[Note: In the following opinion, footnotes and some foreword matter have been deleted. The dissenting opinion written by Justice Breyer has also been omitted.]

Food and Drug Administration v. Brown & Williamson Tobacco Corporation
Supreme Court of the United States
529 U.S. 120; 120 S. Ct. 1291; 146 L. Ed. 2d 121

March 21, 2000

Justice O'Connor delivered the opinion of the Court.

This case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use. In 1996, the Food and Drug Administration (FDA), after having expressly disavowed any such authority since its inception, asserted jurisdiction to regulate tobacco products. See 61 Fed. Reg. 44619-45318. The FDA concluded that nicotine is a "drug" within the meaning of the Food, Drug, and Cosmetic Act (FDCA or Act), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, and that cigarettes and smokeless tobacco are "combination products" that deliver nicotine to the body. 61 Fed. Reg. 44397 (1996). Pursuant to this authority, it promulgated regulations intended to reduce tobacco consumption among children and adolescents. *Id.*, at 44615-44618. The agency believed that, because most tobacco consumers begin their use before reaching the age of 18, curbing tobacco use by minors could substantially reduce the prevalence of addiction in future generations and thus the incidence of tobacco-related death and disease. *Id.*, at 44398-44399.

Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *ETSI Pipeline Project* v. *Missouri*, 484 U.S. 495, 517, 98 L. Ed. 2d 898, 108 S. Ct. 805 (1988). And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

I

The FDCA grants the FDA, as the designee of the Secretary of Health and Human Services, the authority to regulate, among other items, "drugs" and "devices." See 21 U.S.C. §§ 321(g)-(h), 393 (1994 ed. and Supp. III). The Act defines "drug" to include

"articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C). It defines "device," in part, as "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body." § 321(h). The Act also grants the FDA the authority to regulate so-called "combination products," which "constitute a combination of a drug, device, or biologic product." § 353(g)(1). The FDA has construed this provision as giving it the discretion to regulate combination products as drugs, as devices, or as both. See 61 Fed. Reg. 44400 (1996).

On August 11, 1995, the FDA published a proposed rule concerning the sale of cigarettes and smokeless tobacco to children and adolescents. 60 Fed. Reg. 41314-41787. The rule, which included several restrictions on the sale, distribution, and advertisement of tobacco products, was designed to reduce the availability and attractiveness of tobacco products to young people. *Id.*, at 41314. A public comment period followed, during which the FDA received over 700,000 submissions, more than "at any other time in its history on any other subject." 61 Fed. Reg. 44418 (1996).

On August 28, 1996, the FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." *Id.*, at 44396. The FDA determined that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices," and therefore it had jurisdiction under the FDCA to regulate tobacco products as customarily marketed -- that is, without manufacturer claims of therapeutic benefit. *Id.*, at 44397, 44402. First, the FDA found that tobacco products "'affect the structure or any function of the body'" because nicotine "has significant pharmacological effects." *Id.*, at 44631. Specifically, nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight. *Id.*, at 44631-44632. Second, the FDA determined that these effects were "intended" under the FDCA because they "are so widely known and foreseeable that [they] may be deemed to have been intended by the manufacturers," *id.*, at 44687; consumers use tobacco products "predominantly or nearly exclusively" to obtain these effects, *id.*, at 44807; and the statements, research, and actions of manufacturers revealed that they "have 'designed' cigarettes to provide pharmacologically active doses of nicotine to consumers," *id.*, at 44849. Finally, the agency concluded that cigarettes and smokeless tobacco are "combination products" because, in addition to containing nicotine, they include device components that deliver a controlled amount of nicotine to the body, *id.*, at 45208-45216.

Having resolved the jurisdictional question, the FDA next explained the policy justifications for its regulations, detailing the deleterious health effects associated with tobacco use. It found that tobacco consumption was "the single leading cause of preventable death in the United States." *Id.*, at 44398. According to the FDA, "more than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." *Ibid.* The agency also determined that the only way to reduce the amount of tobacco-related illness and mortality was to reduce the level of

addiction, a goal that could be accomplished only by preventing children and adolescents from starting to use tobacco. *Id.*, at 44398-44399. The FDA found that 82% of adult smokers had their first cigarette before the age of 18, and more than half had already become regular smokers by that age. *Id.*, at 44398. It also found that children were beginning to smoke at a younger age, that the prevalence of youth smoking had recently increased, and that similar problems existed with respect to smokeless tobacco. *Id.*, at 44398-44399. The FDA accordingly concluded that if "the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely ever to begin." *Id.*, at 44399.

Based on these findings, the FDA promulgated regulations concerning tobacco products' promotion, labeling, and accessibility to children and adolescents. See *id.*, at 44615-44618. The access regulations prohibit the sale of cigarettes or smokeless tobacco to persons younger than 18; require retailers to verify through photo identification the age of all purchasers younger than 27; prohibit the sale of cigarettes in quantities smaller than 20; prohibit the distribution of free samples; and prohibit sales through self-service displays and vending machines except in adult-only locations. *Id.*, at 44616-44617. The promotion regulations require that any print advertising appear in a black-and-white, text-only format unless the publication in which it appears is read almost exclusively by adults; prohibit outdoor advertising within 1,000 feet of any public playground or school; prohibit the distribution of any promotional items, such as T-shirts or hats, bearing the manufacturer's brand name; and prohibit a manufacturer from sponsoring any athletic, musical, artistic, or other social or cultural event using its brand name. *Id.*, at 44617-44618. The labeling regulation requires that the statement, "A Nicotine-Delivery Device for Persons 18 or Older," appear on all tobacco product packages. *Id.*, at 44617.

The FDA promulgated these regulations pursuant to its authority to regulate "restricted devices." See 21 U.S.C. § 360j(e). The FDA construed § 353(g)(1) as giving it the discretion to regulate "combination products" using the Act's drug authorities, device authorities, or both, depending on "how the public health goals of the act can be best accomplished." 61 Fed. Reg. 44403 (1996). Given the greater flexibility in the FDCA for the regulation of devices, the FDA determined that "the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco." *Id.*, at 44404. Under 21 U.S.C. § 360j(e), the agency may "require that a device be restricted to sale, distribution, or use . . . upon such other conditions as [the FDA] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [the FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." The FDA reasoned that its regulations fell within the authority granted by § 360j(e) because they related to the sale or distribution of tobacco products and were necessary for providing a reasonable assurance of safety. 61 Fed. Reg. 44405-44407 (1996).

Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed suit in United States District Court for the Middle District of North Carolina challenging the regulations. See *Coyne Beahm, Inc.* v. *FDA*, 966 F. Supp. 1374 (1997). They moved for

summary judgment on the grounds that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, the regulations exceeded the FDA's authority under 21 U.S.C. § 360j(e), and the advertising restrictions violated the First Amendment. Second Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97-1604 (CA4), Tab No. 40; Third Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97-1604 (CA4), Tab No. 42. The District Court granted respondents' motion in part and denied it in part. 966 F. Supp. at 1400. The court held that the FDCA authorizes the FDA to regulate tobacco products as customarily marketed and that the FDA's access and labeling regulations are permissible, but it also found that the agency's advertising and promotion restrictions exceed its authority under § 360j(e). *Id.*, at 1380-1400. The court stayed implementation of the regulations it found valid (except the prohibition on the sale of tobacco products to minors) and certified its order for immediate interlocutory appeal. *Id.*, at 1400-1401.

The Court of Appeals for the Fourth Circuit reversed, holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. See 153 F.3d 155 (1998). Examining the FDCA as a whole, the court concluded that the FDA's regulation of tobacco products would create a number of internal inconsistencies. *Id.*, at 162-167. Various provisions of the Act require the agency to determine that any regulated product is "safe" before it can be sold or allowed to remain on the market, yet the FDA found in its rulemaking proceeding that tobacco products are "dangerous" and "unsafe." *Id.*, at 164-167. Thus, the FDA would apparently have to ban tobacco products, a result the court found clearly contrary to congressional intent. *Ibid.* This apparent anomaly, the Court of Appeals concluded, demonstrates that Congress did not intend to give the FDA authority to regulate tobacco. *Id.*, at 167. The court also found that evidence external to the FDCA confirms this conclusion. Importantly, the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, and Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position. See *id.*, at 168-176. In fact, the court reasoned, Congress has considered and rejected many bills that would have given the agency such authority. See *id.*, at 170-171. This, along with the absence of any intent by the enacting Congress in1938 to subject tobacco products to regulation under the FDCA, demonstrates that Congress intended to withhold such authority from the FDA. *Id.*, at 167-176. Having resolved the jurisdictional question against the agency, the Court of Appeals did not address whether the regulations exceed the FDA's authority under 21 U.S.C. § 360j(e) or violate the First Amendment. See 153 F.3d at 176, n. 29.

We granted the Government's petition for certiorari, 526 U.S. 1086 (1999), to determine whether the FDA has authority under the FDCA to regulate tobacco products as customarily marketed.

II

The FDA's assertion of jurisdiction to regulate tobacco products is founded on its conclusions that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices." Again, the FDA found that tobacco products are "intended" to deliver

the pharmacological effects of satisfying addiction, stimulation and tranquilization, and weight control because those effects are foreseeable to any reasonable manufacturer, consumers use tobacco products to obtain those effects, and tobacco manufacturers have designed their products to produce those effects. 61 Fed. Reg. 44632-44633 (1996). As an initial matter, respondents take issue with the FDA's reading of "intended," arguing that it is a term of art that refers exclusively to claims made by the manufacturer or vendor about the product. See Brief for Respondent Brown & Williamson Tobacco Corp. 6. That is, a product is not a drug or device under the FDCA unless the manufacturer or vendor makes some express claim concerning the product's therapeutic benefits. See *id.*, at 6-7. We need not resolve this question, however, because assuming, *arguendo*, that a product can be "intended to affect the structure or any function of the body" absent claims of therapeutic or medical benefit, the FDA's claim to jurisdiction contravenes the clear intent of Congress.

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. Because this case involves an administrative agency's construction of a statute that it administers, our analysis is governed by *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). Under *Chevron*, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.*, at 842. If Congress has done so, the inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.*, at 843; see also *United States* v. *Haggar Apparel Co.*, 526 U.S. 380, 392, 143 L. Ed. 2d 480, 119 S. Ct. 1392 (1999); *Holly Farms Corp.* v. *NLRB*, 517 U.S. 392, 398, 134 L. Ed. 2d 593, 116 S. Ct. 1396 (1996). But if Congress has not specifically addressed the question, a reviewing court must respect the agency's construction of the statute so long as it is permissible. See *INS* v. *Aguirre-Aguirre*, 526 U.S. 415, 424, 143 L. Ed. 2d 590, 119 S. Ct. 1439 (1999); *Auer* v. *Robbins*, 519 U.S. 452, 457, 137 L. Ed. 2d 79, 117 S. Ct. 905 (1997). Such deference is justified because "the responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron, supra*, at 866, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated, see *Rust* v. *Sullivan*, 500 U.S. 173, 187, 114 L. Ed. 2d 233, 111 S. Ct. 1759 (1991).

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning -- or ambiguity -- of certain words or phrases may only become evident when placed in context. See *Brown* v. *Gardner*, 513 U.S. 115, 118, 130 L. Ed. 2d 462, 115 S. Ct. 552 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context"). It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis* v. *Michigan Dept. of Treasury*, 489 U.S. 803, 809, 103 L. Ed. 2d 891, 109 S. Ct. 1500 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 569, 131 L. Ed. 2d 1, 115 S. Ct. 1061 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC* v. *Mandel Brothers, Inc.*, 359 U.S. 385, 389, 3 L. Ed. 2d 893,

79 S. Ct. 818 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See *United States* v. *Estate of Romani,* 523 U.S. 517, 530-531, 140 L. Ed. 2d 710, 118 S. Ct. 1478 (1998); *United States* v. *Fausto,* 484 U.S. 439, 453, 98 L. Ed. 2d 830, 108 S. Ct. 668 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.,* 512 U.S. 218, 231, 129 L. Ed. 2d 182, 114 S. Ct. 2223 (1994).

With these principles in mind, we find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products.

A

Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. See 21 U.S.C. § 393(b)(2) (1994 ed., Supp. III) (defining the FDA's mission); More Information for Better Patient Care: Hearing before the Senate Committee on Labor and Human Resources, 104th Cong., 2d Sess., 83 (1996) (statement of FDA Deputy Commissioner Schultz) ("A fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold"). This essential purpose pervades the FDCA. For instance, 21 U.S.C. § 393(b)(2) (1994 ed., Supp. III) defines the FDA's "mission" to include "protecting the public health by ensuring that . . . drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." The FDCA requires premarket approval of any new drug, with some limited exceptions, and states that the FDA "shall issue an order refusing to approve the application" of a new drug if it is not safe and effective for its intended purpose. §§ 355(d)(1)-(2), (4)-(5). If the FDA discovers after approval that a drug is unsafe or ineffective, it "shall, after due notice and opportunity for hearing to the applicant, withdraw approval" of the drug. 21 U.S.C. §§ 355(e)(1)-(3). The Act also requires the FDA to classify all devices into one of three categories. § 360c(b)(1). Regardless of which category the FDA chooses, there must be a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. §§ 360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Even the "restricted device" provision pursuant to which the FDA promulgated the regulations at issue here authorizes the agency to place conditions on the sale or distribution of a device specifically when "there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360j(e). Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *United States* v. *Rutherford,* 442 U.S. 544, 556, 61 L. Ed. 2d 68, 99 S. Ct. 2470 (1979).

In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness." 61 Fed. Reg. 44412 (1996). It found that the consumption of tobacco products "presents

extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States." *Id.*, at 44398. It stated that "more than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths," and that "tobacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *Ibid.* Indeed, the FDA characterized smoking as "a pediatric disease," *id.*, at 44421, because "one out of every three young people who become regular smokers . . . will die prematurely as a result," *id.*, at 44399.

These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market. Consider, first, the FDCA's provisions concerning the misbranding of drugs or devices. The Act prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). In light of the FDA's findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, § 352(j) deems a drug or device misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." The FDA's findings make clear that tobacco products are "dangerous to health" when used in the manner prescribed. Second, a drug or device is misbranded under the Act "unless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users," except where such directions are "not necessary for the protection of the public health." § 352(f)(1). Given the FDA's conclusions concerning the health consequences of tobacco use, there are no directions that could adequately protect consumers. That is, there are no directions that could make tobacco products safe for obtaining their intended effects. Thus, were tobacco products within the FDA's jurisdiction, the Act would deem them misbranded devices that could not be introduced into interstate commerce. Contrary to the dissent's contention, the Act admits no remedial discretion once it is evident that the device is misbranded.

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See § 360c(b)(1). The agency relies on a device's classification in determining the degree of control and regulation necessary to ensure that there is "a reasonable assurance of safety and effectiveness." 61 Fed. Reg. 44412 (1996). The FDA has yet to classify tobacco products. Instead, the regulations at issue here represent so-called "general controls," which the Act entitles the agency to impose in advance of classification. See *id.*, at 44404-44405. Although the FDCA prescribes no deadline for device classification, the FDA has stated that it will classify tobacco products "in a future rulemaking" as required by the Act. *Id.*, at 44412. Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). As Class III devices, tobacco products would be subject to the FDCA's premarket approval process. See 21 U.S.C. § 360c(a)(1)(C) (1994 ed., Supp. III); 21 U.S.C. § 360e; 61 Fed. Reg. 44412 (1996). Under these provisions, the FDA would be

prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof." 21 U.S.C. § 360e(d)(2)(A). In view of the FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.

The FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them. In fact, based on these provisions, the FDA itself has previously taken the position that if tobacco products were within its jurisdiction, "they would have to be removed from the market because it would be impossible to prove they were safe for their intended use." Public Health Cigarette Amendments of 1971: Hearings before the Commerce Subcommittee on S. 1454, 92d Cong., 2d Sess., 239 (1972) (hereinafter 1972 Hearings) (statement of FDA Commissioner Charles Edwards). See also Cigarette Labeling and Advertising: Hearings before the House Committee on Interstate and Foreign Commerce, 88th Cong., 2d Sess., 18 (1964) (hereinafter 1964 Hearings) (statement of Department of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze that proposed amendments to the FDCA that would have given the FDA jurisdiction over "smoking products" "might well completely outlaw at least cigarettes").

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "the marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." 7 U.S.C. § 1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. See Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. 89-92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102-321, § 202, 106 Stat. 394. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine's pharmacological effects. See, *e.g.*, U.S. Dept. of Health, Education, and Welfare, U.S. Surgeon General's Advisory Committee, Smoking and Health 25-40, 69-75 (1964) (hereinafter 1964 Surgeon General's Report) (concluding that cigarette smoking causes lung cancer, coronary artery disease, and chronic bronchitis and emphysema, and that nicotine has various pharmacological effects, including stimulation, tranquilization, and appetite suppression); U.S. Dept. of Health and Human Services, Public Health Service, Health Consequences of Smoking for Women 7-12 (1980) (finding that mortality rates for lung cancer, chronic lung disease, and coronary heart disease are increased for both women and men smokers, and that smoking during pregnancy is associated with significant adverse health effects on the unborn fetus and newborn child);

U.S. Dept. of Health and Human Services, Public Health Service, Why People Smoke Cigarettes (1983), in Smoking Prevention Education Act, Hearings on H. R. 1824 before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 32-37 (1983) (hereinafter 1983 House Hearings) (stating that smoking is "the most widespread example of drug dependence in our country," and that cigarettes "affect the chemistry of the brain and nervous system"); U.S. Dept. of Health and Human Services, Public Health Service, The Health Consequences of Smoking: Nicotine Addiction 6-9, 145-239 (1988) (hereinafter 1988 Surgeon General's Report) (concluding that tobacco products are addicting in much the same way as heroin and cocaine, and that nicotine is the drug that causes addiction). Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that "commerce and the national economy may be . . . protected to the maximum extent consistent with" consumers "being adequately informed about any adverse health effects." 15 U.S.C. § 1331. Congress' decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy . . . to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.

The FDA apparently recognized this dilemma and concluded, somewhat ironically, that tobacco products are actually "safe" within the meaning of the FDCA. In promulgating its regulations, the agency conceded that "tobacco products are unsafe, as that term is conventionally understood." 61 Fed. Reg. 44412 (1996). Nonetheless, the FDA reasoned that, in determining whether a device is safe under the Act, it must consider "not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." *Id.*, at 44412-44413. Applying this standard, the FDA found that, because of the high level of addiction among tobacco users, a ban would likely be "dangerous." *Id.*, at 44413. In particular, current tobacco users could suffer from extreme withdrawal, the health care system and available pharmaceuticals might not be able to meet the treatment demands of those suffering from withdrawal, and a black market offering cigarettes even more dangerous than those currently sold legally would likely develop. *Ibid.* The FDA therefore concluded that, "while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others, the record does not establish that such a ban is the appropriate public health response under the act." *Id.*, at 44398.

It may well be, as the FDA asserts, that "these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products." *Id.*, at 44413. But the FDA's judgment that leaving tobacco products on the market "is more effective in achieving public health goals than a ban," *ibid.*, is no substitute for the specific safety determinations required by the FDCA's various operative provisions. Several provisions in the Act require the FDA to determine that the *product itself* is safe as used by consumers. That is, the product's probable therapeutic

benefits must outweigh its risk of harm. See *United States* v. *Rutherford*, 442 U.S. at 555 ("The Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"). In contrast, the FDA's conception of safety would allow the agency, with respect to each provision of the FDCA that requires the agency to determine a product's "safety" or "dangerousness," to compare the aggregate health effects of alternative administrative actions. This is a qualitatively different inquiry. Thus, although the FDA has concluded that a ban would be "dangerous," it has *not* concluded that tobacco products are "safe" as that term is used throughout the Act.

Consider 21 U.S.C. § 360c(a)(2), which specifies those factors that the FDA may consider in determining the safety and effectiveness of a device for purposes of classification, performance standards, and premarket approval. For all devices regulated by the FDA, there must at least be a "reasonable assurance of the safety and effectiveness of the device." See 21 U.S.C. §§ 360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Title 21 U.S.C. § 360c(a)(2) provides that

"the safety and effectiveness of a device are to be determined --

"(A) with respect to the persons for whose use the device is represented or intended,

"(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

"(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."

A straightforward reading of this provision dictates that the FDA must weigh the probable therapeutic benefits of the device to the consumer against the probable risk of injury. Applied to tobacco products, the inquiry is whether their purported benefits -- satisfying addiction, stimulation and sedation, and weight control -- outweigh the risks to health from their use. To accommodate the FDA's conception of safety, however, one must read "any probable benefit to health" to include the benefit to public health stemming from adult consumers' continued use of tobacco products, even though the *reduction* of tobacco use is the *raison d'etre* of the regulations. In other words, the FDA is forced to contend that the very evil it seeks to combat is a "benefit to health." This is implausible.

The FDA's conception of safety is also incompatible with the FDCA's misbranding provision. Again, § 352(j) provides that a product is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." According to the FDA's understanding, a product would be "dangerous to health," and therefore misbranded under § 352(j), when, in comparison to leaving the product on the market, a ban would not produce "adverse health consequences" in aggregate. Quite simply, these are different inquiries. Although banning a particular product might be detrimental to public health in aggregate, the product could still be "dangerous to health" when used as directed. Section

352(j) focuses on dangers to the consumer from use of the product, not those stemming from the agency's remedial measures.

Consequently, the analogy made by the FDA and the dissent to highly toxic drugs used in the treatment of various cancers is unpersuasive. See 61 Fed. Reg. 44413 (1996); *post*, at 17 (opinion of BREYER, J.). Although "dangerous" in some sense, these drugs are safe within the meaning of the Act because, for certain patients, the therapeutic benefits outweigh the risk of harm. Accordingly, such drugs cannot properly be described as "dangerous to health" under 21 U.S.C. § 352(j). The same is not true for tobacco products. As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect.

The dissent contends that our conclusion means that "the FDCA requires the FDA to ban outright 'dangerous' drugs or devices," *post*, at 14, and that this is a "perverse" reading of the statute, *id.*, at 14, 21. This misunderstands our holding. The FDA, consistent with the FDCA, may clearly regulate many "dangerous" products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions. What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA's core objective of ensuring that every drug or device is safe and effective.

Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA -- but not banned -- must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic benefits outweigh the risk of harm to the consumer. According to this standard, the FDA has concluded that, although tobacco products might be effective in delivering certain pharmacological effects, they are "unsafe" and "dangerous" when used for these purposes. Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.

B

In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The "classic judicial task of reconciling many laws enacted over time,

and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States* v. *Fausto*, 484 U.S. at 453. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States* v. *Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it has not been expressly amended." 523 U.S. at 530-531.

Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health. See *supra*, at 14. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U.S.C. §§ 1331, 1333, 4402; prohibit the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission (FCC), see §§ 1335, 4402(f); require the Secretary of Health and Human Services (HHS) to report every three years to Congress on research findings concerning "the addictive property of tobacco," 42 U.S.C. § 290aa-2(b)(2); and make States' receipt of certain federal block grants contingent on their making it unlawful "for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," § 300x-26(a)(1).

In adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine's pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.

On January 11, 1964, the Surgeon General released the report of the Advisory Committee on Smoking and Health. That report documented the deleterious health effects of smoking in great detail, concluding, in relevant part, "that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate." 1964 Surgeon General's Report 31. It also identified the pharmacological effects of nicotine, including "stimulation," "tranquilization," and "suppression of appetite." *Id.*, at 74-75. Seven days after the report's release, the Federal Trade Commission (FTC) issued a notice of proposed rulemaking, see 29 Fed. Reg. 530-532 (1964), and in June 1964, the FTC promulgated a final rule requiring cigarette manufacturers "to disclose, clearly and prominently, in all advertising and on every pack, box, carton or other container . . . that cigarette smoking is dangerous to health and may cause death from cancer and other diseases," *id.*, at 8325. The rule was to become effective January 1, 1965, but, on a request from Congress, the FTC postponed enforcement for six months. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 513-514, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992).

In response to the Surgeon General's report and the FTC's proposed rule, Congress convened hearings to consider legislation addressing "the tobacco problem." 1964 Hearings 1. During those deliberations, FDA representatives testified before Congress that the agency lacked jurisdiction under the FDCA to regulate tobacco products. Surgeon General Terry was asked during hearings in 1964 whether HEW had the "authority to brand or label the packages of cigarettes or to control the advertising there." *Id.*, at 56. The Surgeon General stated that "we do not have such authority in existing laws governing the . . . Food and Drug Administration." *Ibid.* Similarly, FDA Deputy Commissioner Rankin testified in 1965 that "the Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims." Cigarette Labeling and Advertising -- 1965: Hearings on H. R. 2248 before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 193 (hereinafter 1965 Hearings). See also Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in 1972 Hearings 240 ("Tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic"). In fact, HEW Secretary Celebrezze urged Congress *not* to amend the FDCA to cover 'smoking products" because, in light of the findings in the Surgeon General's report, such a "provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people." 1964 Hearings 18.

The FDA's disavowal of jurisdiction was consistent with the position that it had taken since the agency's inception. As the FDA concedes, it never asserted authority to regulate tobacco products as customarily marketed until it promulgated the regulations at issue here. See Brief for Petitioners 37; see also Brief for Appellee (FDA) in *Action on Smoking and Health* v. *Harris*, 210 U.S. App. D.C. 123, 655 F.2d 236 (CADC 1980), in 9 Rec. in No. 97-1604 (CA4), Tab No. 4, pp. 14-15 ("In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor").

The FDA's position was also consistent with Congress' specific intent when it enacted the FDCA. Before the Act's adoption in 1938, the FDA's predecessor agency, the Bureau of Chemistry, announced that it lacked authority to regulate tobacco products under the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, unless they were marketed with therapeutic claims. See U.S. Dept. of Agriculture, Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements P13, Opinion of Chief of Bureau C. L. Alsberg). In 1929, Congress considered and rejected a bill "to amend the Food and Drugs Act of June 30, 1906, by extending its provisions to tobacco and tobacco products." S. 1468, 71st Cong., 1st Sess., 1. See also 71 Cong. Rec. 2589 (1929) (remarks of Sen. Smoot). And, as the FDA admits, there is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the

applicability of the Act to tobacco products. See Brief for Petitioners 22, n. 4. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter. Of course, whether the Congress that enacted the FDCA specifically intended the Act to cover tobacco products is not determinative; "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale* v. *Sundowner Offshore Services, Inc.*, 523 U.S. 75, 79, 140 L. Ed. 2d 201, 118 S. Ct. 998 (1998); see also *TVA* v. *Hill*, 437 U.S. 153, 185, 98 S. Ct. 2279, 57 L. Ed. 2d 117 (1978) ("It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated"). Nonetheless, this intent is certainly relevant to understanding the basis for the FDA's representations to Congress and the background against which Congress enacted subsequent tobacco-specific legislation.

Moreover, before enacting the FCLAA in 1965, Congress considered and rejected several proposals to give the FDA the authority to regulate tobacco. In April 1963, Representative Udall introduced a bill "to amend the Federal Food, Drug, and Cosmetic Act so as to make that Act applicable to smoking products." H. R. 5973, 88th Cong., 1st Sess., 1. Two months later, Senator Moss introduced an identical bill in the Senate. S. 1682, 88th Cong., 1st Sess. (1963). In discussing his proposal on the Senate floor, Senator Moss explained that "this amendment simply places smoking products under FDA jurisdiction, along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963). In December 1963, Representative Rhodes introduced another bill that would have amended the FDCA "by striking out 'food, drug, device, or cosmetic, each place where it appears therein and inserting in lieu thereof 'food, drug, device, cosmetic, or smoking product.'" H. R. 9512, 88th Cong., 1st Sess., § 3 (1963). And in January 1965, five months before passage of the FCLAA, Representative Udall again introduced a bill to amend the FDCA "to make that Act applicable to smoking products." H. R. 2248, 89th Cong., 1st Sess., 1. None of these proposals became law.

Congress ultimately decided in 1965 to subject tobacco products to the less extensive regulatory scheme of the FCLAA, which created a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Pub. L. 89-92, § 2, 79 Stat. 282. The FCLAA rejected any regulation of advertising, but it required the warning, "Caution: Cigarette Smoking May Be Hazardous to Your Health," to appear on all cigarette packages. *Id.*, § 4, 79 Stat. 283. In the Act's "Declaration of Policy," Congress stated that its objective was to balance the goals of ensuring that "the public may be adequately informed that cigarette smoking may be hazardous to health" and protecting "commerce and the national economy . . . to the maximum extent." *Id.*, § 2, 79 Stat. 282 (codified at 15 U.S.C. § 1331).

Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by . . . this Act, shall be required on any cigarette package." *Id.*, § 5(a), 79 Stat. 283. The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today. The labeling

requirements currently imposed by the FDCA, which are essentially identical to those in force in 1965, require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers. See 21 U.S.C. § 352; 21 U.S.C. § 352 (1964 ed. and Supp. IV). As discussed earlier, the Act requires that all products bear "adequate directions for use . . . as are necessary for the protection of users," 21 U.S.C. § 352(f)(1); 21 U.S.C. § 352(f)(1) (1964 ed.); requires that all products provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," 21 U.S.C. § 352(f)(2); 21 U.S.C. § 352(f)(2) (1964 ed.); and deems a product misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U.S.C. § 352(j); 21 U.S.C. § 352(j) (1964 ed.). In this sense, the FCLAA was -- and remains -- incompatible with FDA regulation of tobacco products. This is not to say that the FCLAA's preemption provision by itself necessarily foreclosed FDA jurisdiction. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. at 518-519. But it is an important factor in assessing whether Congress ratified the agency's position -- that is, whether Congress adopted a regulatory approach to the problem of tobacco and health that contemplated no role for the FDA.

Further, the FCLAA evidences Congress' intent to preclude *any* administrative agency from exercising significant policymaking authority on the subject of smoking and health. In addition to prohibiting any additional requirements for cigarette labeling, the FCLAA provided that "no statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Pub. L. 89-92, § 5(b), 79 Stat. 283. Thus, in reaction to the FTC's attempt to regulate cigarette labeling and advertising, Congress enacted a statute reserving exclusive control over both subjects to itself.

Subsequent tobacco-specific legislation followed a similar pattern. By the FCLAA's own terms, the prohibition on any additional cigarette labeling or advertising regulations relating to smoking and health was to expire July 1, 1969. See § 10, 79 Stat. 284. In anticipation of the provision's expiration, both the FCC and the FTC proposed rules governing the advertisement of cigarettes. See 34 Fed. Reg. 1959 (1969) (FCC proposed rule to "ban the broadcast of cigarette commercials by radio and television stations"); *id.*, at 7917 (FTC proposed rule requiring manufacturers to disclose on all packaging and in all print advertising "'that cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases'"). After debating the proper role for administrative agencies in the regulation of tobacco, see generally Cigarette Labeling and Advertising -- 1969: Hearings before the House Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess., pt. 2 (1969), Congress amended the FCLAA by banning cigarette advertisements "on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission" and strengthening the warning required to appear on cigarette packages. Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, §§ 4, 6, 84 Stat. 88-89. Importantly, Congress extended indefinitely the prohibition on any other regulation of cigarette labeling with respect to smoking and health (again despite the importance of labeling regulation under the FDCA). § 5(a), 84 Stat. 88 (codified at 15

U.S.C. § 1334(a)). Moreover, it expressly forbade the FTC from taking any action on its pending rule until July 1, 1971, and it required the FTC, if it decided to proceed with its rule thereafter, to notify Congress at least six months in advance of the rule's becoming effective. § 7(a), 84 Stat. 89. As the chairman of the House committee in which the bill originated stated, "the Congress -- the body elected by the people -- must make the policy determinations involved in this legislation -- and not some agency made up of appointed officials." 116 Cong. Rec. 7920 (1970) (remarks of Rep. Staggers).

Four years later, after Congress had transferred the authority to regulate substances covered by the Hazardous Substances Act (HSA) from the FDA to the Consumer Products Safety Commission (CPSC), the American Public Health Association, joined by Senator Moss, petitioned the CPSC to regulate cigarettes yielding more than 21 milligrams of tar. See *Action on Smoking and Health* v. *Harris*, 210 U.S. App. D.C. 123, 655 F.2d 236, 241 (CADC 1980); R. Kluger, Ashes to Ashes 375-376 (1996). After the CPSC determined that it lacked authority under the HSA to regulate cigarettes, a District Court held that the Act did, in fact, grant the CPSC such jurisdiction and ordered it to reexamine the petition. See *American Public Health Association* v. *Consumer Product Safety Commission*, [1972-1975 Transfer Binder] CCH Consumer Prod. Safety Guide P75,081 (DC 1975), vacated as moot, No. 75-1863 (CADC 1976). Before the CPSC could take any action, however, Congress mooted the issue by adopting legislation that eliminated the agency's authority to regulate "tobacco and tobacco products." Consumer Product Safety Commission Improvements Act of 1976, Pub. L. 94-284, § 3(c), 90 Stat. 503 (codified at 15 U.S.C. § 1261(f)(2)). Senator Moss acknowledged that the "legislation, in effect, reversed" the District Court's decision, 121 Cong. Rec. 23563 (1975), and the FDA later observed that the episode was "particularly" "indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal Agencies," Letter to Action on Smoking and Health (ASH) Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 59. A separate statement in the Senate Report underscored that the legislation's purpose was to "unmistakably reaffirm the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, . . . and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 94-251, p. 43 (1975) (additional views of Sens. Hartke, Hollings, Ford, Stevens, and Beall).

Meanwhile, the FDA continued to maintain that it lacked jurisdiction under the FDCA to regulate tobacco products as customarily marketed. In 1972, FDA Commissioner Edwards testified before Congress that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." 1972 Hearings 239, 242. He further stated that the FDA believed that the Public Health Cigarette Smoking Act "demonstrates that the regulation of cigarettes is to be the domain of Congress," and that "labeling or banning cigarettes is a step that can be taken only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent." *Ibid.*

In 1977, ASH filed a citizen petition requesting that the FDA regulate cigarettes, citing many of the same grounds that motivated the FDA's rulemaking here. See Citizen

Petition, No. 77P-0185 (May 26, 1977), 10 Rec. in No. 97-1604 (CA4), Tab No. 22, pp. 1-10. ASH asserted that nicotine was highly addictive and had strong physiological effects on the body; that those effects were "intended" because consumers use tobacco products precisely to obtain those effects; and that tobacco causes thousands of premature deaths annually. *Ibid.* In denying ASH's petition, FDA Commissioner Kennedy stated that "the interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors." Letter to ASH Executive Director Banzhaf (Dec. 5, 1977), App. 47. After the matter proceeded to litigation, the FDA argued in its brief to the Court of Appeals that "cigarettes are not comprehended within the statutory definition of the term 'drug' absent objective evidence that vendors represent or intend that their products be used as a drug." Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 210 U.S. App. D.C. 123, 655 F.2d 236 (CADC 1980), 9 Rec. in No. 97-1604 (CA4), Tab No. 4, pp. 27-28. The FDA also contended that Congress had "long been aware that the FDA does not consider cigarettes to be within its regulatory authority in the absence of health claims made on behalf of the manufacturer or vendor," and that, because "Congress has never acted to disturb the agency's interpretation," it had "acquiesced in the FDA's interpretation of the statutory limits on its authority to regulate cigarettes." *Id.*, at 23, 27, n.23. The Court of Appeals upheld the FDA's position, concluding that "if the statute requires expansion, that is the job of Congress." *Action on Smoking and Health* v. *Harris*, 655 F.2d at 243. In 1980, the FDA also denied a request by ASH to commence rulemaking proceedings to establish the agency's jurisdiction to regulate cigarettes as devices. See Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 50-51. The agency stated that "insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act [21 U.S.C. § 321(h)]." *Id.*, at 67.

In 1983, Congress again considered legislation on the subject of smoking and health. HHS Assistant Secretary Brandt testified that, in addition to being "a major cause of cancer," smoking is a "major cause of heart disease" and other serious illnesses, and can result in "unfavorable pregnancy outcomes." 1983 House Hearings 19-20. He also stated that it was "well-established that cigarette smoking is a drug dependence, and that smoking is addictive for many people." *Id.*, at 20. Nonetheless, Assistant Secretary Brandt maintained that "the issue of regulation of tobacco . . . is something that Congress has reserved to itself, and we do not within the Department have the authority to regulate nor are we seeking such authority." *Id.*, at 74. He also testified before the Senate, stating that, despite the evidence of tobacco's health effects and addictiveness, the Department's view was that "Congress has assumed the responsibility of regulating . . . cigarettes." Smoking Prevention and Education Act: Hearings on S. 772 before the Senate Committee on Labor and Human Resources, 98th Cong., 1st Sess., 56 (1983) (hereinafter 1983 Senate Hearings).

Against this backdrop, Congress enacted three additional tobacco-specific statutes over the next four years that incrementally expanded its regulatory scheme for tobacco products. In 1983, Congress adopted the Alcohol and Drug Abuse Amendments, Pub. L. 98-24, 97 Stat. 175 (codified at 42 U.S.C. § 290aa *et seq.*), which require the Secretary of

HHS to report to Congress every three years on the "addictive property of tobacco" and to include recommendations for action that the Secretary may deem appropriate. A year later, Congress enacted the Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200, which amended the FCLAA by again modifying the prescribed warning. Notably, during debate on the Senate floor, Senator Hawkins argued that the Act was necessary in part because "under the Food, Drug and Cosmetic Act, the Congress exempted tobacco products."130 Cong. Rec. 26953 (1984). And in 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), Pub. L. 99-252, 100 Stat. 30 (codified at 15 U.S.C. § 4401 *et seq.*), which essentially extended the regulatory provisions of the FCLAA to smokeless tobacco products. Like the FCLAA, the CSTHEA provided that "no statement relating to the use of smokeless tobacco products and health, other than the statements required by [the Act], shall be required by any Federal agency to appear on any package . . . of a smokeless tobacco product." § 7(a), 100 Stat. 34 (codified at 15 U.S.C. § 4406(a)). Thus, as with cigarettes, Congress reserved for itself an aspect of smokeless tobacco regulation that is particularly important to the FDCA's regulatory scheme.

In 1988, the Surgeon General released a report summarizing the abundant scientific literature demonstrating that "cigarettes and other forms of tobacco are addicting," and that "nicotine is psychoactive" and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." 1988 Surgeon General's Report 14. The report further concluded that the "pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.*, at 15. In the same year, FDA Commissioner Young stated before Congress that "it doesn't look like it is possible to regulate [tobacco] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings before a Subcommittee of the House Committee on Appropriations, 100th Cong., 2d Sess., 409 (1988). At the same hearing, the FDA"s General Counsel testified that "what is fairly important in FDA law is whether a product has a therapeutic purpose," and "cigarettes themselves are not used for a therapeutic purpose as that concept is ordinarily understood." *Id.*, at 410. Between 1987 and 1989, Congress considered three more bills that would have amended the FDCA to grant the FDA jurisdiction to regulate tobacco products. See H. R. 3294, 100th Cong., 1st Sess. (1987); H. R. 1494, 101st Cong., 1st Sess. (1989); S. 769, 101st Cong., 1st Sess. (1989). As before, Congress rejected the proposals. In 1992, Congress instead adopted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102-321, § 202, 106 Stat. 394 (codified at 42 U.S.C. § 300x *et seq.*), which creates incentives for States to regulate the retail sale of tobacco products by making States' receipt of certain block grants contingent on their prohibiting the sale of tobacco products to minors.

Taken together, these actions by Congress over the past 35 years preclude an interpretation of the FDCA that grants the FDA jurisdiction to regulate tobacco products. We do not rely on Congress' failure to act -- its consideration and rejection of bills that would have given the FDA this authority -- in reaching this conclusion. Indeed, this is not

a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position. To the contrary, Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco. In doing so, Congress has been aware of tobacco's health hazards and its pharmacological effects. It has also enacted this legislation against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed. Further, Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health. Moreover, the substance of Congress' regulatory scheme is, in an important respect, incompatible with FDA jurisdiction. Although the supervision of product labeling to protect consumer health is a substantial component of the FDA's regulation of drugs and devices, see 21 U.S.C. § 352 (1994 ed. and Supp. III), the FCLAA and the CSTHEA explicitly prohibit any federal agency from imposing any health-related labeling requirements on cigarettes or smokeless tobacco products, see 15 U. S. C. §§ 1334(a), 4406(a).

Under these circumstances, it is clear that Congress' tobacco-specific legislation has effectively ratified the FDA's previous position that it lacks jurisdiction to regulate tobacco. As in *Bob Jones Univ.* v. *United States*, 461 U.S. 574, 76 L. Ed. 2d 157, 103 S. Ct. 2017 (1983), "it is hardly conceivable that Congress -- and in this setting, any Member of Congress -- was not abundantly aware of what was going on." *Id.*, at 600-601. Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA. As a result, Congress' tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed.

Although the dissent takes issue with our discussion of the FDA's change in position, *post*, at 26-29, our conclusion does not rely on the fact that the FDA's assertion of jurisdiction represents a sharp break with its prior interpretation of the FDCA. Certainly, an agency's initial interpretation of a statute that it is charged with administering is not "carved in stone." *Chevron*, 467 U.S. at 863; see also *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U.S. 735, 742, 135 L. Ed. 2d 25, 116 S. Ct. 1730 (1996). As we recognized in *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983), agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *Id.*, at 42 (quoting *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968)). The consistency of the FDA's prior position is significant in this case for a different reason: it provides important context to Congress' enactment of its tobacco-specific legislation. When the FDA repeatedly informed Congress that the FDCA does not grant it the authority to regulate tobacco products, its statements were consistent with the agency's unwavering position since its inception, and with the position that its predecessor agency had first taken in 1914. Although not crucial, the consistency of the FDA's prior position bolsters the conclusion that when Congress created a distinct regulatory scheme addressing the subject of tobacco and health, it understood that the FDA is without

jurisdiction to regulate tobacco products and ratified that position.

The dissent also argues that the proper inference to be drawn from Congress' tobacco-specific legislation is "critically ambivalent." *Post*, at 22. We disagree. In that series of statutes, Congress crafted a specific legislative response to the problem of tobacco and health, and it did so with the understanding, based on repeated assertions by the FDA, that the agency has no authority under the FDCA to regulate tobacco products. Moreover, Congress expressly preempted any other regulation of the labeling of tobacco products concerning their health consequences, even though the oversight of labeling is central to the FDCA's regulatory scheme. And in addressing the subject, Congress consistently evidenced its intent to preclude any federal agency from exercising significant policymaking authority in the area. Under these circumstances, we believe the appropriate inference -- that Congress intended to ratify the FDA's prior position that it lacks jurisdiction -- is unmistakable.

The dissent alternatively argues that, even if Congress' subsequent tobacco-specific legislation did, in fact, ratify the FDA's position, that position was merely a contingent disavowal of jurisdiction. Specifically, the dissent contends that "the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory 'intent' requirement." *Post*, at 30. A fair reading of the FDA's representations prior to 1995, however, demonstrates that the agency's position was essentially unconditional. See, *e.g.*, 1972 Hearings 239, 242 (statement of Commissioner Edwards) ("Regulation of cigarettes is to be the domain of Congress," and "any such move by FDA would be inconsistent with the clear congressional intent"); 1983 House Hearings 74 (statement of Assistant Secretary Brandt) ("The issue of regulation of tobacco . . . is something that Congress has reserved to itself"); 1983 Senate Hearings 56 (statement of Assistant Secretary Brandt) ("Congress has assumed the responsibility of regulating . . . cigarettes"); Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 210 U.S. App. D.C. 123, 655 F.2d 236 (CADC 1980), 9 Rec. in No. 97-1604 (CA4), Tab No. 4, pp. 27, n. 23 (because "Congress has never acted to disturb the agency's interpretation," it "acquiesced in the FDA's interpretation"). To the extent the agency's position could be characterized as equivocal, it was only with respect to the well-established exception of when the manufacturer makes express claims of therapeutic benefit. See, *e.g.*, 1965 Hearings 193 (statement of Deputy Commissioner Rankin) ("The Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Kennedy (Dec. 5, 1977), App. 47 ("The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 67 ("Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction"). Thus, what Congress ratified was the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed.

C

Finally, our inquiry into whether Congress has directly spoken to the precise question at issue is shaped, at least in some measure, by the nature of the question presented. Deference under *Chevron* to an agency's construction of a statute that it administers is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. See *Chevron*, 467 U.S. at 844. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation. Cf. Breyer, Judicial Review of Questions of Law and Policy, 38 Admin. L. Rev. 363, 370 (1986) ("A court may also ask whether the legal question is an important one. Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters to answer themselves in the course of the statute's daily administration").

This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. See Brief for Petitioners 35-36; Reply Brief for Petitioners 14. Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

Our decision in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218, 129 L. Ed. 2d 182, 114 S. Ct. 2223 (1994), is instructive. That case involved the proper construction of the term "modify" in § 203(b) of the Communications Act of 1934. The FCC contended that, because the Act gave it the discretion to "modify any requirement" imposed under the statute, it therefore possessed the authority to render voluntary the otherwise mandatory requirement that long distance carriers file their rates. *Id.*, at 225. We rejected the FCC's construction, finding "not the slightest doubt" that Congress had directly spoken to the question. *Id.*, at 228. In reasoning even more apt here, we concluded that "it is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion -- and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate-filing requirements." *Id.*, at 231.

As in *MCI*, we are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion. To find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act -- a concept central to the FDCA's regulatory scheme -- but also ignore the plain implication of Congress' subsequent tobacco-specific legislation. It is therefore clear, based on the

FDCA's overall regulatory scheme and the subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products.

* * *

By no means do we question the seriousness of the problem that the FDA has sought to address. The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States. Nonetheless, no matter how "important, conspicuous, and controversial" the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, *post*, at 31, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And "'in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.'" *United States* v. *Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 800, 22 L. Ed. 2d 726, 89 S. Ct. 1410 (1969) (quoting *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600, 95 L. Ed. 566, 71 S. Ct. 515 (1951)). Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here. For these reasons, the judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.