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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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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), 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 en-

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acted 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. 8–40.

(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. 8–10.

(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. 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. 10–20.

(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

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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. 20–37.

(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*, 512 U. S., 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. 37–39.

(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. 40.

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.