Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.* BROWN & WILLIAMSON TOBACCO CORP. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 98–1152. Argued December 1, 1999—Decided March 21, 2000

The Food, Drug, and Cosmetic Act (FDCA or Act), 21 U. S. C. § 301 *et seq.*, grants the Food and Drug Administration (FDA), as the designee of the Secretary of Health and Human Services (HHS), the authority to regulate, among other items, "drugs" and "devices," §§ 321(g)–(h), 393. In 1996, the FDA asserted jurisdiction to regulate tobacco products, concluding that, under the FDCA, nicotine is a "drug" and cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body. Pursuant to this authority, the FDA promulgated regulations governing tobacco products' promotion, labeling, and accessibility to children and adolescents. The FDA found that tobacco use is the Nation's leading cause of premature death, resulting in more than 400,000 deaths annually, and that most adult smokers begin when they are minors. The regulations therefore aim to reduce tobacco use by minors so as to substantially reduce the prevalence of addiction in future generations, and thus the incidence of tobacco-related death and disease. Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed this suit challenging the FDA's regulations. They moved for summary judgment on the ground, *inter alia*, that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, that is, without manufacturer claims of therapeutic benefit. The District Court upheld the FDA's authority, but the Fourth Circuit reversed, holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. The court concluded that construing the FDCA to include tobacco products would lead to several internal inconsistencies in the Act. It also found that evidence external to the FDCA—that the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, that Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position, and that Congress has considered and rejected many bills that would have given the agency such authority—confirms this conclusion.

Held: 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 to regulate tobacco products as customarily marketed. Pp. 131–161.

Syllabus

(a) Because this case involves an agency's construction of a statute it administers, the Court's analysis is governed by *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, under which a reviewing court must first ask whether Congress has directly spoken to the precise question at issue, *id.*, at 842. If so, the court must give effect to Congress' unambiguously expressed intent. *E. g.*, *id.*, at 843. If not, the court must defer to the agency's construction of the statute so long as it is permissible. See, *e. g.*, *INS* v. *Aguirre-Aguirre*, 526 U. S. 415, 424. In determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme. *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569. In addition, 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, *e. g.*, *United States* v. *Estate of Romani*, 523 U. S. 517, 530–531. Finally, the court 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. Pp. 131–133.

(b) 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 that remains on the market must be safe and effective for its intended use. See, *e. g.*, § 393(b)(2). That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit. *United States* v. *Rutherford*, 442 U. S. 544, 556. In its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding, see, *e. g.*, § 331(a), and device classification, see, *e. g.*, § 360e(d)(2)(A), provisions. In fact, based on such provisions, the FDA itself has previously asserted 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. Congress, however, has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects.

Syllabus

See 15 U. S. C. § 1331. Thus, an FDA ban would plainly contradict congressional intent. Apparently recognizing this dilemma, the FDA has concluded that tobacco products are actually "safe" under the FDCA because banning them would cause a greater harm to public health than leaving them on the market. But this safety determination—focusing on the relative harms caused by alternative remedial measures—is not a substitute for those required by the FDCA. Various provisions in the Act require the agency to determine that, at least for some consumers, the product's therapeutic benefits outweigh the risks of illness or serious injury. This the FDA cannot do, because tobacco products are unsafe for obtaining any therapeutic benefit. 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. Pp. 133–143.

(c) The history of tobacco-specific legislation also demonstrates that Congress has spoken directly to the FDA's authority to regulate tobacco products. Since 1965, Congress has enacted six separate statutes addressing the problem of tobacco use and human health. 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 electronic communication medium regulated by the Federal Communications Commission, see §§ 1335, 4402(f); require the Secretary of HHS to report every three years to Congress on research findings concerning tobacco's addictive property, 42 U. S. C. § 290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their prohibiting any tobacco product manufacturer, retailer, or distributor from selling or distributing any such product to individuals under age 18, § 300x–26(a)(1). This tobacco-specific legislation has created a specific regulatory scheme for addressing the problem of tobacco and health. And it was adopted against the backdrop of the FDA consistently and resolutely stating that it was without authority under the FDCA to regulate tobacco products as customarily marketed. In fact, Congress several times considered and rejected bills that would have given the FDA such authority. Indeed, Congress' actions in this area have evidenced a clear intent to preclude a meaningful policymaking role for any administrative agency. Further, Congress' tobacco legislation prohibits any additional regulation of tobacco product labeling with respect to tobacco's health consequences, a central aspect of regulation under the FDCA. Under these circumstances, it is evident that Congress has ratified the FDA's previous, long-held position that it lacks jurisdiction to regulate tobacco products as customarily marketed. Congress has

created a distinct scheme for addressing the subject, and that scheme excludes any role for FDA regulation. Pp. 143–159.

(d) Finally, the Court's inquiry is shaped, at least in some measure, by the nature of the question presented. *Chevron* deference 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 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. This is hardly an ordinary case. Contrary to the agency's position from its inception until 1995, 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. It is highly unlikely that Congress would leave the determination as to whether the sale of tobacco products would be regulated, or even banned, to the FDA's discretion in so cryptic a fashion. See *MCI Telecommunications*, *supra*, at 231. Given tobacco's unique political history, as well as the breadth of the authority that the FDA has asserted, the Court is obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power. Pp. 159–161.

(e) No matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. Courts must take care not to extend a statute's scope beyond the point where Congress indicated it would stop. *E. g.*, *United States* v. *Article of Drug . . . Bacto-Unidisk*, 394 U. S. 784, 800. P. 161.

153 F. 3d 155, affirmed.

O'Connor, J., delivered the opinion of the Court, in which Rehnquist, C. J., and Scalia, Kennedy, and Thomas, JJ., joined. Breyer, J., filed a dissenting opinion, in which Stevens, Souter, and Ginsburg, JJ., joined, *post,* p. 161.

Solicitor General Waxman argued the cause for petitioners. With him on the briefs were *Acting Assistant Attorney General Ogden*, *Deputy Solicitor General Kneedler*, *Deputy Assistant Attorney General Schultz*, *Irving L. Gornstein*, *Eugene Thirolf*, *Douglas Letter*, *Gerald C. Kell*, *Chris-*

tine N. Kohl, *Margaret Jane Porter*, *Karen E. Schifter*, and *Patricia J. Kaeding*.

Richard M. Cooper argued the cause for respondents. With him on the brief for respondent R. J. Reynolds Tobacco Co. was *Steven M. Umin*. *Andrew S. Krulwich*, *Bert W. Rein*, *Thomas W. Kirby*, and *Michael L. Robinson* filed a brief for respondent Brown & Williamson Tobacco Corp. *Larry B. Sitton* filed a brief for respondents United States Tobacco Co. et al. *William C. MacLeod* filed a brief for respondents National Association of Convenience Stores et al. *Peter T. Grossi, Jr.*, *Arthur N. Levine*, *Jeff Richman*, *Richard A. Merrill*, and *Herbert Dym* filed a brief for respondents Philip Morris Inc. et al.*

---

*Briefs of *amici curiae* urging reversal were filed for the State of Minnesota et al. by *Mike Hatch*, Attorney General of Minnesota, *James S. Alexander*, Assistant Attorney General, *Louise H. Renne*, and by the Attorneys General for their respective States as follows: *Bruce M. Botelho* of Alaska, *Janet Napolitano* of Arizona, *Mark Pryor* of Arkansas, *Bill Lockyer* of California, *Ken Salazar* of Colorado, *Richard Blumenthal* of Connecticut, *Robert A. Butterworth* of Florida, *Earl I. Anzai* of Hawaii, *Alan G. Lance* of Idaho, *James E. Ryan* of Illinois, *Jeffrey A. Modisett* of Indiana, *Thomas J. Miller* of Iowa, *Carla J. Stovall* of Kansas, *Andrew Ketterer* of Maine, *J. Joseph Curran, Jr.*, of Maryland, *Thomas F. Reilly* of Massachusetts, *Jennifer M. Granholm* of Michigan, *Mike Moore* of Mississippi, *Jeremiah W. Nixon* of Missouri, *Joseph P. Mazurek* of Montana, *Frankie Sue Del Papa* of Nevada, *Philip T. McLaughlin* of New Hampshire, *John J. Farmer, Jr.*, of New Jersey, *Patricia A. Madrid* of New Mexico, *Eliot Spitzer* of New York, *Heidi Heitkamp* of North Dakota, *Betty D. Montgomery* of Ohio, *W. A. Drew Edmondson* of Oklahoma, *Hardy Myers* of Oregon, *D. Michael Fisher* of Pennsylvania, *Sheldon Whitehouse* of Rhode Island, *Mark Barnett* of South Dakota, *John Cornyn* of Texas, *Jan Graham* of Utah, *William H. Sorrell* of Vermont, *Christine O. Gregoire* of Washington, *Darrell V. McGraw, Jr.*, of West Virginia, *James E. Doyle* of Wisconsin, and *Gay Woodhouse* of Wyoming; for Action on Smoking and Health by *John F. Banzhaf III* and *Kathleen E. Scheg;* for the American Cancer Society, Inc., by *Russell E. Brooks*, *David R. Gelfand*, *Charles W. Westland*, and *William J. Dalton;* for the American

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 (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 unam-

---

College of Chest Physicians by *Raymond D. Cotton;* and for Public Citizen, Inc., et al. by *Allison M. Zieve, Alan B. Morrison,* and *David C. Vladeck.*

Briefs of *amici curiae* urging affirmance were filed for the Pacific Legal Foundation by *Anne M. Hayes* and *M. Reed Hopper;* for the Product Liability Advisory Council, Inc., by *Kenneth S. Geller;* and for the Washington Legal Foundation et al. by *Daniel J. Popeo* and *Richard A. Samp.*

biguously expressed intent of Congress." *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (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 (HHS), 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 biological 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 sub-

missions, 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, "[m]ore 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 advertis-

ing 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 in 1938 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 federal parties' 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 (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 (1999); *Holly Farms Corp.* v. *NLRB*, 517 U. S. 392, 398 (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 (1999); *Auer* v. *Robbins*, 519 U. S. 452, 457 (1997). Such deference is justified because "[t]he 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 (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 (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 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC* v. *Mandel Brothers, Inc.*, 359 U. S. 385, 389 (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 (1998); *United States* v. *Fausto*, 484 U. S. 439, 453 (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 (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 Comm'r 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 "[m]ission" to include "protect[ing] 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 (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 "[m]ore 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 "[t]obacco 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 "[t]he 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 "[i]f 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 "[u]nless 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 "presen[t] 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 in the proposed 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 us[e]." 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 Comm'r 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 Dept. of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze that proposed amendments to the FDCA that would have given the FDA jurisdiction over "smoking product[s]" "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 "[t]he 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 "be[ing] 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 ("[T]he 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'être* 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 177 (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 174, and that this is a "perverse" reading of the statute, *post,* at 174, 180. 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 stand-

ard, 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 ha[s] 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 137–138. 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 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 (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 "[t]he 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 ("[T]obacco 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*, 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 ¶ 13, Opinion of Chief of Bureau C. L. Alsberg). In 1929, Congress considered and rejected a bill "[t]o 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 (1998); see also *TVA* v. *Hill*, 437 U. S. 153, 185 (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 "[t]o 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 FCLAA'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 pre-empted 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." Pub. L. 89–92, § 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 "[i]f 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 pre-emption 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 "[n]o 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*, 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 HSA 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 ¶ 75,081 (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, reverse[d]" 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 Comm'r 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 fur-

ther 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 take[n] 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 "[t]he 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*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, at 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 "[i]f 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 Comm'r Goyan (Nov. 25, 1980), App. 50–51. The agency stated that "[i]nsofar 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 FCLAA was necessary in part because "[u]nder 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 "[n]o 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 "[c]igarettes 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 "[c]igarettes 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 legisla-

tion 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 (1983), "[i]t 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 186–189, 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 (1996). As we recognized in *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29 (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 182. 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 pre-empted 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 appro-

priate 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 189–190. 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 Comm'r Edwards) ("[R]egulation of cigarettes is to be the domain of Congress," and "[a]ny such move by FDA would be inconsistent with the clear congressional intent"); 1983 House Hearings 74 (statement of Assistant Secretary Brandt) ("[T]he 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*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, at 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 Comm'r 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 Comm'r 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 Comm'r Goyan (Nov. 25, 1980), *id.*, at 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*, *supra*, 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 policy-making 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 (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 "[i]t 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 190, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And "'[i]n 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 (1969) (quoting *62 Cases of Jam* v. *United States*, 340 U. S. 593, 600 (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.

JUSTICE BREYER, with whom JUSTICE STEVENS, JUSTICE SOUTER, and JUSTICE GINSBURG join, dissenting.

The Food and Drug Administration (FDA) has the authority to regulate "articles (other than food) intended to affect the structure or any function of the body . . . ." Federal Food, Drug, and Cosmetic Act (FDCA), 21 U. S. C. § 321(g)(1)(C). Unlike the majority, I believe that tobacco products fit within this statutory language.

In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are "intended to affect" the body's "structure" and "function," in the literal sense of these words.

Second, the statute's basic purpose—the protection of public health—supports the inclusion of cigarettes within its scope. See *United States* v. *Article of Drug . . . Bacto-Unidisk*, 394 U. S. 784, 798 (1969) (FDCA "is to be given *a liberal construction consistent with [its] overriding purpose to protect the public health*" (emphasis added)). Unregulated tobacco use causes "[m]ore than 400,000 people [to] die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. 44398 (1996). Indeed, tobacco products kill more people in this country every year "than . . . AIDS . . . , car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined.*" *Ibid.* (emphasis added).

Despite the FDCA's literal language and general purpose (both of which support the FDA's finding that cigarettes come within its statutory authority), the majority nonetheless reads the statute as *excluding* tobacco products for two basic reasons:

> (1) the FDCA does not "fit" the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy, *ante*, at 139–141; and
>
> (2) Congress has enacted other statutes, which, when viewed in light of the FDA's long history of denying

> tobacco-related jurisdiction and considered together with Congress' failure explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco, *ante*, at 155–156.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA's remedial alternatives. See *infra*, at 174–181. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. See *infra*, at 181–186; cf. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U. S. C. § 321 (1994 ed., Supp. III)) (statute "shall" *not* "be construed to affect the question of whether" the FDA "has any authority to regulate any tobacco product").

The bulk of the opinion that follows will explain the basis for these latter conclusions. In short, I believe that the most important indicia of statutory meaning—language and purpose—along with the FDCA's legislative history (described briefly in Part I) are sufficient to establish that the FDA has authority to regulate tobacco. The statute-specific arguments against jurisdiction that the tobacco companies and the majority rely upon (discussed in Part II) are based on erroneous assumptions and, thus, do not defeat the jurisdiction-supporting thrust of the FDCA's language and purpose. The inferences that the majority draws from later legislative history are not persuasive, since (as I point out in Part III) one can just as easily infer from the later laws that Congress did not intend to affect the FDA's tobacco-related authority at all. And the fact that the FDA changed its mind about the scope of its own jurisdiction is legally insignificant because (as Part IV establishes) the agency's reasons for changing course are fully justified. Finally, as I explain in Part V, the degree of accountability that likely will attach to the FDA's action in this case should alleviate any concern

that Congress, rather than an administrative agency, ought to make this important regulatory decision.

I

Before 1938, the federal Pure Food and Drug Act contained only two jurisdictional definitions of "drug":

> "[1] medicines and preparations recognized in the United States Pharmacopoeia or National Formulary . . . and [2] any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease." Act of June 30, 1906, ch. 3915, § 6, 34 Stat. 769.

In 1938, Congress added a third definition, relevant here:

> "(3) articles (other than food) intended to affect the structure or any function of the body . . . ." Act of June 25, 1938, ch. 675, § 201(g), 52 Stat. 1041 (codified at 21 U. S. C. § 321(g)(1)(C)).

It also added a similar definition in respect to a "device." See § 201(h), 52 Stat. 1041 (codified at 21 U. S. C. § 321(h)). As I have mentioned, the literal language of the third definition and the FDCA's general purpose both strongly support a projurisdiction reading of the statute. See *supra,* at 161–162.

The statute's history offers further support. The FDA drafted the new language, and it testified before Congress that the third definition would expand the FDCA's jurisdictional scope significantly. See Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 15–16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107–108 (1979) (hereinafter Leg. Hist.). Indeed, "[t]he purpose" of the new definition was to "make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions." *Id.*, at 108. While the drafters focused specifically upon the need to give the FDA jurisdiction

over "slenderizing" products such as "antifat remedies," *ibid.*, they were aware that, in doing so, they had created what was "admittedly an inclusive, a wide definition," *id.*, at 107. And that broad language was included *deliberately,* so that jurisdiction could be had over "*all* substances and preparations, other than food, and *all* devices intended to affect the structure or any function of the body . . . ." *Ibid.* (emphasis added); see also Hearings on S. 2800 before the Senate Committee on Commerce, 73d Cong., 2d Sess., 516 (1934), reprinted in 2 Leg. Hist. 519 (statement of then-FDA Chief Walter Campbell acknowledging that "[t]his definition of 'drugs' is all-inclusive").

After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress," 1 J. O'Reilly, Food and Drug Administration § 6.01, p. 6–1 (2d ed. 1995) (hereinafter O'Reilly), and that, in a sense, the FDCA "must be regarded as a *constitution*" that "establish[es] general principles" and "permit[s] implementation within broad parameters" so that the FDA can "implement these objectives through the most effective and efficient controls that can be devised." Hutt, Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act, 28 Food Drug Cosm. L. J. 177, 178–179 (1973) (emphasis added). This Court, too, has said that the

> "historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show . . . that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *Bacto-Unidisk*, 394 U. S., at 798.

That Congress would grant the FDA such broad jurisdictional authority should surprise no one. In 1938, the President and much of Congress believed that federal administrative agencies needed broad authority and would exercise that authority wisely—a view embodied in much Second New

Deal legislation. Cf. *Gray* v. *Powell,* 314 U. S. 402, 411–412 (1941) (Congress "could have legislated specifically" but decided "to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable" determination). Thus, at around the same time that it added the relevant language to the FDCA, Congress enacted laws granting other administrative agencies even broader powers to regulate much of the Nation's transportation and communication. See, *e. g.,* Civil Aeronautics Act of 1938, ch. 601, § 401(d)(1), 52 Stat. 987 (Civil Aeronautics Board to regulate airlines within confines of highly general "public convenience and necessity" standard); Motor Carrier Act of 1935, ch. 498, § 204(a)(1), 49 Stat. 546 (Interstate Commerce Commission to establish "reasonable requirements" for trucking); Communications Act of 1934, ch. 652, § 201(a), 48 Stat. 1070 (Federal Communications Commission (FCC) to regulate radio, later television, within confines of even broader "public interest" standard). Why would the 1938 New Deal Congress suddenly have hesitated to delegate to so well established an agency as the FDA all of the discretionary authority that a straightforward reading of the relevant statutory language implies?

Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislators might not have expected. Such a possibility is inherent in the very nature of a broad delegation. In 1938, it may well have seemed unlikely that the FDA would ever bring cigarette manufacturers within the FDCA's statutory language by proving that cigarettes produce chemical changes in the body and that the makers "intended" their product chemically to affect the body's "structure" or "function." Or, back then, it may have seemed unlikely that, even assuming such proof, the FDA actually would exercise its discretion to regulate so popular a product. See R. Kluger, Ashes to Ashes 105 (1997) (in the 1930's "Americans were in love with smoking . . .").

But it should not have seemed unlikely that, assuming the FDA decided to regulate and proved the particular jurisdictional prerequisites, the courts would rule such a jurisdictional assertion fully authorized. Cf. *United States* v. *Southwestern Cable Co.*, 392 U. S. 157, 172 (1968) (reading Communications Act of 1934 as authorizing FCC jurisdiction to regulate cable systems while noting that "Congress could not in 1934 have foreseen the development of" advanced communications systems). After all, this Court has read more narrowly phrased statutes to grant what might have seemed even more unlikely assertions of agency jurisdiction. See, *e. g.*, *Permian Basin Area Rate Cases*, 390 U. S. 747, 774–777 (1968) (statutory authority to regulate interstate "transportation" of natural gas includes authority to regulate "prices" charged by field producers); *Phillips Petroleum Co.* v. *Wisconsin*, 347 U. S. 672, 677–684 (1954) (independent gas producer subject to regulation despite Natural Gas Act's express exemption of gathering and production facilities).

I shall not pursue these general matters further, for neither the companies nor the majority denies that the FDCA's literal language, its general purpose, and its particular legislative history favor the FDA's present jurisdictional view. Rather, they have made several specific arguments in support of one basic contention: Even if the statutory delegation is broad, it is not broad *enough* to include tobacco. I now turn to each of those arguments.

II

A

The tobacco companies contend that the FDCA's words cannot possibly be read to mean what they literally say. The statute defines "device," for example, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body . . . ." 21

U. S. C. §321(h). Taken literally, this definition might include everything from room air conditioners to thermal pajamas. The companies argue that, to avoid such a result, the meaning of "drug" or "device" should be confined to *medical* or *therapeutic* products, narrowly defined. See Brief for Respondent United States Tobacco Co. 8–9.

The companies may well be right that the statute should not be read to cover room air conditioners and winter underwear. But I do not agree that we must accept their proposed limitation. For one thing, such a cramped reading contravenes the established purpose of the statutory language. See *Bacto-Unidisk*, 394 U. S., at 798 (third definition is "clearly, broader than any strict medical definition"); 1 Leg. Hist. 108 (definition covers products "that cannot be alleged to be treatments for diseased conditions"). For another, the companies' restriction would render the other two "drug" definitions superfluous. See 21 U. S. C. §§321(g)(1)(A), (g)(1)(B) (covering articles in the leading pharmacology compendia and those "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease").

Most importantly, the statute's language itself supplies a different, more suitable, limitation: that a "drug" must be a *chemical* agent. The FDCA's "device" definition states that an article which affects the structure or function of the body is a "device" only if it "does *not* achieve its primary intended purposes through chemical action within . . . the body," and "is *not* dependent upon being metabolized for the achievement of its primary intended purposes." §321(h) (emphasis added). One can readily infer from this language that at least an article that *does* achieve its primary purpose through chemical action within the body and that *is* dependent upon being metabolized is a "drug," provided that it otherwise falls within the scope of the "drug" definition. And one need not hypothesize about air conditioners or thermal

pajamas to recognize that the chemical nicotine, an important tobacco ingredient, meets this test.

Although I now oversimplify, the FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain. See 61 Fed. Reg. 44698–44699 (1966). Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reactions that alter one's mood and produce feelings of sedation and stimulation. See *id.*, at 44699, 44739. Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity. See *id.*, at 44739. And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction. See *id.*, at 44700, 44721–44722. The upshot is that nicotine stabilizes mood, suppresses appetite, tranquilizes, and satisfies a physical craving that nicotine itself has helped to create—all through chemical action within the body after being metabolized.

This physiology—and not simply smoker psychology—helps to explain why as many as 75% of adult smokers believe that smoking "reduce[s] nervous irritation," 60 Fed. Reg. 41579 (1995); why 73% of young people (10- to 22-year-olds) who begin smoking say they do so for "relaxation," 61 Fed. Reg. 44814 (1996); and why less than 3% of smokers succeed in quitting each year, although 70% want to quit, *id.*, at 44704. That chemistry also helps to explain the Surgeon General's findings that smokers believe "smoking [makes them] feel better" and smoke more "in situations involving negative mood." *Id.*, at 44814. And, for present purposes, that chemistry demonstrates that nicotine affects the "structure" and "function" of the body in a manner that is quite similar to the effects of other regulated substances. See *id.*, at 44667 (FDA regulates Valium, NoDoz, weight-loss products). Indeed, addiction, sedation, stimulation, and weight loss are *precisely* the kinds of product effects that the FDA typically reviews and controls. And, since the nicotine in cigarettes

plainly is not a "food," its chemical effects suffice to establish that it is as a "drug" (and the cigarette that delivers it a drug-delivery "device") for the purpose of the FDCA.

B

The tobacco companies' principal definitional argument focuses upon the statutory word "intended." See 21 U. S. C. § 321(g)(1)(C). The companies say that "intended" in this context is a term of art. See Brief for Respondent Brown & Williamson Tobacco Corp. 2. They assert that the statutory word "intended" means that the product's maker has made an *express claim* about the effect that its product will have on the body. *Ibid.* Indeed, according to the companies, the FDA's inability to prove that cigarette manufacturers make such claims is precisely why that agency historically has said it lacked the statutory power to regulate tobacco. See *id.*, at 19–20.

The FDCA, however, does not use the word "claimed"; it uses the word "intended." And the FDA long ago issued regulations that say the relevant "intent" can be shown not only by a manufacturer's "expressions," *but also* "by the circumstances surrounding the distribution of the article." 41 Fed. Reg. 6896 (1976) (codified at 21 CFR § 801.4 (1999)); see also 41 Fed. Reg. 6896 (1976) ("objective intent" shown if "article is, with the knowledge [of its makers], offered and used" for a particular purpose). Thus, even in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product. See, *e. g.,* 60 Fed. Reg. 41527–41531 (1995) (describing agency's regulation of topical hormones, sunscreens, fluoride, tanning lamps, thyroid in food supplements, novelty condoms—all marketed without express claims); see also 1 O'Reilly § 13.04, at 13–15 ("Sometimes the very nature of the material makes it a drug . . .").

Courts ordinarily reverse an agency interpretation of this kind only if Congress has clearly answered the interpretive

question or if the agency's interpretation is unreasonable. *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (1984). The companies, in an effort to argue the former, point to language in the legislative history tying the word "intended" to a technical concept called "intended use." But nothing in Congress' discussion either of "intended" or "intended use" suggests that an express claim (which *often* shows intent) is *always* necessary. Indeed, the primary statement to which the companies direct our attention says only that a manufacturer can determine what kind of regulation applies—"food" or "drug"—because, "through his representations in connection with its sale, [the manufacturer] can determine" whether an article is to be used as a "food," as a "drug," or as "both." S. Rep. No. 361, 74th Cong., 1st Sess., 4 (1935), reprinted in 3 Leg. Hist. 696.

Nor is the FDA's "objective intent" interpretation unreasonable. It falls well within the established scope of the ordinary meaning of the word "intended." See *Agnew* v. *United States*, 165 U. S. 36, 53 (1897) (intent encompasses the known consequences of an act). And the companies acknowledge that the FDA can regulate a drug-like substance in the ordinary circumstance, *i. e.*, where the manufacturer makes an express claim, so it is not unreasonable to conclude that the agency retains such power where a product's effects on the body are so well known (say, like those of aspirin or calamine lotion), that there is no *need* for express representations because the product speaks for itself.

The companies also cannot deny that the evidence of their intent is sufficient to satisfy the statutory word "intended" as the FDA long has interpreted it. In the first place, there was once a time when they actually *did* make express advertising claims regarding tobacco's mood-stabilizing and weight-reducing properties—and historical representations can portend present expectations. In the late 1920's, for example, the American Tobacco Company urged weight-conscious smokers to "'Reach for a Lucky instead of a

sweet.'" Kluger, Ashes to Ashes, at 77–78. The advertisements of R J Reynolds (RJR) emphasized mood stability by depicting a pilot remarking that "'It Takes Steady Nerves to Fly the Mail at Night . . . . That's why I smoke Camels. And I smoke plenty!'" *Id.*, at 86. RJR also advertised the stimulating quality of cigarettes, stating in one instance that "'You get a Lift with a Camel,'" and, in another, that Camels are "'A Harmless Restoration of the Flow of Natural Body Energy.'" *Id.*, at 87. And claims of medical proof of mildness (and of other beneficial effects) once were commonplace. See, *e. g.*, *id.*, at 93 (Brown & Williamson advertised Kool-brand mentholated cigarettes as "a tonic to hot, tired throats"); *id.*, at 101, 131 (Philip Morris contended that "'[r]ecognized laboratory tests have conclusively proven the advantage of Phillip *[sic]* Morris'"); *id.*, at 88 (RJR proclaimed "'For Digestion's sake, smoke Camels! . . . Camels make mealtime more pleasant—digestion is stimulated—alkalinity increased'"). Although in recent decades cigarette manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the companies no longer need to express—that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.

Second, even though the companies refused to acknowledge publicly (until only very recently) that the nicotine in cigarettes has chemically induced, and habit-forming, effects, see, *e. g.*, Regulation of Tobacco Products (Part 1): Hearings before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994) (hereinafter 1994 Hearings) (heads of seven major tobacco companies testified under oath that they believed "nicotine is *not* addictive" (emphasis added)), the FDA recently has gained access to solid, documentary evidence proving that cigarette manufacturers have long *known* tobacco produces these effects within the body through the metabolizing of chemicals, and that they

have long *wanted* their products to produce those effects in this way.

For example, in 1972, a tobacco-industry scientist explained that "'[s]moke is beyond question the most optimized vehicle of nicotine,'" and "'the cigarette is the most optimized dispenser of smoke.'" 61 Fed. Reg. 44856 (1996) (emphasis deleted). That same scientist urged company executives to

> "'[t]hink of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine [and] [t]hink of a puff of smoke as the vehicle of nicotine.'" *Ibid.* (Philip Morris) (emphasis deleted).

That same year, other tobacco industry researchers told their superiors that

> "'in different situations and at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer. . . . Therefore, [tobacco] products may, in a sense, compete with a variety of other products with certain types of drug action.'" *Id.*, at 44669 (RJR) (emphasis deleted).

A draft report prepared by authorities at Philip Morris said that nicotine

> "'is a physiologically active, nitrogen containing substance [similar to] quinine, cocaine, atropine and morphine. [And] [w]hile each of these [other] substances can be used to affect human physiology, nicotine has a particularly broad range of influence.'" *Id.*, at 44668–44669.

And a 1980 manufacturer's study stated that

> "'the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking

> behaviour, providing the motivation for and the degree of satisfaction required by the smoker.'" *Id.*, at 44936 (Brown & Williamson).

With such evidence, the FDA has more than sufficiently established that the companies "intend" their products to "affect" the body within the meaning of the FDCA.

C

The majority nonetheless reaches the "inescapable conclusion" that the language and structure of the FDCA as a whole "simply do not fit" the kind of public health problem that tobacco creates. *Ante*, at 143. That is because, in the majority's view, the FDCA requires the FDA to ban outright "dangerous" drugs or devices (such as cigarettes); yet, the FDA concedes that an immediate and total cigarette-sale ban is inappropriate. *Ibid.*

This argument is curious because it leads with similarly "inescapable" force to precisely the opposite conclusion, namely, that the FDA *does* have jurisdiction but that it must ban cigarettes. More importantly, the argument fails to take into account the fact that a statute interpreted as requiring the FDA to pick a more dangerous over a less dangerous remedy would be a perverse statute, *causing*, rather than preventing, unnecessary harm whenever a total ban is likely the more dangerous response. And one can at least imagine such circumstances.

Suppose, for example, that a commonly used, mildly addictive sleeping pill (or, say, a kind of popular contact lens), plainly within the FDA's jurisdiction, turned out to pose serious health risks for certain consumers. Suppose further that many of those addicted consumers would ignore an immediate total ban, turning to a potentially more dangerous black-market substitute, while a less draconian remedy (say, adequate notice) would wean them gradually away to a safer product. Would the FDCA still *force* the FDA to impose

the more dangerous remedy? For the following reasons, I think not.

First, the statute's language does not restrict the FDA's remedial powers in this way. The FDCA permits the FDA to regulate a "combination product"—*i. e.*, a "device" (such as a cigarette) that contains a "drug" (such as nicotine)—under its "device" provisions. 21 U. S. C. § 353(g)(1). And the FDCA's "device" provisions explicitly grant the FDA wide remedial discretion. For example, where the FDA cannot "otherwise" obtain "reasonable assurance" of a device's "safety and effectiveness," the agency may restrict by regulation a product's "sale, distribution, or use" upon "*such . . . conditions as the Secretary may prescribe.*" § 360j(e)(1) (emphasis added). And the statutory section that most clearly addresses the FDA's power to ban (entitled "Banned devices") says that, where a device presents "an unreasonable and substantial risk of illness or injury," the Secretary "*may*"—not *must*—"initiate a proceeding . . . to make such device a banned device." § 360f(a) (emphasis added).

The Court points to other statutory subsections which it believes require the FDA to ban a drug or device entirely, even where an outright ban risks more harm than other regulatory responses. See *ante*, at 135–136. But the cited provisions do no such thing. It is true, as the majority contends, that "the FDCA requires the FDA to place all devices" in "one of three classifications" and that Class III devices require "premarket approval." *Ante*, at 136. But it is not the case that the FDA *must* place cigarettes in Class III because tobacco itself "presents a potential unreasonable risk of illness or injury." 21 U. S. C. § 360c(a)(1)(C). In fact, Class III applies *only* where *regulation* cannot otherwise "provide reasonable assurance of . . . safety." §§ 360c(a)(1)(A), (B) (placing a device in Class I or Class II when regulation can provide that assurance). Thus, the statute plainly allows the FDA to consider the relative, overall "safety" of

a device in light of its regulatory alternatives, and where the FDA has chosen the least dangerous path, *i. e.*, the safest path, then it can—and does—provide a "reasonable assurance" of "safety" within the meaning of the statute. A good football helmet provides a reasonable assurance of safety for the player even if the sport itself is still dangerous. And the safest regulatory choice by definition offers a "reasonable" assurance of safety in a world where the other alternatives are yet more dangerous.

In any event, it is not entirely clear from the statute's text that a Class III categorization would require the FDA affirmatively to *withdraw* from the market dangerous devices, such as cigarettes, which are already widely distributed. See, *e. g.*, § 360f(a) (when a device presents an "unreasonable and substantial risk of illness or injury," the Secretary "may" make it "a banned device"); § 360h(a) (when a device "presents an unreasonable risk of substantial harm to the public health," the Secretary "may" require "notification"); § 360h(b) (when a defective device creates an "unreasonable risk" of harm, the Secretary "may" order "[r]epair, replacement, or refund"); cf. 2 O'Reilly § 18.08, at 18–29 (point of Class III "premarket approval" is to allow "careful scientific review" of each "truly new" device "*before* it is exposed" to users (emphasis added)).

Noting that the FDCA requires banning a "misbranded" drug, the majority also points to 21 U. S. C. § 352(j), which deems a drug or device "misbranded" if "it is dangerous to health when used" as "prescribed, recommended, or suggested in the labeling." See *ante*, at 135. In addition, the majority mentions § 352(f)(1), which calls a drug or device "misbranded" unless "its labeling bears . . . adequate directions for use" as "are necessary for the protection of users." *Ibid.* But this "misbranding" language is not determinative, for it permits the FDA to conclude that a drug or device is *not* "dangerous to health" and that it *does* have "adequate"

directions *when regulated so as to render it as harmless as possible*. And surely the agency can determine that a substance is comparatively "safe" (*not* "dangerous") whenever it would be *less* dangerous to make the product available (subject to regulatory requirements) than suddenly to withdraw it from the market. Any other interpretation risks substantial harm of the sort that my sleeping pill example illustrates. See *supra*, at 174–175. And nothing in the statute prevents the agency from adopting a view of "safety" that would avoid such harm. Indeed, the FDA already seems to have taken this position when permitting distribution of toxic drugs, such as poisons used for chemotherapy, that are dangerous for the user but are not deemed "dangerous to health" in the relevant sense. See 61 Fed. Reg. 44413 (1996).

The tobacco companies point to another statutory provision which says that if a device "would cause serious, adverse health consequences or death, the Secretary *shall* issue" a cease distribution order. 21 U. S. C. § 360h(e)(1) (emphasis added). But that word "shall" in this context cannot mean that the Secretary must resort to the recall remedy *whenever* a device would have serious, adverse health effects. Rather, that language must mean that the Secretary "shall issue" a cease distribution order in compliance with the section's procedural requirements *if* the Secretary chooses *in her discretion* to use that particular subsection's recall remedy. Otherwise, the subsection would trump and make meaningless the same section's provision of other lesser remedies such as simple "notice" (which the Secretary similarly can impose if, but only if, she finds that the device "presents an unreasonable risk of substantial harm to the public"). § 360h(a)(1). And reading the statute to compel the FDA to "recall" every dangerous device likewise would conflict with that same subsection's statement that the recall remedy "shall be *in addition to* [the other] remedies provided" in the statute. § 360h(e)(3) (emphasis added).

The statute's language, then, permits the agency to choose remedies consistent with its basic purpose—the overall protection of public health.

The second reason the FDCA does not require the FDA to select the more dangerous remedy, see *supra*, at 175, is that, despite the majority's assertions to the contrary, the statute does not distinguish among the kinds of health effects that the agency may take into account when assessing safety. The Court insists that the statute only permits the agency to take into account the health risks and benefits of the "*product itself*" as used by individual consumers, *ante*, at 140, and, thus, that the FDA is prohibited from considering that a ban on smoking would lead many smokers to suffer severe withdrawal symptoms or to buy possibly stronger, more dangerous, black market cigarettes—considerations that the majority calls "the aggregate health effects of alternative administrative actions." *Ibid.* But the FDCA expressly *permits* the FDA to take account of comparative safety in precisely this manner. See, *e. g.*, 21 U. S. C. § 360h(e)(2)(B)(i)(II) (no device recall if "risk of recal[l]" presents "a greater health risk than" no recall); § 360h(a) (notification "unless" notification "would present a greater danger" than "no such notification").

Moreover, one cannot distinguish in this context between a "specific" health risk incurred by an individual and an "aggregate" risk to a group. *All* relevant risk is, at bottom, risk to an individual; *all* relevant risk attaches to "the product itself"; and *all* relevant risk is "aggregate" in the sense that the agency aggregates health effects in order to determine risk to the individual consumer. If unregulated smoking will kill 4 individuals out of a typical group of 1,000 people, if regulated smoking will kill 1 out of 1,000, and if a smoking ban (because of the black market) will kill 2 out of 1,000; then these three possibilities mean that in each group four, one, and two individuals, on average, will die respectively. And the risk to each individual consumer is 4/1,000,

1/1,000, and 2/1,000 respectively. A "specific" risk to an individual consumer and "aggregate" risks are two sides of the same coin; each calls attention to the same set of facts. While there may be a theoretical distinction between the risk of the product itself and the risk related to the presence or absence of an intervening voluntary act (*e. g.*, the search for a replacement on the black market), the majority does not rely upon any such distinction, and the FDA's history of regulating "replacement" drugs such as methadone shows that it has long taken likely actual alternative consumer behavior into account.

I concede that, as a matter of logic, one could consider the FDA's "safety" evaluation to be different from its choice of remedies. But to read the statute to forbid the agency from taking account of the realities of consumer behavior either in assessing safety or in choosing a remedy could increase the risks of harm—doubling the risk of death to each "individual user" in my example above. Why would Congress insist that the FDA ignore such realities, even if the consequent harm would occur only unusually, say, where the FDA evaluates a product (a sleeping pill; a cigarette; a contact lens) that is already on the market, potentially habit forming, or popular? I can find no satisfactory answer to this question. And that, I imagine, is why the statute itself says nothing about any of the distinctions that the Court has tried to draw. See 21 U. S. C. § 360c(a)(2) (instructing FDA to determine the safety and effectiveness of a "device" in part by weighing "*any* probable benefit to health . . . against *any* probable risk of injury or illness . . ." (emphasis added)).

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes. A different set of words, added to the FDCA in 1958 by the Delaney Amendment, provides that "no [food] additive shall be deemed to be safe if it is found [after appropriate tests] to induce cancer when ingested by man or animal." § 348(c)(3). The FDA

once interpreted this language as requiring it to ban any food additive, no matter how small the amount, that appeared in any food product if that additive was ever found to induce cancer in any animal, no matter how large a dose needed to induce the appearance of a single carcinogenic cell. See H. R. Rep. No. 95–658, p. 7 (1977) (discussing agency's view). The FDA believed that the statute's ban mandate was absolute and prevented it from establishing a level of "safe use" or even to judge whether "the benefits of continued use outweigh the risks involved." *Id.*, at 5. This interpretation—which in principle could have required the ban of everything from herbal teas to mushrooms—actually led the FDA to ban saccharine, see 42 Fed. Reg. 19996 (1977), though this extremely controversial regulatory response never took effect because Congress enacted, and has continually renewed, a law postponing the ban. See Saccharin Study and Labeling Act, Pub. L. 95–203, § 3, 91 Stat. 1452; *e. g.*, Pub. L. 102–142, Tit. VI, 105 Stat. 910.

The Court's interpretation of the statutory language before us risks Delaney-type consequences with even less linguistic reason. Even worse, the view the Court advances undermines the FDCA's overall health-protecting purpose by placing the FDA in the strange dilemma of either banning completely a potentially dangerous drug or device or doing nothing at all. Saying that I have misunderstood its conclusion, the majority maintains that the FDA "may clearly regulate many 'dangerous' products without banning them." *Ante*, at 142. But it then adds that the FDA *must* ban—rather than otherwise regulate—a drug or device that "cannot be used safely for any therapeutic purpose." *Ibid.* If I misunderstand, it is only because this linchpin of the majority's conclusion remains unexplained. *Why* must a widely used but unsafe device be withdrawn from the market when that particular remedy threatens the health of many and is thus more dangerous than another regulatory response? It is, indeed, a perverse interpretation that reads the FDCA

to require the ban of a device that has no "safe" therapeutic purpose where a ban is the most dangerous remedial alternative.

In my view, where linguistically permissible, we should interpret the FDCA in light of Congress' overall desire to protect health. That purpose requires a flexible interpretation that both permits the FDA to take into account the realities of human behavior and allows it, in appropriate cases, to choose from its arsenal of statutory remedies. A statute so interpreted easily "fit[s]" this, and other, drug- and device-related health problems.

III

In the majority's view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA's exercise of jurisdiction? With one exception, see *infra*, at 184–185, the majority points to no such provision. Do they somehow repeal the principles of law (discussed in Part II, *supra*) that otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of "partial repeal"). Perhaps the later laws "shape" and "focus" what the 1938 Congress meant a generation earlier. *Ante*, at 143. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation* v. *LTV Corp.*, 496 U. S. 633, 650 (1990) (later history is a " 'hazardous basis for inferring the intent of an earlier' Congress" (quoting *United States* v. *Price*, 361 U. S. 304, 313 (1960))). And, while the majority suggests that the subsequent history "control[s] our construction" of the FDCA, see *ante*, at 143 (citation and internal quotation marks omitted), this Court

expressly has held that such subsequent views are not "controlling." *Haynes* v. *United States*, 390 U. S. 85, 87–88, n. 4 (1968); accord, *Southwestern Cable Co.*, 392 U. S., at 170 (such views have "'very little, if any, significance'"); see also *Sullivan* v. *Finkelstein*, 496 U. S. 617, 632 (1990) (SCALIA, J., concurring) ("Arguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote").

Regardless, the later statutes do not support the majority's conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA's jurisdiction, the laws they enacted did not embody any such "no jurisdiction" assumption. And one cannot automatically *infer* an antijurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely, the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. See, *e. g.*, Cigarette Labeling and Advertising—1965: Hearings on H. R. 2248 et al. before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 19 (1965) (hereinafter 1965 Hearings) (statement of Rep. Fino that the proposed legislation would *not* "erode" agency authority). As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) "ratif[ying]" a no-jurisdiction assumption, see *ante*, at 158, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are "equally tenable," *Pension Benefit Guaranty Corp.*, *supra*, at 650 (citation and internal quotation marks omitted); *Johnson* v. *Transportation Agency, Santa Clara Cty.*, 480 U. S. 616, 672 (1987) (SCALIA, J., dissenting), prevents the majority from drawing from the later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco—a circum-

stance that the majority finds significant. See *ante*, at 144, 147–148, 155. But cf. *Southwestern Cable Co.*, *supra*, at 170 (failed requests do not prove agency "did not already possess" authority). In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, *e. g.*, S. 1262, 104th Cong., 1st Sess., § 906 (1995) (failed bill seeking to amend FDCA to say 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"); see also H. R. 516, 105th Cong., 1st Sess., § 2 (1997) (similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996) (Georgia legislators unsuccessfully requested that Congress "rescind any action giving the FDA authority" over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995) (failed bill "[t]o prohibit the [FDA] regulation of the sale or use of tobacco"); H. R. 2414, 104th Cong., 1st Sess., § 2(a) (1995) (similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

The majority also mentions the speed with which Congress acted to take jurisdiction away from other agencies once they tried to assert it. See *ante*, at 145, 149–151. But such a congressional response again proves nothing. On the one hand, the speedy reply might suggest that Congress somehow resented agency assertions of jurisdiction in an area it desired to reserve for itself—a consideration that supports the majority. On the other hand, Congress' quick reaction with respect to *other* agencies' regulatory efforts contrasts dramatically with its failure to enact any responsive law (at any speed) after the FDA asserted jurisdiction over tobacco more than three years ago. And that contrast supports the opposite conclusion.

In addition, at least one post-1938 statute reveals quite a different congressional intent than the majority infers. See note following 21 U. S. C. § 321 (1994 ed., Supp. III) (FDA Modernization Act of 1997) (law "shall *[not]* be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product," and "[s]uch authority, if any, shall be exercised under the [FDCA] as in effect on the day before the date of [this] enactment"). Consequently, it appears that the only interpretation that can reconcile *all* of the subsequent statutes is the inference that Congress did not intend, either explicitly or implicitly, for its later laws to answer the question of the scope of the FDA's jurisdictional authority. See 143 Cong. Rec. S8860 (Sept. 5, 1997) (the Modernization Act will "not interfere or substantially negatively affect any of the FDA tobacco authority").

The majority's historical perspective also appears to be shaped by language in the Federal Cigarette Labeling and Advertising Act (FCLAA), 79 Stat. 282, 15 U. S. C. § 1331 *et seq.* See *ante*, at 148–149. The FCLAA requires manufacturers to place on cigarette packages, etc., health warnings such as the following:

> "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy." 15 U. S. C. § 1333(a).

The FCLAA has an express pre-emption provision which says that "[n]o statement relating to smoking and health, other than the statement required by [this Act], shall be required on any cigarette package." § 1334(a). This pre-emption clause plainly prohibits the FDA from requiring on "any cigarette package" any other "statement relating to smoking and health," but no one contends that the FDA has failed to abide by this prohibition. See, *e. g.*, 61 Fed. Reg. 44399 (1996) (describing the other regulatory prescriptions). Rather, the question is whether the FCLAA's pre-emption

provision does *more*. Does it forbid the FDA to regulate at all?

This Court has already answered that question expressly and in the negative. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992). *Cipollone* held that the FCLAA's pre-emption provision does not bar state or federal regulation outside the provision's literal scope. *Id.*, at 518. And it described the pre-emption provision as "merely prohibit[ing] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels . . . ." *Ibid.*

This negative answer is fully consistent with Congress' intentions in regard to the pre-emption language. When Congress enacted the FCLAA, it focused upon the regulatory efforts of the Federal Trade Commission (FTC), not the FDA. See 1965 Hearings 1–2. And the Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, § 7(c), 84 Stat. 89, expressly amended the FCLAA to provide that "[n]othing in this Act shall be construed to affirm or deny the [FTC's] holding that it has the authority to issue trade regulation rules" for tobacco. See also H. R. Conf. Rep. No. 91–897, p. 7 (1970) (statement of House Managers) (we have "no intention to resolve the question as to whether" the FTC could regulate tobacco in a different way); see also 116 Cong. Rec. 7921 (1970) (statement of Rep. Satterfield) (same). Why would one read the FCLAA's pre-emption clause—a provision that Congress intended to limit even in respect to the agency directly at issue—so broadly that it would bar a different agency from engaging in any other cigarette regulation at all? The answer is that the Court need not, and should not, do so. And, inasmuch as the Court already has declined to view the FCLAA as pre-empting the entire field of tobacco regulation, I cannot accept that that same law bars the FDA's regulatory efforts here.

When the FCLAA's narrow pre-emption provision is set aside, the majority's conclusion that Congress clearly intended for its tobacco-related statutes to be the exclusive

"response" to "the problem of tobacco and health," *ante,* at 157, is based on legislative silence. Notwithstanding the views voiced by various legislators, Congress itself has addressed expressly the issue of the FDA's tobacco-related authority only once—and, as I have said, its statement was that the statute was *not* to "be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product." Note following 21 U. S. C. § 321 (1994 ed., Supp. III). The proper inference to be drawn from *all* of the post-1965 statutes, then, is one that interprets Congress' general legislative silence consistently with this statement.

IV

I now turn to the final historical fact that the majority views as a factor in its interpretation of the subsequent legislative history: the FDA's former denials of its tobacco-related authority.

Until the early 1990's, the FDA expressly maintained that the 1938 statute did not give it the power that it now seeks to assert. It then changed its mind. The majority agrees with me that the FDA's change of positions does not make a significant legal difference. See *ante,* at 156–157; see also *Chevron,* 467 U. S., at 863 ("An initial agency interpretation is not instantly carved in stone"); accord, *Smiley* v. *Citibank (South Dakota), N. A.,* 517 U. S. 735, 742 (1996) ("[C]hange is not invalidating"). Nevertheless, it labels those denials "important context" for drawing an inference about Congress' intent. *Ante,* at 157. In my view, the FDA's change of policy, like the subsequent statutes themselves, does nothing to advance the majority's position.

When it denied jurisdiction to regulate cigarettes, the FDA consistently stated *why* that was so. In 1963, for example, FDA administrators wrote that cigarettes did not satisfy the relevant FDCA definitions—in particular, the "intent" requirement—because cigarette makers did not sell their product with accompanying "therapeutic claims."

Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 before the Consumer Subcommittee of the Senate Committee on Commerce, 92d Cong., 2d Sess., 240 (1972) (hereinafter FDA Enforcement Letter). And subsequent FDA Commissioners made roughly the same assertion. One pointed to the fact that the manufacturers only "recommended" cigarettes "for smoking pleasure." Two others reiterated the evidentiary need for "health claims." Yet another stressed the importance of proving "intent," adding that "[w]e have not had sufficient evidence" of "intent with regard to nicotine." See, respectively, *id.*, at 239 (Comm'r Edwards); Letter of Dec. 5, 1977, App. 47 (Comm'r Kennedy); 1965 Hearings 193 (Comm'r Rankin); 1994 Hearings 28 (Comm'r Kessler). Tobacco company counsel also testified that the FDA lacked jurisdiction because jurisdiction "depends on . . . intended use," which in turn "depends, *in general*, on the claims and representations made by the manufacturer." Health Consequences of Smoking: Nicotine Addiction, Hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 100th Cong., 2d Sess., 288 (1988) (testimony of Richard Cooper) (emphasis added).

Other agency statements occasionally referred to additional problems. Commissioner Kessler, for example, said that the "enormous social consequences" flowing from a decision to regulate tobacco counseled in favor of obtaining specific congressional "guidance." 1994 Hearings 69; see also *ante*, at 153 (quoting statement of Health and Human Services Secretary Brandt to the effect that Congress wanted to make the relevant jurisdictional decision). But a fair reading of the FDA's denials suggests that the overwhelming problem was one of proving the requisite manufacturer intent. See *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236, 238–239 (CADC 1980) (FDA "comments" reveal its "understand-

ing" that "the crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent").

What changed? For one thing, the FDA obtained evidence sufficient to prove the necessary "intent" despite the absence of specific "claims." See *supra*, at 172–174. This evidence, which first became available in the early 1990's, permitted the agency to demonstrate that the tobacco companies *knew* nicotine achieved appetite-suppressing, mood-stabilizing, and habituating effects through chemical (not psychological) means, even at a time when the companies were publicly denying such knowledge.

Moreover, scientific evidence of adverse health effects mounted, until, in the late 1980's, a consensus on the seriousness of the matter became firm. That is not to say that concern about smoking's adverse health effects is a new phenomenon. See, *e. g.*, Higginson, A New Counterblast, in Out-door Papers 179, 194 (1863) (characterizing tobacco as "'a narcotic poison of the most active class'"). It is to say, however, that convincing epidemiological evidence began to appear mid-20th century; that the first Surgeon General's Report documenting the adverse health effects appeared in 1964; and that the Surgeon General's Report establishing nicotine's addictive effects appeared in 1988. At each stage, the health conclusions were the subject of controversy, diminishing somewhat over time, until recently—and only recently—has it become clear that there is a wide consensus about the health problem. See 61 Fed. Reg. 44701–44706 (1996).

Finally, administration policy changed. Earlier administrations may have hesitated to assert jurisdiction for the reasons prior Commissioners expressed. See *supra*, at 186–187 and this page. Commissioners of the current administration simply took a different regulatory attitude.

Nothing in the law prevents the FDA from changing its policy for such reasons. By the mid-1990's, the evidence

needed to prove objective intent—even without an express claim—had been found. The emerging scientific consensus about tobacco's adverse, chemically induced, health effects may have convinced the agency that it should spend its resources on this important regulatory effort. As for the change of administrations, I agree with then-JUSTICE REHNQUIST's statement in a different case, where he wrote:

> "The agency's changed view . . . seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration." *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 59 (1983) (concurring in part and dissenting in part).

V

One might nonetheless claim that, even if my interpretation of the FDCA and later statutes gets the words right, it lacks a sense of their "music." See *Helvering* v. *Gregory,* 69 F. 2d 809, 810–811 (CA2 1934) (L. Hand, J.) ("[T]he meaning of a [statute] may be more than that of the separate words, as a melody is more than the notes . . ."). Such a claim might rest on either of two grounds.

First, one might claim that, despite the FDA's legal right to change its mind, its original statements played a critical part in the enactment of the later statutes and now should play a critical part in their interpretation. But the FDA's

traditional view was largely premised on a perceived inability to prove the necessary statutory "intent" requirement. See, *e. g.*, FDA Enforcement Letter 240 ("The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions . . . for food, drug, device or cosmetic"). The statement, "we cannot assert jurisdiction over substance X unless it is treated as a food," would not bar jurisdiction if the agency later establishes that substance X is, and is intended to be, eaten. The FDA's denials of tobacco-related authority sufficiently resemble this kind of statement that they should not make the critical interpretive difference.

Second, one might claim that courts, when interpreting statutes, should assume in close cases that a decision with "enormous social consequences," 1994 Hearings 69, should be made by democratically elected Members of Congress rather than by unelected agency administrators. Cf. *Kent* v. *Dulles*, 357 U. S. 116, 129 (1958) (assuming Congress did not want to delegate the power to make rules interfering with exercise of basic human liberties). If there is such a background canon of interpretation, however, I do not believe it controls the outcome here.

Insofar as the decision to regulate tobacco reflects the policy of an administration, it is a decision for which that administration, and those politically elected officials who support it, must (and will) take responsibility. And the very importance of the decision taken here, as well as its attendant publicity, means that the public is likely to be aware of it and to hold those officials politically accountable. Presidents, just like Members of Congress, are elected by the public. Indeed, the President and Vice President are the *only* public officials whom the entire Nation elects. I do not believe that an administrative agency decision of this magnitude—one that is important, conspicuous, and controversial—can escape the kind of public scrutiny that is essential in any de-

mocracy. And such a review will take place whether it is the Congress or the Executive Branch that makes the relevant decision.

* * *

According to the FDA, only 2.5% of smokers successfully stop smoking each year, even though 70% say they want to quit and 34% actually make an attempt to do so. See 61 Fed. Reg. 44704 (1996) (citing Centers for Disease Control and Prevention, Cigarette Smoking Among Adults—United States, 1993; 43 Morbidity and Mortality Weekly Report 929 (Dec. 23, 1994)). The fact that only a handful of those who try to quit smoking actually succeed illustrates a certain reality—the reality that the nicotine in cigarettes creates a powerful physiological addiction flowing from chemically induced changes in the brain. The FDA has found that the makers of cigarettes "intend" these physical effects. Hence, nicotine is a "drug"; the cigarette that delivers nicotine to the body is a "device"; and the FDCA's language, read in light of its basic purpose, permits the FDA to assert the disease-preventing jurisdiction that the agency now claims.

The majority finds that cigarettes are so dangerous that the FDCA would require them to be banned (a result the majority believes Congress would not have desired); thus, it concludes that the FDA has no tobacco-related authority. I disagree that the statute would require a cigarette ban. But even if I am wrong about the ban, the statute would restrict only the agency's choice of remedies, not its jurisdiction.

The majority also believes that subsequently enacted statutes deprive the FDA of jurisdiction. But the later laws say next to nothing about the FDA's tobacco-related authority. Previous FDA disclaimers of jurisdiction may have helped to form the legislative atmosphere out of which Congress' own tobacco-specific statutes emerged. But a legislative atmosphere is not a law, unless it is embodied in a statutory word or phrase. And the relevant words and phrases here reveal

nothing more than an intent not to change the jurisdictional status quo.

The upshot is that the Court today holds that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the Court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify. The majority's conclusion is counterintuitive. And, for the reasons set forth, I believe that the law does not require it.

Consequently, I dissent.