities. See supra note 193 (describing the FDA's authority to regulate advertising of restricted devices). The FDA, by classifying tobacco products as restricted devices, claimed the authority to regulate tobacco advertising. See 21 U.S.C. \S\ 352(r) (1994) (providing FDA authority to regulate advertising of restricted devices). Significantly, when Congress granted the authority to regulate restricted device advertising to the FDA, it expressly removed that authority from the FTC's jurisdiction. See supra note 193 (explaining Congress' decision to remove the jurisdiction to regulate restricted device advertising from the FTC). If tobacco products were indeed restricted devices, the FTC's authority to regulate tobacco advertising pursuant to the FCLAA and the CSTHEA would be in doubt. See supra notes 123-35 and accompanying text (describing the FTC's authority to regulate tobacco advertising).

\footnote{285} 21 U.S.C. \S\ 355 (1994) (providing that all new drugs must be safe and effective); id. 360c (requiring devices to be safe and effective).
FDA to ban products that cannot reasonably meet this statutory burden.\textsuperscript{286} The FDA maintains that, in the case of tobacco products, the safety requirement is a discretionary measure that it may address with a "staged, multi-tiered approach."\textsuperscript{287} Tobacco products, however, are absolutely unsafe when used as intended.\textsuperscript{288} Thus, the FDA's interpretation clearly is contrary to the FDCA, especially in light of the profound health consequences of tobacco.\textsuperscript{289}

C. An Issue for Congress

Tobacco products are a cultural tradition,\textsuperscript{290} an economic success,\textsuperscript{291} and a health disaster.\textsuperscript{292} In addition, tobacco products do not fit neatly within the FDCA's framework.\textsuperscript{293} Therefore, cigarettes and smokeless tobacco products present the FDA with a difficult dilemma: forego regulation and await clear direction from Congress, or creatively interpret the FDCA to allow jurisdiction. Because tobacco products are truly unique, the FDA should not attempt to force the issue of tobacco regulation under the current version of the FDCA. If further regulation of tobacco is desirable under the FDCA, Congress should create a separate chapter for tobacco products.\textsuperscript{294}

A separate chapter for tobacco products would allow Congress to address the unique problems that cigarettes and smokeless tobacco present.\textsuperscript{295} Indeed, only congressional action could retain the essential elements of the FDA's current proposal without changing the meaning of

\begin{itemize}
\item \textsuperscript{286} Id. §§ 355, 360c.
\item \textsuperscript{287} Analysis Regarding Agency Jurisdiction, supra note 9, at 41,523-24.
\item \textsuperscript{288} See id. at 41,523-24 (recognizing that tobacco products are unsafe).
\item \textsuperscript{289} Id.; see Morbidity and Mortality Wkly Rep., supra note 15, at 645-49 (estimating that cigarette smoking is responsible for over 400,000 deaths each year).
\item \textsuperscript{290} See Smoking and Health in the Americas, supra note 14, at 23-49 (describing the emergence of the cigarette and use of tobacco products in general from 1534 to the modern day).
\item \textsuperscript{291} See id. at 115-36 (describing the economic factors related to tobacco consumption in the Americas).
\item \textsuperscript{292} See id. at 61-97 (describing the prevalence of tobacco consumption and associated mortality rates).
\item \textsuperscript{293} See supra notes 201-89 accompanying text (describing the ways in which the FDA's tobacco jurisdiction conflicts with the current version of the FDCA).
\item \textsuperscript{294} See, e.g., H.R. 4350, 102d Cong., 2d Sess. (1992) (attempting to amend the FDCA to grant the FDA express jurisdiction over tobacco). This was exactly the approach taken by the failed amendments to the FDCA that expressly would have granted the FDA the jurisdiction to regulate tobacco. Id. § 5. Indeed, these amendments even created separate misbranding and adulteration provisions for tobacco products, thus recognizing the unique features of tobacco products. Id.
\item \textsuperscript{295} See supra notes 290-92 and accompanying text (discussing the historical, cultural, economical, and public health aspects of tobacco use).
\end{itemize}
the FDCA's safety and efficacy requirements. In addition, the separate chapter approach would benefit the regulated industry, the FDA, and the public. First, clear direction from Congress would afford certainty for the tobacco industry. Under the FDA's current proposal, the Agency retains the authority to subject tobacco products to any or all of its drug and device provisions, including its premarket approval authority. Second, the separate chapter approach, which would require express congressional approval, might enhance the availability of Agency resources to enforce tobacco regulations. Finally, the process of amending the Act would provide more meaningful opportunities for public participation than notice and comment rulemaking.

296. The FDA’s jurisdictional analysis, if successful, would set a dangerous precedent by changing the meaning of the safety and efficacy requirements. See supra notes 283-89 (arguing that the FDA’s assertion of tobacco jurisdiction contradicted its quintessential mission to ensure reasonably safe and effective drugs and devices).

297. The scope of the FDA’s proposed regulatory scheme is uncertain. On the one hand, the proposed regulations outline the planned restrictions on the advertising and distribution of tobacco products explicitly. See supra notes 193-200 and accompanying text (describing proposed regulations). On the other hand, the FDA also notes that tobacco products, as “devices,” will be subject to “pre-existing requirements” in the Act and the regulations. Proposed Regulations, supra note 9, at 41,352. These requirements include general device labelling requirements, 21 C.F.R. pt. 801 (1995), registration requirements, id. pt. 807 (1995), and good manufacturing practice requirements, id. pt. 820. Additionally, the Agency’s proposal would permit it to subject tobacco products to its new drug authority, 21 U.S.C. § 355 (1994), or its authority to ban devices that present an “unreasonable and substantial risk of illness,” id. § 360f(a)(1). Thus, the Agency’s current proposal constitutes only a fraction of the potential regulatory scheme.

298. See supra note 297 (discussing the scope of the potential regulatory scheme for tobacco products).

299. The FDA’s current proposal did not include an estimate of administrative costs. See Proposed Regulations, supra note 9, at 41,365-68 (describing “regulatory costs” without reference to cost to the FDA). However, in response to congressional inquiries, the FDA estimated the cost of tobacco-related work to require about $3.5 million and 27 full-time employees in fiscal year 1995. Letters from Diane E. Thompson, Associate Commissioner for Legislative Affairs, FDA, to the Honorable Mitch McConnell, United States Senate, and the Honorable Joe Skeen, Chairman, Subcommittee on Agriculture, United States House of Representatives (Feb. 7, 1996). Accordingly, the FDA’s tobacco effort is certain to divert funding from other Agency responsibilities, such as the drug approval process. See Ellen McCleskey, FDA: Budget, Election Pressures Could Delay Agency Reform in 1996; Gingrich a Factor, 4 Health Care Pol’y Daily (BNA) No. 5, at 159, 159-61 (1996) (noting that FDA insiders are troubled by the FDA’s decision to commit Agency resources to tobacco regulation). If Congress amended the FDCA to grant express tobacco jurisdiction, however, the Agency would be in a better position to request additional resources. Even with express authority, of course, political realities often render such budget matters uncertain.

300. See E. Donald Elliot, Re-Inventing Rulemaking, 1992 DUKE L.J. 1490. Professor Elliot asserts that notice-and-comment rulemaking is an ineffective formality:

No administrator in Washington turns to full-scale notice-and-comment rulemaking when she is genuinely interested in obtaining input from interested parties. Notice-and-comment rulemaking is to public participation as Japanese Kabuki
Tobacco products exert a tremendous toll on the health of the nation. The FDA, recognizing the health consequences associated with tobacco use, has asserted jurisdiction over tobacco products with a commendable goal in mind: a reduction of the number of tobacco users under eighteen years of age. The FDA’s legal analysis of its jurisdiction, however, is problematic in several respects. First, Congress did not intend for the FDA to regulate tobacco. This intention was expressed explicitly through failed attempts to amend the FDCA to grant tobacco jurisdiction, and through a comprehensive federal tobacco regulatory scheme that did not create a role for the FDA. Second, even if Congress has not spoken directly on the issue of the FDA’s authority to regulate tobacco, the FDA’s interpretation of the FDCA as allowing jurisdiction over tobacco products cannot pass judicial muster. Indeed, the FDA’s jurisdictional interpretation is manifestly contrary to FDCA organization and precedent. Executive branch agencies, such as the FDA, derive their power by congressional mandate. Unreasonably broad interpretations of statutory definitions defy congressional intent. Thus, if the FDA is to regulate tobacco products as drugs or devices under the FDCA, it is for Congress, and not the FDA, to make this determination.

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