No. 98-1152

IN THE SUPREME COURT OF THE UNITED STATES

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioner

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.,
Respondent

BRIEF FOR RESPONDENT R.J. REYNOLDS TOBACCO COMPANY

Filed September 10, 1999

QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act ("FDCA") as "drugs" and medical "devices" even though (1) FDA's theories for categorizing tobacco products as drugs and devices are unprecedented, would make many medically important drugs and devices unlawful, and would expand FDA's jurisdiction far beyond Congress's intent; (2) Congress has enacted a series of tobacco-specific statutes, which establish the congressional policy and program for regulation of tobacco products with respect to health, advertising, and underage access, and give FDA no role; (3) the tobacco-specific statutes are premised on the continued marketing of tobacco products with specified warnings, but the FDCA would require that tobacco products be banned; and (4) regulation of tobacco products as devices would oust the States from the lead role in regulating local retail sales of tobacco products?

RULE 29.6 LISTING

Pursuant to Supreme Court Rule 29.6, Respondent submits the following corporate information:

The parent company of R.J. Reynolds Tobacco Company is R.J. Reynolds Tobacco Holdings, Inc. R.J. Reynolds Tobacco Company has no nonwholly owned subsidiaries.

The corporate transactions referred to in the Rule 29.6 listing in Respondents' Brief in Opposition to Petition for a Writ of Certiorari have been completed. The international tobacco business of R.J. Reynolds Tobacco Company was sold to Japan Tobacco, Inc.; and R.J. Reynolds Tobacco Company was separated from its former parent company, RJR Nabisco Holdings Corp., by a stock spin-off.

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BRIEF FOR RESPONDENT R.J. REYNOLDS TOBACCO COMPANY

OPINIONS BELOW

The opinions below are identified in Brief for Petitioners ("Pet. Br.") 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at Pet. Br. 1.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Brief for Petitioners fails to list the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, the ADAMHA Reorganization Act ("ADAMHA Amendments"), and other tobacco-specific statutes, which are set forth in Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App.").

STATEMENT[1]

This case is about who has the power to make national policy for the regulation of tobacco products.[2] Federal statutes specifically addressed to tobacco already state

[1] Lodged with the Court is a compilation of all materials cited herein, except published judicial decisions, statutes, regulations, *Federal Register* documents, the 1964 Surgeon General's report on smoking and health, and briefs and appendices herein.

[2] FDA's assertion of jurisdiction relates to cigarettes and smokeless tobacco products. *See* 21 C.F.R. § 897.1(a) (1999). All references herein to "tobacco products" are to cigarettes and smokeless tobacco products "as customarily marketed." The words "as customarily marketed" are FDA's. *See* Letter from Mark Novitch for Comm'r Jere Goyan to John F. Banzhaf, III, and Peter N. Georgiades (Nov. 25, 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP) ("Novitch/Goyan Ltr.") (Joint Appendix ("Jt. App.") 50, 67). Those words refer to the marketing of cigarettes and smokeless tobacco products with the customary claims (*e.g.*, "good taste"), in contrast to claims of a health benefit.

"the policy of the Congress . . . to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health. . . ." 15 U.S.C. § 1331. Because the Food and Drug Administration ("FDA") nevertheless asserts that it has the power to regulate, and ban, tobacco products under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "1938 Act"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-97 (1994 & Supp. III 1997)), the issue is whether the FDCA, read together with the tobacco-specific statutes, authorizes FDA to do so.

Until 1995, FDA repeatedly disclaimed authority to regulate tobacco products, even though, throughout this century, they have been widely considered to have harmful effects, *see, e.g., Austin v. State*, 101 Tenn. 563, 566-67, 48 S.W. 305, 306 (1898), *aff'd*, 179 U.S. 343 (1900). In light of FDA's longstanding position, and with a view to the many competing interests relating to tobacco, Congress, starting in 1965, has enacted, *outside the FDCA*, a series of tobacco-specific statutes that provide for the regulation of tobacco products with respect to health, underage access, and related issues. The regulation of tobacco products has been a highly political matter, which Congress has addressed in legislation many times in the last 34 years, without providing any role for FDA. In reaching out now to regulate this large, separate, long-established economic sector it has never regulated before, FDA relies on unprecedented and problematic interpretations of definitional and operative provisions of the FDCA. Those interpretations cause sharp conflicts with the tobacco-specific statutes, and oust the States from the lead role in regulating underage access to tobacco products, despite congressional legislation specifically designed to strengthen the State role.

Since early in this century, tobacco products have been commonly used, and tobacco and tobacco products have constituted a major sector of the U.S. economy. See Opp. Cert. 2-3. Under the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) ("1906 Act"), FDA never claimed jurisdiction over them. Nothing in the 1938 Act's text or legislative history suggests that Congress drafted it to grant FDA such jurisdiction or to accommodate potential application to such products.

From 1938 to 1995, FDA repeatedly disclaimed jurisdiction over tobacco products—in formal decisions, in testimony to Congress, and in the routine administration of the FDCA. FDA adhered to that position despite (i) widespread belief that cigarettes are harmful to health, and (ii) scientific knowledge that they have foreseeable effects on the functioning of the body, as reflected in medical and scientific literature and government reports. FDA continued to adhere to it even after (iii) concerns about smoking and health reached the national political agenda in 1964, (iv) concerns about underage smoking led Congress in 1970 to ban cigarette advertising on television and radio, (v) cigarette manufacturers began disclosing tar and nicotine ratings in advertising in the early 1970s, thereby making clear that cigarette designs achieve predictable tar yields (associated with predictable nicotine yields), and (vi) the National Institute on Drug Abuse in 1979 issued a report declaring cigarettes addictive. See Opp. Cert. 4-6, 8, 11.

In 1964-65, Congress, for the first time, fully considered the issue of smoking and health. FDA testified that it had no jurisdiction.[3] In light of FDA's position, Congress

[3] *Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking*, 88th Cong. 56 (1964) (testimony of Surgeon General Terry) ("*1964 Hearings*"); *Ciga-*

in 1965 enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified, as amended, at 15 U.S.C. §§ 1331-41 (1994)) (Opp. Cert. App. 1a-5a, 55a-68a). Thereafter, in 1970, 1983, 1984, 1986, and 1992, it enacted additional statutes addressing tobacco and health. Opp. Cert. App. 1a-85a, 101a-106a. Thus, Congress has created and actively overseen a separate regulatory program for tobacco and health; and, as new information (of the sort FDA now relies on) has been presented to it, it has enacted additional tobacco-specific statutes.

These statutes provide in a careful and balanced way for the regulation of tobacco products with respect to health and related matters. Congress decided that tobacco products would not be banned but would bear warnings, that advertising them on television and radio would be prohibited, that "the addictive property of tobacco" would be the subject of reports to Congress from the Department of Health and Human Services ("HHS"), that their ingredients would be reviewed by HHS and would also be the subject of reports to Congress from HHS, and that the States would be given financial incentives to enact and effectively enforce restrictions on underage access. None of these regulatory controls is administered by FDA.

Today, these statutes embody Congress's policy and program for the very areas FDA now seeks to regulate differently. Congress's ongoing weighing of the competing interests—including health, federalism, the autonomy of adults, law enforcement, State and regional concerns,

rette Labeling and Advertising—1965: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong. 193 (1965) (testimony of FDA Dep. Comm'r Rankin) ("*1965 Hearings*"). FDA did not say to Congress (as it now says, 61 Fed. Reg. 44,396, 45,222 (1996)) that it regulates cigarettes whenever it has evidence that brings them within the FDCA's definitions.

and the national economy—has been an inherently *political* undertaking. The current regulatory system established by the tobacco-specific statutes, together with the absence of FDA jurisdiction over tobacco products sold without therapeutic claims, marks the place where " 'opposing social and political forces have come to rest.' " *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) (quoting prior decisions).

Nevertheless, in 1995 FDA proposed, 60 Fed. Reg. 41,314 (1995), and in 1996 it made final, its own assertion of jurisdiction and regulatory controls over tobacco products, 61 Fed. Reg. 44,396 (1996). It decided that they are both "drugs" and "devices," *id.* at 45,208-16, and that it may selectively apply to them some, but not all, of the FDCA's mandatory provisions that protect consumers with respect to all "drugs" and/or all "devices," *id.* at 44,403-04; 60 Fed. Reg. 41,348-49. On the basis of its study of their health effects, *id.* at 41,318-21, FDA found that tobacco products are "unsafe," and "dangerous," 61 Fed. Reg. 44,412; *see also id.* at 44,405, 44,571; 60 Fed. Reg. 41,349. Previously as well, FDA and HHS had advised Congress that cigarettes cannot satisfy the FDCA's requirement of safety, and that consequently cigarettes could not be marketed under the FDCA.[4] Now, however, in asserting jurisdiction over tobacco products, FDA abandons its prior understanding that the FDCA precludes the marketing of unsafe drugs and devices.

Although prohibition of alcohol occurred by constitutional amendment, FDA claims that Congress in 1938

[4] *1964 Hearings* 18 (Letter from HEW Sec. Anthony Celebrezze to Hon. Oren Harris); *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92d Cong. 242 (1972) (testimony of FDA Comm'r Edwards) ("*1972 Hearings*"); *Smoking Prevention Education Act: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong. 84 (1983) (Testimony of Ass't Sec. for Health Brandt).

gave it discretion to ban tobacco products by administrative action. *See* 61 Fed. Reg. 44,405, 44,412-13; 60 Fed. Reg. 41,349, 41,523-24. In 1996, it found the question whether to ban them a "close" one, 61 Fed. Reg. 44,416, but explained that, for now, it had rejected a ban because "there could be significant health risks to many" tobacco users, "the health care system [might] be overwhelmed by the treatment demands that these people would create," and a "black market and smuggling would develop . . . ." 61 Fed. Reg. 44,413. Thus, FDA's policymaking extended far beyond the effectiveness and safety of medical products.

Accepting FDA's factual findings *arguendo*, respondents moved in the district court for summary judgment on four grounds: (1) that the FDCA does not apply to tobacco products; (2) that, under FDA's findings, tobacco products cannot be either "devices," as distinct from "drugs," or "combination drug/devices," and that FDA does not have discretion to apply to them some mandatory statutory provisions but not others; (3) that FDA's restrictions on tobacco product advertising are not authorized by the FDCA, 21 U.S.C. § 360j(e); and (4) that those restrictions violate the First Amendment. The district court rejected the first two grounds, held that the adverising restrictions are unauthorized, and therefore did not reach the fourth ground. Pet. App. 76a-134.

The court of appeals reversed, with one dissent. It held that "it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products . . . ." Pet. App. 31a. This conclusion followed from the court's analysis of the FDCA and the tobacco-specific statutes. ". . . FDA's need to maneuver around the obstacles created by the operative provisions of the [FDCA] reflects congressional intent not to include tobacco products within the scope of the FDA's authority." *Id.* at 29a-30a. "The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco . . . ." *Id.* at 30a. "Congressional policy, as set out in the [FCLAA], cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products." *Id.* at 44a. Finally, the court observed: "neither federal agencies nor the courts can substitute their policy judgments for those of Congress." *Id.* at 53a.

Having ruled against FDA on the jurisdictional issue, the court of appeals vacated, and expressly stated no view on, the district court's judgment that the advertising restrictions are unauthorized, *id.* at 54a n.29; and it did not reach any other issue, see *id.* at 1a-54a. FDA's petition for rehearing *en banc* was denied. *Id.* at 137a-46a.

SUMMARY OF ARGUMENT

Prior to its tobacco rulemaking, FDA applied the FDCA's "drug" and "device" provisions only to products whose "intended use," as determined by marketing claims and representations, was to provide "medical" (*i.e.*, health-related) benefits. Accordingly, FDA consistently held that the FDCA does not apply to tobacco products.[5]

In its rulemaking, FDA did not rely on claims or representations by tobacco product manufacturers as establish-

[5] The general history of FDA's interpretation of the FDCA with respect to tobacco products and of Congress's enactment of tobacco-specific statutes on the basis of its understanding that FDA had no jurisdiction over such products is presented in the Brief of Philip Morris Incorporated and Lorillard Tobacco Company. The Brief of Brown & Williamson Tobacco Corp. presents the history and role of the concept of "intended use" in food and drug law. The Brief of United States Tobacco Co., *et al.* shows that the uses and effects that are relevant under the FDCA's definitions of "drug" and "device" relate to medical or health-related benefits. The Brief of the National Association of Convenience Stores and Acme Retail, Inc. shows that FDA's decision to regulate tobacco products as "devices" preempts or otherwise nullifies a host of State and local enactments relating to tobacco products.

ing an "intended use" to obtain a medical benefit. Instead, FDA departed from the prior settled interpretation of the FDCA's definitions by creating new theories of "intended use," which, if applied consistently, would make unlawful many genuine and medically important drugs and medical devices, and would extend to other products plainly beyond FDA's jurisdiction. FDA's new theories create serious anomalies in other statutes as well.

As the court of appeals held, even if the definitions of "drug" and "device" could be stretched to reach tobacco products, the language and structure of the FDCA as a whole plainly show that Congress did not intend to subject them to the FDCA. FDA's failure to find that tobacco products are effective and safe for any intended use makes it impossible to reconcile their continued marketing as "drugs" and "devices" with the FDCA's requirements that all marketed "drugs" and "devices" be effective and safe. Thus, FDA's assertion of jurisdiction necessarily leads to a ban, a result contrary to congressional intent and unacceptable even to FDA.

Having found tobacco products unsafe, FDA seeks to regulate them without reference to any statutory standard. To avoid both a ban contrary to congressional intent and the constitutional problem resulting from standardless regulation, the Court should interpret the FDCA as not reaching tobacco products.

FDA's assertion of jurisdiction is also irreconcilable with the tobacco-specific statutes. It conflicts with the congressional policy on smoking and health set forth in statutory text, and with the program established by those statutes for the regulation of tobacco products with respect to health and related matters. Moreover, without a clear statement from Congress, and in the teeth of legislation supporting the lead role of the States in controlling underage access to tobacco products, FDA's regulations seize the lead role for FDA.

Ultimately, FDA is left with a plea for *Chevron* deference. Deference is not warranted here. The issue of statutory interpretation relates to mutliple statutes, only one of which is administered by FDA; that issue involves policymaking of a kind suitable only for Congress; and FDA has reversed a long-settled interpretation. Moreover, the possibility of *Chevron* deference does not arise until after the Court has concluded that the relevant statutes do not reflect a clear congressional intent; but, here, they do.

In sum, FDA seeks to "cut a great road through the law," *TVA v. Hill*, 437 U.S. 154, 195 (1978) (quoting R. Bolt, *A Man for All Seasons*, Act I (1960)), to seize power over tobacco products. Among the felled trees are long-established principles of food and drug law and statutes designed by Congress to address the concerns raised by tobacco products in a way quite different from FDA's.

ARGUMENT

I. THE TEXT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IS INCONSISTENT WITH ITS APPLICATION TO TOBACCO PRODUCTS.

The FDCA is one of many statutes that protect the public health, each in a congressionally prescribed domain—*e.g.*, the Consumer Product Safety Act, 15 U.S.C. §§ 2051-84; the Federal Hazardous Substances Act, *id.* §§ 1261-78; the Toxic Substances Control Act, *id.* §§ 2601-92; the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y; the FCLAA; the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-08; and, with respect to advertising, the Federal Trade Commission Act, *id.* §§ 41-77.

Thus, the FDCA is not, as the Government contends, an essentially limitless "comprehensive, prophylactic statute designed to protect the public health and safety." Pet. Br. 36. Rather, it protects the public health in the respects, to the extent, and in the manner set forth in its

text. *Cf. Director, Office of Workers' Compensation Programs v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 135-36 (1995). It specifies and defines the categories of products it covers: foods, drugs, devices, and cosmetics, 21 U.S.C. § 321(f)-(g)(1) & (h)-(i); and it is designed for regulation of those kinds of products. It is not designed for regulation of tobacco products or other products, which may present health risks in contexts quite different from those of foods, drugs, devices, and cosmetics. As FDA, itself, has recognized, the FDCA does not "provide authority suitable to the regulation of cigarettes." Novich/Goyan Ltr. 3 (Jt. App. 50, 54); *see also* Opp. Cert. 12 n.9.[6]

An agency may not usurp the role of Congress as the initiator of major change in the regulation of a large sector of the economy, in the allocation of federal administrative jurisdiction, or in the wholesale reorientation of its organic statute. The claim that FDA may dramatically expand the scope and change the operation of the FDCA to do whatever it thinks serves the public interest is ultimately lawless.

> [N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law.

Rodriguez v. United States, 480 U.S. 522, 525-26 (1987) (emphasis in original).

[6] If, as FDA contends, tobacco products are "drugs" and "devices," then FDA's jurisdiction also reaches tobacco, itself, which is a "component" of such products. *See* 21 U.S.C. § 321(g)(1)(D) & (h). Therefore, FDA's jurisdiction would reach tobacco farms, warehouses, etc., which would be subject to FDA inspection under *id.* § 374.

A. The FDCA's Definitions Do Not Reach Tobacco Products.

Since long before 1938, tobacco products have been thought of as a separate category of products, at the same level of generality as "foods," "drugs," medical "devices," and "cosmetics," and not as a subcategory of any of them. Opp. Cert. 2 & n.3. Tobacco products are also different from them with respect to problems presented, public policy, and politics.

Although the terms "drug" and "device" can embrace new products developed after 1938, tobacco products and concerns about their safety were already prominent in the 1930s. *Id.* at 2-3.[7] The text of the FDCA reflects an understanding that it applies to products marketed for health-related benefits, not to tobacco products. The Government's contrary contention, that the FDCA's definitions "have a scope as broad as their language prescribes," Pet. Br. 21, and therefore reach tobacco products, cannot survive analysis.

1. *"Intended Use" Is a Term of Art in Food and Drug Law, and Its Claims-Based Meaning Is Necessary to the Proper Operation of the Law.*

The definitions of "drug" and "device" apply to "articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ." 21 U.S.C. § 321(g)(1)(C) & (h)(3). The term "intended to affect" was added to food and drug law in 1938. 52 Stat. 1041. It is patterned after "intended for use" in 21 U.S.C. § 321(g)(1)(B) & (h)(2), which derives from section 6 of the 1906 Act, 34 Stat. 769 ("intended

[7] *See also, e.g., Illinois Cigarette Serv. Co. v. City of Chicago*, 89 F.2d 610, 613 (7th Cir. 1937); *Ploch v. City of St. Louis*, 345 Mo. 1069, 1076-77, 138 S.W.2d 1020, 1023 (1940); *Commonwealth v. McCrary*, 250 Ky. 182, 187, 61 S.W.2d 1043, 1045 (1933); *Ford Hopkins Co. v. Iowa City*, 216 Iowa 1286, 1293-94, 248 N.W. 668, 672 (1933).

to be used"). These terms are referred to together as "intended use." See 21 C.F.R. §§ 201.128, 801.4 (1999).[8]

"Intended use" is a term of art, to which administrative and judicial interpretation has given a special meaning, different from the dictionary definitions of its separate words, and with no origin in the common law.[9] Congress in 1938 articulated this special meaning:

> The use to which the product is *to be* put will determine the category into which it will fall. . . . The manufacturer of the article, through his *representations* in connection with its *sale*, can *determine* the use to which the article is to be put.

S. Rep. No. 361, 74th Cong. 4 (1935) (emphasis added).[10] Courts and, until now, FDA, have treated this passage as authoritative. *See ASH v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980); *United States v. An Article . . . "Sudden Change,"* 409 F.2d 734, 739 n.3 (2d Cir. 1969); *United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951); 56 Fed. Reg. 60,537, 60,546 (1991).[11]

[8] All references herein to the C.F.R. are to the 1999 edition.

[9] Contrary to Pet. Br. 25, "effects" that are intended is not the "decisive factor" in the definitions. The definitions do not use the word "effects." As shown in *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (water with therapeutic claims is a drug), even a product whose manufacturer knows it has no therapeutic effects can be a drug or device if such effects are claimed.

[10] The phrase "is to be put" (rather than "is put") signifies intended rather than actual use. Contrary to the district court's suggestion, Pet. App. 106a, the Report could not have used "will" rather than "can" in the second quoted sentence because use of "will" would have made the sentence a prediction of future behavior rather than a statement of legal capacity.

[11] Intended use, so understood, is analogous to congressional intent, which is not determined from the private thoughts, conversations, or papers of Members of Congress, but only from what is said in certain types of *public* materials, *i.e.*, statutes, and sometimes legislative history. It is in this sense that longstanding FDA regulations define "intended use" as involving an "*objective* intent," 21 C.F.R. §§ 201.128, 801.4 (emphasis added), a term unknown to ordinary English and the common law. All subjective intent is inferred from objective materials. Therefore, an "objective intent" is not subjective intent, however evidenced. Here, it is the intent communicated in the market by the claims and representations in a product's labeling and advertising. That intent is "objective" in that its locus is not the mind of any person, but the marketing communications, themselves.

Thus, the regulations' requirement of "objective intent" clearly precludes FDA's current theory that an intended use can derive from what manufacturers "have in mind," Pet. Br. 3, *e.g.*, subjective intent, knowledge, or desire. The regulations also make no reference to, and therefore preclude as a basis for "intended use," foreseeability, product design, and actual use for a purpose for which a product is not "offered" (*i.e.*, claimed).

Thus, a manufacturer can "determine," not merely influence, its product's intended use through "representations in connection with . . . sale." Such representations can determine an intended use that is within the FDCA "drug" and "device" definitions or one that is not. This understanding of "intended use" led FDA to conclude repeatedly that the FDCA does not apply to tobacco products in the absence of therapeutic claims because their customary claims are outside the FDCA's definitions.[12]

[12] "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 in the [FDCA] . . . ." Letter from FDA Bureau of Enforcement to Directors of Bureaus, Divisions, and Districts (May 24, 1963), *reprinted in 1972 Hearings* 240. "[FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *1965 Hearings* 193. "[C]igarettes recommended for smoking pleasure are beyond the [FDCA]." *1972 Hearings* 239 (testimony of FDA Comm'r Edwards). "[I]nsofar as rulemaking would relate to cigarettes . . . as customarily marketed, . . . FDA has no jurisdiction." Novitch/Goyan Ltr. 12 (Jt. App. 50, 67). *See also* 61 Fed. Reg. 45,194, 45,198-99. Thus, contrary to Pet. Br. 42, there was absolutely no "uncertainty . . . about FDA's position."

United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), and *United States v. 345 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959), do not support the broad proposition that "FDA has previously regulated tobacco products when it has found sufficient evidence that they

Accordingly, FDA has regulated nicotine-containing drugs labeled for smoking cessation, without simultaneously claiming jurisdiction over tobacco products: the former make therapeutic claims; the latter do not.[13]

The theories of "intended use" on which FDA now relies are unprecedented. Until the tobacco rulemaking, neither FDA nor any court had ever held that a foreseeable or widespread consumer use, internal company statements, or a product's design could establish an intended use. Even a manufacturer's undistributed promotional materials with therapeutic claims do not establish an intended use because they have not been *communicated* in the *market*. *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497 (8th Cir. 1995). In the present context, foreseeable use, widespread consumer use, and known or desired use are merely ongoing actual use. FDA's theories would substitute "use" for "intended use."

Basing FDA jurisdiction on claims in the market has worked well, and consistently with congressional intent, since 1906. The claims-based understanding has kept FDA jurisdiction within the limits envisioned in 1938 by

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were intended to affect the structure or any function of the body," Pet. Br. 24. Rather, they held only that cigarettes bearing therapeutic claims—*i.e.*, uncustomary claims—were drugs. Literally any consumer product is a drug or device subject to the FDCA if marketed with a therapeutic claim. *See, e.g., United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph records); *United States v. Undetermined Quantities of Article of Device*, 1982-1985 Developments, Med. Devices Rep. (CCH) ¶ 15,055 (W.D. Mich. Nov. 22, 1982) (tape recordings). FDA has not historically regulated either the recording industry or the tobacco industry.

[13] The suggestion at Pet. Br. 23 that FDA has jurisdiction over tobacco products *because* it has jurisdiction over nicotine-containing products that make therapeutic claims simply ignores the distinction between the presence and absence of such claims, and FDA's longstanding prior reliance on that distinction, see n.12, *supra*. In addition, the tobacco-specific statutes discussed at pp. 35-44, *infra*, preclude FDA jurisdiction over tobacco products, but not over nicotine-containing non-tobacco products.

Congress and FDA,[14] while enabling FDA to protect the public from any product with an improper health claim.

Claims in the market—oral or written; on labels, in advertising, or in salespersons' presentations—provide an objective, easily identifiable and administrable basis for determining FDA jurisdiction. Virtually no product (especially a new one) can be marketed without some claim(s), express or implied. Even a product name, by itself, may have a secondary meaning that constitutes a claim, *e.g.*, "Prozac." (Tobacco products, of course, are marketed with customary claims.) A product outside FDA's jurisdiction could be regulated by another agency. Thus, a nicotine inhaler marketed for "pleasure," Reply Brief for the Petitioners [in support of Petition for a Writ of Certiorari] 5 ("Pet. Rep."), would be subject to regulation under the Consumer Product Safety Act, and, potentially, the Controlled Substances Act. Street drugs, Pet. Rep. 5, already are regulated under the latter.

FDA's theory that any use that is foreseeable, widespread, known to a manufacturer, or reflected in product design is an intended use is unworkable. In food and drug law, the concept of "intended use" governs two important kinds of determination: (1) whether an approved drug or device needs additional approval for its distribution to be lawful (the issue of "off-label" uses), and (2) whether a product is, indeed, a drug or device (the issue of jurisdiction). See Pet. Br. 27 n.5. FDA's new theories lead to intolerable results in both areas.

Off-Label Uses. In deciding whether a drug or device should be (or remain) approved, FDA is required to assess its effectiveness and safety under the "conditions [of use] prescribed, recommended, or suggested in [its]

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[14] *See Foods, Drugs, and Cosmetics: Hearings Before the Senate Comm. on Commerce*, 73d Cong., 518 (1934) (testimony of FDA Chief Campbell).

labeling." 21 U.S.C. §§ 355(d)(1)-(2) & (4)-(5) & (e)(1)-(3), 360c(a)(2)(B), 360e(d)(2)(A)-(B) & (e)(1)(A)-(B). Those conditions are determined by the manufacturer, subject to FDA approval: if FDA finds that a drug or device would be ineffective or unsafe under a particular condition, the product will not be (or remain) approved with that condition. Consequently, FDA approves a drug or device with labeling that specifies particular intended uses (*i.e.*, "indications" for use, which are manufacturer claims), for which FDA has found it effective and safe. *See* 21 U.S.C. §§ 355(b)(1)(F) & (d)(1)-(2) & (4)-(5), 360c(a)(2)(B), 360e(c)(1)(F) & (d)(2); 21 C.F.R. §§ 314.105(b)-(c), 814.44(d)(1). Addition of a new intended use creates a different product. *See*, as to drugs, *id.* § 310.3(h)(4). In general, adequate directions for all intended uses must be in labeling for consumers (non-prescription products) or physicians (prescription products), 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5(a), 201.100(c)(1), 801.5(a), 801.109(c); Pet. Br. 27 n.5. Any new labeled use must be approved, 21 C.F.R. §§ 314.70(b)(3)(i), 814.39(a)(1)-(2).

However, because Congress intended that FDA not regulate the practice of medicine, physicians may freely prescribe an approved drug or device for unapproved uses (called "off-label" or "unlabeled" uses, because not referred to in the FDA-approved labeling). 37 Fed. Reg. 16,503 (1972); *see also, e.g.*, 59 Fed. Reg. 59,820. 59,821 (1994); 44 Fed. Reg. 37,434, 37,435-36 (1979).

> [U]nlabeled uses . . . may reflect approaches to drug therapy that have been extensively reported in medical literature. . . . Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations. . . . Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

FDA, *Use of Approved Drugs for Unlabeled Indications*, FDA Drug Bulletin, Apr. 1982, at 3. Thus, many drugs (and devices) have medically important off-label uses that are widespread, foreseeable, known to manufacturers, and reflected in their internal papers.

FDA has never treated an off-label use as an intended use where the manufacturer or other vendor did not *claim* the use in connection with sale. If FDA did so, all products with such uses by physicians treating patients or by consumers would be unlawful because they would lack approval, and their labeling would lack adequate directions, for all intended uses.

Basing "intended use" on widespread actual use or otherwise foreseeable use would also make the line between "intended" and not-intended uses uncertain, shifting, and beyond the control of manufacturers. The frequency of particular off-label uses may be difficult to determine, and may fluctuate over time. Consequently, with respect to many off-label uses, manufacturers and FDA would have no reliable means of knowing at any given time whether they are "intended" or not, and thus whether the products being so used are lawful or unlawful.

Therefore, FDA's new theories of "intended use," created to reach tobacco products, cannot be applied consistently without making many medically important drugs and devices unlawful and placing FDA in conflict with Congress's intent that it not regulate medical practice (by deeming unlawful those products that physicians put to off-label use). Theories created "for this day and train only," *Smith v. Allwright*, 321 U.S. 649, 669 (1944) (Roberts, J., dissenting), cannot be sustained.

Jurisdictional Determinations. FDA relies on a literal reading of the FDCA's definitions. Here, however, as in *Lewis v. United States*, 523 U.S. 155, 160 (1998), "a literal reading . . . would dramatically separate the statute from its intended purposes" because the FDCA would apply to a vast array of products that Congress clearly did not intend FDA to regulate. One example is guns. Bullets enter the body; they are commonly used to "affect the structure or . . . function of the body of man or other animals," 21 U.S.C. § 321(h); and their manufacturers design them for, know of, desire, and foresee such uses. Other articles that foreseeably affect bodily functions include thermal clothing, air conditioners, exercise equipment, scuba-diving gear, mattresses, and even roller-coasters and horror movies.

It is no response that FDA could exercise discretion to decline jurisdiction and thereby avoid absurd results. FDA's jurisdiction would then be based not on law, but on agency discretion. But "[t]he determination of the extent of authority given to a delegated agency by Congress is not left for the decision of him in whom authority is vested." *Addison v. Holly Hill Fruit Prods., Inc.*, 322 U.S. 607, 616 (1944).

The *dictum* in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), invoked at Pet. Br. 23, is not to the contrary. The Court there held only that "the literal language" of the FDCA's definition of "drug" does not require contact with the body. Here, as shown at pp. 21-35, *infra*, "the literal language" of the FDCA, *taken as a whole*, excludes tobacco products. The Court there relied on the lack of a countervailing congressional direction to exclude an antibiotic sensitivity disk. 394 U.S. at 792. Here, there are congressional directions in the FDCA that unsafe "drugs" and "devices" not be marketed, and in the tobacco-specific statutes that

the health aspects of tobacco products be regulated only under those statutes and under a policy of giving specified warnings while protecting the national economy. Moreover, the *Bacto-Unidisk dictum* does not apply to a situation, like that here, of multiple relevant statutes with countervailing purposes. Finally, FDA, itself, has held that *Bacto-Unidisk* provides no basis for asserting jurisdiction over cigarettes. *See* Letter from Comm'r Donald Kennedy to John F. Banzhaf, III, at 4 (Dec. 5, 1977) (FDA Dkt. 77P-0185) (Jt. App. 44, 49).[15]

2. *FDA's Interpretation of "Intended Use" Would Create Anomalies in Other Statutes.*

The Consumer Product Safety Act ("CPSA") exempts from the term "consumer product" "drugs" and "devices" "as such terms are defined in . . . the [FDCA]." 15 U.S.C. § 2052(a)(1)(H) (1994). If every consumer product that foreseeably affects the structure or function of the body (or that fits within any of FDA's other new theories of "intended use") is a "drug" or "device," then every such product is excluded from the jurisdiction of the CPSA—whether or not FDA actually regulates it. There are many such products. Indeed, the products the Consumer Product Safety Commission actively regulates are precisely those that foreseeably can affect consumers adversely (*e.g.*, space heaters, electric hair curlers, playground equipment).

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[15] The Court in *Bacto-Unidisk* interpreted 21 U.S.C. § 321(g)(1)(B) (the disease-treatment definition of "drug"). FDA here relies on *id.* §§ 321(g)(1)(C) & (h)(3) (the structure-or-function definitions of "drug" and "device"). As to *those* definitions, FDA "has . . . recognized implicit limitations upon [their] scope." *ASH v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980). Moreover, FDA agrees that the other principal provisions of the "drug" and "device" definitions, 21 U.S.C. § 321(g)(1)(A) & (h)(1) (compendial recognition), are not to be read literally. *See National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 337 n.11 (2d Cir. 1977).

The CPSA separately excludes from the definition of "consumer product" "tobacco and tobacco products." *Id.* § 2052(a)(1)(B). Thus, in Congress's dictionary, the terms "tobacco and tobacco products" refer to a class of articles different from "drugs" and "devices" (as defined in the FDCA).[16] FDA's interpretation would make section 2052(a)(1)(B) superfluous. The same problem would arise under the definition of "chemical substance" in the Toxic Substances Control Act, *id.* § 2602(2)(B), and under the definition of "hazardous substance" in the Federal Hazardous Substances Act, *id.* § 1261(f)(2).

The Controlled Substances Act ("CSA") defines "controlled substance" to include all "drugs," as defined in the FDCA, and to exclude "tobacco." 21 U.S.C. § 802(6), (12) (1994). Thus, if tobacco is an FDCA "drug," it is both included in (contrary to expressed congressional intent), and excluded from, the definition of "controlled substance." The same problem would arise under the definition of "consumer commodity" in the Fair Packaging and Labeling Act, 15 U.S.C. § 1459 (1994).

The text of the CSA also contradicts the Government's claim that any product that is taken into the body, has a pharmacological effect, and may be dangerous, has "the classic characteristics of [FDCA] drugs and devices." Pet. Br. 24. The definition of "controlled substance" includes, *in addition to* FDCA "drugs," any "other substance, or immediate precursor, included in" one of the CSA's Schedules. 21 U.S.C. § 802(6). Thus, the CSA demonstrates that the FDCA's definition of "drug" does *not* embrace all substances that are taken into the body and have pharmacological effects and dangerous abuse potential—the kinds of substances Congress intended to reach in the CSA, *see generally, id.* § 811. Although Congress found that "[m]any" controlled substances have "a useful and legitimate medical purpose," *id.* § 801(1), and therefore are within FDA's jurisdiction, the ones that do not, *e.g.*, hallucinogens, are outside FDA's jurisdiction because they are not marketed with medical claims.

[16] Similarly, the Chairman of the Federal Trade Commission ("FTC"), whose statute includes essentially the same definitions of "food," "drug," "device," and "cosmetic" as the FDCA, *compare* 21 U.S.C. § 321(f)-(g)(1) & (h)-(i) *with* 15 U.S.C. § 55(b)-(e), advised Congress in 1964: "A cigarette is not a drug. It is not a food. It is not a device. It is not a cosmetic. It is a thing, a product." *1964 Hearings* 125.

These statutes further demonstrate that Congress distinguishes between FDCA "drugs" (and "devices") and tobacco products. Moreover, these statutes constitute a pattern of congressional decisions to exclude tobacco products from health-and-safety statutes other than the tobacco-specific statutes, and thereby to reserve to Congress, itself, the role of regulatory policy-maker as to tobacco and health.[17]

B. The FDCA as a Whole Cannot Apply to Tobacco Products.

The FDCA as a whole precludes application of its definitions of "drug" and "device" to tobacco products, and therefore removes any asserted definitional ambiguity on that point. "Ambiguity is a creature not of definitional possibilities but of statutory context." *Brown v. Gardner,* 513 U.S. 115, 118 (1994). Therefore, "[t]he

[17] The Government infers from the absence of an express exclusion in the FDCA's definitions of "drug" and "device" that Congress intended to leave FDA free to regulate tobacco products as drugs and devices. Pet. Br. 18-19. Because, however, FDA advised Congress in 1964-65 that it had no jurisdiction under the FDCA, see n.3, *supra*, an interpretation it had adhered to for more than 25 years and continued to adhere to for another 30 years, the only reasonable inferences are that it was unnecessary to amend the FDCA to exclude tobacco products, and that Congress intended tobacco products to be regulated, with respect to health, under the tobacco-specific statutes exclusively. FDA so concluded in Novitch/Goyan Ltr. 6-7 (Jt. App. 50, 58-59). *See also* authorities cited in Opp. Cert. 27, n.24.

plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). *See also, e.g., United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) (provision ambiguous in isolation may be clarified by remainder of statute because only one meaning produces substantive result compatible with the rest of the law).

Accordingly, the FDCA's jurisdictional reach cannot be determined solely by its definitions. Jurisdiction is conferred by imposition of requirements or prohibitions, and by delegation of administrative and enforcement authority. Definitions impose no duties and delegate no power. An interpretation of a definition must yield the kind of results Congress intended when it is implemented by a statute's operative provisions.

Thus, in *Gustafson v. Alloyd Co.*, 513 U.S. 561 (1995), although section 2(10) of the Securities Act of 1933 defined the term "prospectus," the Court determined the scope of that term and the scope of the statute by examining an operative provision: "Although § 10 does not define what a prospectus is, it does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and *coherent regulatory scheme* . . . ." *Id.* at 569 (emphasis added). *See also Chemehuevi Tribe v. FPC*, 420 U.S. 395, 403-04 (1975) ("[o]ther provisions of the Act make more apparent the limitations intended by Congress upon the reach of [the section relied on]").

This Court frequently has refused to apply a statute's definitions so broadly (even within their literal meaning) as to reach results not intended by the statute's operative provisions. *See, e.g., Reves v. Ernst & Young*, 494 U.S. 56, 63 (1990) ("the phrase 'any note' should not be interpreted to mean literally 'any note,' but must be understood against the backdrop of *what Congress was attempting to accomplish* . . . .") (emphasis added); *Norfolk Redevelopment & Hous. Auth. v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 36 (1983) (although C&P literally met statutory definition of "displaced person," Court "must . . . be satisfied that Congress *addressed the problem* of utility relocation costs in the [statute] before [it] can conclude that C&P is entitled to the benefits it seeks") (emphasis added). *See also Helvering v. Gregory*, 69 F.2d 809, 810 (2d Cir. 1934) (L. Hand, J.) ("*[I]t does not follow that Congress meant to cover* such a transaction, . . . even though the facts answer the dictionary definitions of each term used in the statutory definition.") (emphasis added), *aff'd*, 293 U.S. 465 (1935).

Here, application of the FDCA to tobacco products would destroy its "coherent regulatory scheme." In the FDCA, Congress did not "address[] the problem" of how to regulate such products; regulation of them was not "what Congress was attempting to accomplish." When the FDCA is viewed as a whole, "it does not follow [from its definitions] that Congress meant to cover" tobacco products, or left the question open to FDA's future determination.

In *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218 (1994), the Federal Communications Commission ("FCC") had broadly interpreted the term "modify" so as to exempt certain carriers from the statutory requirement to file tariffs. In rejecting the FCC's interpretation, the Court observed that it was "highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion . . . ." *Id.* at 231. It is at least equally unlikely that Congress intended to leave to FDA the determination whether tobacco products will be regulated under the FDCA and even banned.

1. *The FDCA Is Designed To Ensure that "Drugs" and "Devices" Are Effective and Safe, But FDA Has Not Found that Tobacco Products Are Effective or Safe.*

"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." *More Information for Better Patient Care: Hearing Before the Senate Comm. on Labor and Human Resources,* 104th Cong. 83 (1996) (statement of FDA Dep. Comm'r Schultz). This is the heart of the FDCA.

Contrary to the implication at Pet. Br. 36, 37, the statutory standards for approval are not that a drug or device is "sufficiently effective" and "sufficiently safe." A drug must have been affirmatively "show[n]" to be "effective" and "safe." 21 U.S.C. §§ 355(d)(1)-(2) & (4)-(5). For a device, there must be an affirmative "showing of reasonable assurance that [it] is safe" and "effective." *Id.* §§ 360c(a)(1)(A)(i) & (a)(1)(B), & (a)(1)(C)(i), 360e(d)(2)(A)-(B). These showings must be made on the basis of data from scientific studies. *Id.* §§ 355(b)(1)(A) & (d)(1)-(2) & (4)-(5); 360c(a)(3), 360e(c)(1)(A).

A drug or device is "effective" when, but only when, for those who use it, it provides the health benefits represented in its labeling. *See, e.g., id.* §§ 355(d)(5), 360c(a)(2), 360e(d)(2)(B). A drug or device is "safe" when, but only when, for those who use it, those health benefits outweigh its risks. *See, e.g., United States v. Rutherford,* 442 U.S. 544, 555-56 (1979); *Drug Safety (Part 1): Hearing Before a Subcomm. of the House Comm. on Government Operations,* 88th Cong. 150 (1964) (testimony of FDA Comm'r Larrick). The FDCA 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.

21 U.S.C. § 360c(a)(2)(A)-(C). Thus, for example, an artificial heart may have a substantial risk of failure leading to death, but if it sustains life it may be "safe."

After an extensive review of their health effects, FDA has *not* found that tobacco products are, or that there is "reasonable assurance" that they are, "effective" or "safe," or even that they are "sufficiently effective" or "sufficiently safe." To the contrary, it has found them "unsafe" and "dangerous." See p. 5, *supra.* Under FDA's findings, the risks tobacco products pose are not justified by any affirmative benefits to health.

The attempt at Pet. Br. 32 to analogize tobacco products to toxic anti-cancer drugs fails because the toxicity of such drugs is outweighed by their beneficial effects in treating cancer. FDA has not found that tobacco products provide any medical benefit, *e.g.*, that any person's health would be better if he or she smoked than if he or she did not. Although FDA says that tobacco products are addictive, *i.e.*, that they effectively sustain addiction (viewed by FDA as a disease), it has not found that they are effective or safe in *treating* addiction. Perpetuating an addiction is *not treating* it. A therapeutic substance that would prevent the symptoms of withdrawal from an addicting substance would provide a "benefit to health," but continuing to consume the addicting substance (and in that way avoiding withdrawal symptoms) does not provide a "benefit to health." FDA has not found that tobacco products help a

patient avoid continued addiction to a more harmful substance (as methadone helps avoid continued addiction to heroin). Nor has it found that avoidance of withdrawal symptoms medically justifies continued smoking or makes cigarettes therapeutically "effective" or "safe." Nor has FDA found that tobacco products provide a significant benefit in, or are safe for, tranquilization, stimulation, or weight control. In sum, FDA has not found that any tobacco product provides a benefit to health that justifies its risks for any user.

What FDA has found (for now) is that a tobacco-product ban would have gravely adverse consequences *for society*. For example, FDA refers to burdens on health-care institutions and risks from prospective black market products, 61 Fed. Reg. 44,413; and a black market harms law-enforcement, the economy, and society generally. Considerations of this sort, however, are not a statutorily permitted basis for concluding that a drug or device is, or has a "reasonable assurance" of being, "effective" and "safe." Under section 360c(a)(2)(A)-(C), such conclusions must be drawn "with respect to the persons for whose use the device is represented or intended," "with respect to the conditions of use prescribed, recommended, or suggested in the labeling," and by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Given its findings, FDA could not draw such conclusions here, and has not tried to do so.

FDA's weighing of the risks presented by tobacco products against the risks that would be presented by a ban (or its weighing of the risks and benefits of a *ban* rather than those of *tobacco products*, themselves) is not "the mirror image of the analysis approved in *Rutherford*," Pet. Br. 34, but a refusal to perform that analysis. No drug or device has ever been found safe on that basis. The FDCA clearly requires a comparison, on the basis of

scientific data, between the risks and probable benefits of a *drug* or *device* to the *health* of its *users*. FDA would treat section 360c(a)(2)(A)-(C) as satisfied, instead, by hypotheses as to miscellaneous adverse social consequences of the withdrawal of products that provide no benefit to health. FDA's rulemaking made no attempt to justify such a startling new interpretation of this fundamental requirement of the law.

2. *The FDCA's Operative Provisions Cannot Accommodate the Ongoing Distribution of Tobacco Products.*

To permit the continued distribution of tobacco products under the FDCA, FDA must ignore or distort many of its other important consumer-protection provisions.

1. A drug or device is misbranded and therefore unlawful, 21 U.S.C. § 331(a), if "it is dangerous to health when used in the . . . manner . . . suggested in the labeling thereof." *Id.* § 352(j). FDA has found that "cigarettes and smokeless tobacco are dangerous . . . ." 61 Fed. Reg. 44,420; *see also id.* at 44,412, but it never explains why section 352(j) does not apply to these products.[18]

2. Before any "new drug" (defined in 21 U.S.C. § 321(p)) is marketed, it must have been approved by FDA as effective and safe. *See* 21 U.S.C. §§ 331(d), 355. Under FDA's theory that tobacco products combine a drug (nicotine) with device "components," a nicotine-containing tobacco product is an unapproved new drug.[19]

[18] Indeed, Congress in 1970 directed that cigarettes be labeled as "Dangerous to Your Health," Pub. L. No. 91-222, § 4, 84 Stat. 88 (1970); but Congress did not ban them. Section 352(j) does not allow FDA to consider the factors that led Congress to permit the continued distribution of cigarettes, *see* 15 U.S.C. § 1331(2).

[19] If a tobacco product is a "drug," it is a "new drug" because it is not "generally recognized . . . as safe and effective" within 21 U.S.C. § 321(p).

Its sale, therefore, violates sections 355 and 331(d). FDA simply disregards the settled law that the FDCA prohibits it from allowing the marketing of an unapproved new drug. *See Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979); *Hoffmann-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890 (D.D.C. 1975).

3. A drug or device is misbranded if it fails to bear "adequate directions for use," 21 U.S.C. § 352(f)(1), including, *inter alia*, directions necessary and sufficient to enable a lay person to use the drug or device *safely* for its intended use. *See* 61 Fed. Reg. 44,464; 21 C.F.R. §§ 201.5, 801.5. FDA has found that, even with the current Surgeon General's warnings required by 15 U.S.C. §§ 1333, 4402, tobacco products are unsafe. Thus, in FDA's view, the warnings fail to provide adequate directions for use; and FDA does not propose any different or additional directions (which would be barred by *id.* §§ 1334(a), 4406(a), discussed at pp. 40, 42-43, *infra*). Therefore, it must be FDA's view that adequate directions for use of tobacco products cannot be written.[20]

4. A drug or device is misbranded if it fails to bear "adequate warnings against use . . . by children." 21 U.S.C. § 352(f)(2).[21] No exemption is authorized. FDA says its tobacco regulations are needed to prevent a "pediatric disease," resulting from tobacco use by children.

[20] Section 352(f)(1) permits FDA to exempt any drug or device from its requirement, but only where other circumstances (*e.g.*, a physician's prescription) reasonably assure its safe use. *See* 21 C.F.R. §§ 201.100-201.129, 801.109-801.127. FDA has never before exempted a drug or device without this assurance. FDA's only asserted justification for exempting tobacco products is that "the way in which these products are used is common knowledge." 61 Fed. Reg. 44,465. Under FDA's findings, however, such knowledge does not reasonably assure *safe* use.

[21] The warning need not be addressed *to* children. It may be addressed to adults to prevent use by children, *e.g.*, "Keep out of the reach of children."

61 Fed. Reg. 45,238. Yet, to avoid a conflict between the FDCA and the tobacco-specific statutes, FDA finds that *the current Surgeon General's warnings are "adequate warnings against use . . . by children."* *Id.* at 44,465 (emphasis added). This disingenuous finding, necessary to avoid a ban under section 352(f)(2), is absurd in light of everything else FDA says about tobacco products, including its finding that the current warnings are "not very effective with young people now." 61 Fed. Reg. 44,511.

5. The FDCA requires FDA to classify devices into one of three classes. 21 U.S.C. § 360c(b)(1). Each requires reasonable assurance that a marketed device is effective and safe. *Id.* § 360c(a). FDA's findings require it to put tobacco products in Class III, which covers devices that present "a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)(ii)(II). Such devices must undergo FDA review before commercial distribution. *Id.* § 360e(a). Here, unless manufacturers could show that there is "reasonable assurance" that their tobacco products are effective and safe, *id.* § 360e(d)(2)(A)-(B), the products would have to be removed from the market, *id.* §§ 331(a), 351(f).

FDA's proposed rule ignored classification; but, in response to comments, FDA said it intends to classify tobacco products at some unspecified time. 61 Fed. Reg. 44,412. FDA thus has shifted from ignoring the statutory mandate to suspending it. Although the FDCA does not set a deadline for classification, where, as here, a supposed device cannot satisfy the requirements applicable to *any* class, indefinite postponement of classification is unlawful. *Heckler v. Chaney*, 470 U.S. 821, 833 (1985) ("Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers.").

6. To protect consumers from unsafe devices, the FDCA provides:

> If [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary *shall* issue an order requiring the appropriate person . . . to immediately cease distribution of such device . . . .

21 U.S.C. § 360h(e)(1) (emphasis added). Although the finding of "reasonable probability" is discretionary, once FDA makes that finding the statutory text ("shall") mandates a cease-distribution order. All the discretion FDA needs in administering section 360h(e)(1) relates to the making of the predicate finding. Here, FDA has chosen to make that finding. *See* 61 Fed. Reg. 44,398. To read "shall" here as "may," as FDA now must do to avoid a ban, is contrary to the statutory text, subverts its purpose of protecting consumers, and is unnecessary to its practical administration.[22]

In sum, to avoid the ultimate anomaly of a ban, FDA must disregard or distort key consumer-protection provisions of the FDCA. FDA's extremely broad interpretation of the FDCA's definitions (to expand its own jurisdiction) contrasts strikingly with its narrow interpretations or total disregard of the FDCA's operative consumer-protection provisions (which preclude its preferred tobacco regulatory program). FDA has tried to "forc[e] a square peg into a round hole." *Rowland v. California Men's Colony*, 506 U.S. 194, 200 (1993).

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[22] A cease-distribution order is not, itself, an enforcement action, and so is not a matter of discretion. The order establishes a legal prohibition against further distribution of the product, violation of which may or may not (within FDA's discretion in individual cases) lead to an enforcement action. The order is analogous to an order denying approval of a product.

This transformation of the FDCA is not necessitated by statutory obsolescence. The FDCA is not in need of updating due to congressional neglect or new circumstances. Congress has amended it at least 57 times since 1938, 25 times in the last 19 years. Op. Cert. 19. Most of the circumstances FDA relies on to justify its assertion of jurisdiction became known to the public and Congress during the development of the tobacco-specific statutes from 1964 to 1992.

The point of this analysis is not, as suggested in the dissent below, that, by leaving tobacco products on the market, FDA has failed to exercise its jurisdiction properly. Rather, as the panel majority recognized, the point is that *any* exercise of such jurisdiction, other than a ban, would be contrary to the operative provisions of the FDCA. Since even FDA acknowledges that a ban would be unacceptable, 61 Fed. Reg. 44,413, the only proper conclusion is that the FDCA does not apply to tobacco products. *See, e.g., United States v. X-Citement Video, Inc.*, 513 U.S. 64, 67-69 (1994); *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 510-11 (1989).[23]

The Government now argues, for the first time, that, if FDA jurisdiction requires a ban, that result should be viewed with equanimity (even though no one supports a ban) because Congress can enact new legislation to

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[23] The Attorney General has concluded that FDA lacks authority to permit the continued marketing of an unsafe product. 43 Op. Att'y Gen. No. 19-20 (1979). There, FDA determined that nitrite caused cancer and so was *per se* "unsafe" under 21 U.S.C. § 348(c)(3)(A) (1976) (since repealed). The Attorney General concluded that, once FDA determined that nitrite was unsafe, it had no authority to permit its continued marketing, even during a limited phase-out. Although the standard of safety for a food additive such as nitrite was different from that for a drug or device, the Attorney General's reasoning also applies to a drug or device found unsafe.

avoid it. Pet. Br. 34-37. This surprising new position should be rejected.

First, it is never a defense for a defective statutory interpretation that Congress can remedy its defects by new legislation.

Second, a ban under the FDCA would be incompatible with "the policy of the Congress," set forth in 15 U.S.C. § 1331, and with the tobacco-specific statutes generally, see pp. 35-44, *infra*. Congress made the political decision in 1965, and has adhered to it ever since, that there is to be no federal ban.

Third, a tobacco ban would be contrary to Congress's intent in enacting the FDCA. In view of the significant place of tobacco products in American life in 1938, widespread concerns about their safety, and the then recent end of alcohol prohibition in 1933, a ban on tobacco products was not reasonably within the contemplation of the enacting Congress. By 1938, we had learned from Prohibition that a ban on a previously lawful product used recreationally for many years by many millions of people is futile and harmful. The 1938 Act's requirements that drugs be shown to be safe and that unsafe drugs and devices not be distributed, 52 Stat. 1051, 1052, precluded any understanding that the FDCA could apply to tobacco products as drugs or devices. *Cf. Sutton v. United Air Lines, Inc.*, 119 S. Ct. 2139, 2147-49 (1999).

Fourth, a ban is, indeed, unacceptable, *even to FDA*. Although the Government's brief now says a ban is tolerable, FDA endorsed and quoted the President's view that a ban "would be wrong." 61 Fed. Reg. 44,419. FDA "strongly" rejected "any claim that the rule is a prelude to or would lead to prohibition," *id.*, and went out of its way to describe some of the harms a ban would cause, *id.* at 44,413. Therefore, FDA's assertion of jurisdiction cannot be upheld on the view, vigorously rejected by FDA

but now advanced *post hoc* by counsel, that a ban is tolerable. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

Finally, petitioners' contention that a ban is acceptable would not save any of FDA's regulations. There is no showing that FDA would have interpreted the FDCA's definitions as it has if it had accepted the conclusion that the outcome of an assertion of jurisdiction, in the absence of new legislation, would be a ban instead of its regulatory program. Therefore, FDA's assertion of jurisdiction cannot be upheld on the theory that a ban is acceptable. *SEC v. Chenery Corp.*, 318 U.S. 180 (1943).[24]

C. The FDCA Provides No Standard for Ongoing Regulation of Tobacco Products.

FDA has not made the findings of therapeutic effectiveness and safety required by the FDCA to support the distribution of tobacco products as "drugs" and "devices." To the contrary, it has found them "unsafe." See p. 5, *supra*. In nevertheless permitting their continued marketing, FDA has abandoned the FDCA's standards for "drugs" and "devices," and is on its own. A proposed statutory interpretation that would create a standardless delegation should be rejected. *E.g., Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1980) (plurality opinion); *National Cable Television Ass'n v. United States*, 415 U.S. 336, 342 (1974); *see also Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989). Here, the breach of the constitutional requirement of a statutory standard would be

[24] The asserted analogy to saccharin, Pet. Br. 36-37, is inapt. FDA's proposed ban in 1977 was a routine application of the FDCA to an unusually popular product. Saccharin indisputably was within FDA's jurisdiction. It had been the subject of ongoing regulation and prior regulatory actions by FDA for nearly two decades. *See* 24 Fed. Reg. 9368 (1959); 37 Fed. Reg. 2437 (1972); 38 Fed. Reg. 13,733 (1973); 42 Fed. Reg. 1461 (1977).

more egregious than in most other cases that present a delegation problem because FDA does not even contend that Congress has ever made a focused decision to authorize it to regulate tobacco products.

If tobacco products need not be effective and safe, what statutory standard must they meet? What standard provides the "intelligible principle," *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928), that is necessary (i) to ensure that Congress has made the "important choices of social policy," *Industrial Union Dep't*, 448 U.S. at 685 (Rehnquist, J., concurring), (ii) to direct FDA's exercise of its claimed delegated authority over the regulation of tobacco products, (iii) to provide a basis for judicial review and congressional oversight, and (iv) to guide regulated parties in complying with the statute? FDA has no answer because the FDCA provides no substitute for the standards of effectiveness and safety, no standard at all for ongoing regulation of unsafe drugs and devices.

Moreover, how will FDA know whether or when to ban tobacco products? If the FDCA's standards of effectiveness and safety do not require a ban now, the FDCA provides no standard for weighing all relevant factors (which FDA recognizes include smuggling, black markets, and other matters that go well beyond public health) and deciding whether to ban them in the future. FDA's claimed discretion to ban is standardless discretion.

That FDA seeks to free itself from the requirements Congress put into the FDCA, and has embarked on an exercise of unauthorized political policy-making, is shown by the fact that FDA seeks to regulate tobacco products like no drug or device in the FDCA's history. Despite its findings as to their health effects, FDA's announced program ignores their composition, imposes no performance standards, permits continued (or even expanded) sales to adults without a prescription, and permits the introduction

of new tobacco products. FDA has not applied the FDCA's operative provisions faithfully, but has evaded them, see pp. 24-30, *supra*, so as to gain power to regulate tobacco products while avoiding an immediate ban. FDA has chosen to focus its regulations on their labeling and advertising (long regulated by the FTC [25]) and their retail display, handling, and sale (long regulated by the States [26]). FDA says it "believes that adults should continue to have the freedom to choose whether or not they will use tobacco products." 61 Fed. Reg. 44,418. But *Rutherford* held such freedom unavailable under the FDCA as to a drug not shown to be effective and safe. Moreover, even if all its regulations were fully complied with, FDA would still view every tobacco product as ineffective for therapy and unsafe for use by any person at any time (indeed, as ineffective and unsafe for each user as before). That is an absurd outcome of regulation of any "drug" or "device" under the FDCA.

II. WHEN THE FDCA IS READ WITH THE TOBACCO-SPECIFIC STATUTES, IT IS CLEAR THAT IT DOES NOT APPLY TO TOBACCO PRODUCTS.

Any possible ambiguity about whether the FDCA applies to tobacco products is removed by the statutes in

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[25] *See, e.g.*, 15 U.S.C. § 1333(c); *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *aff'g on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952). The issue whether FDA or the FTC would have authority over the advertising of the products FDA otherwise regulates was highly controversial, and substantially delayed enactment of the original FDCA. The resolution was that all such authority would be delegated to the FTC, and none to FDA. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2, 13-14, 17, 18-19, 21 (1938). Subsequently, Congress has given FDA only very limited authority over advertising. *See* 21 U.S.C. §§ 343(a)(2) (vitamins and minerals), 352(n) (prescription drugs), 352(q)(1) (restricted devices), 352(r) (same).

[26] See pp. 45-46, *infra*.

which Congress specifically addressed tobacco and health, and did not provide any role for FDA. Where two or more statutes are arguably relevant, "[c]ourts may properly take into account the later Act when asked to extend the reach of the earlier Act's vague language to the limits which, read literally, the words might permit." *NLRB v. Drivers, Chauffeurs, Helpers Local 639*, 362 U.S. 274, 291-92 (1960). Here, as to health regulation of tobacco products, the tobacco-specific statutes are not only later and more specific than the FDCA definitions on which FDA exclusively relies, but also reflect the understanding of FDA and Congress that the FDCA does not apply to tobacco products.

United States v. Fausto, 484 U.S. 439 (1988), describes the technique of interpretation most appropriate to the multi-statute aspect of this case: "This 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." *Id.* at 453. *See also, e.g., International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 569-70 (1979) (preclusion by later statute of new interpretation of earlier one); *King v. Smith*, 392 U.S. 309, 325-26 (1968).

Although the tobacco-specific statutes do not repeal any part of the FDCA or "preempt" any action by FDA, they do set forth the federal policy and regulatory program that Congress intends shall apply to tobacco and health. Therefore, they preclude any new interpretation of the FDCA that would apply it to tobacco products so as to authorize a different federal policy or program.

A. The Federal Cigarette Labeling and Advertising Act of 1965 Created a "Comprehensive" Program for Regulating Cigarette Labeling and Advertising.

In January 1964, the first Surgeon General's Report on Smoking and Health raised the question of what the federal government should do about smoking and health. U.S. Dep't of HEW, *Smoking and Health: Report of the Advisory Committee to the Surgean General of the Public Health Service* (1964). HEW Secretary Celebrezze told Congress that jurisdiction under the FDCA "might well" lead to a ban. See n. 4, *supra*. So informed, Congress did not give FDA jurisdiction, but instead enacted the FCLAA, which embodies Congress's fundamental political choice not to ban cigarettes, and establishes a policy as to smoking and health that sets the boundaries of the federal regulatory role.

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) *commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy* and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331 (Opp. Cert. App. 55a) (emphasis added). As originally enacted in 1965, section 1331(1) read: "the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes." 79 Stat. 282 (Op. Cert. App. 1a).

Clause (B) of subsection (2) states a policy against "diverse, nonuniform, and confusing" labeling and advertising regulations. Contrary to that policy, FDA's as-

sertion of jurisdiction imposes on tobacco products the FDCA's labeling provisions for drugs and devices generally, 21 U.S.C. § 352, 21 C.F.R. pts. 201, 801, and the labeling and advertising provisions of its tobacco regulations, *id.* §§ 897.24-897.34. These are in addition to the FCLAA's labeling and advertising provisions, which Congress characterized as already "comprehensive." [27]

Clause (A), which the Government ignores, states a broader policy of protecting commerce and the national economy. This policy is not limited to—or satisfied by—mere avoidance of regulations covered by clause (B). When read together with the other provisions relating to tobacco and health in the FCLAA and the other tobacco-specific statutes, it clearly expresses a congressional intent that there be no ban on national commerce in cigarettes whose labels and advertisements include the warnings prescribed in the FCLAA (*i.e.*, no federal ban).[28]

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[27] A contemporaneous definition of "comprehensive" is: "covering completely: inclusive." *Webster's Seventh New Collegiate Dictionary* 170-71 (1965). Congress's characterization of its program as "comprehensive" is not an empirical description. It is a statement of intent, part of a "Declaration of Policy," 15 U.S.C. § 1331.

The reliance on *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), at Pet. Br. 45 is misplaced. By its "fairness doctrine" the FCC sought to protect balanced public discourse, not public health. The challenged FCC ruling did not regulate cigarettes or their manufacturing, labeling, or advertising. The court held only that the FCLAA did not preclude the FCC from requiring that broadcasters who air cigarette advertisements also air anti-smoking messages. *Id.* at 1089. That is sharply different from approving FDA's assertion of jurisdiction for the purpose of imposing, not "other types of regulation," but regulation of what the *Banzhaf* court identified as the specific focus of the FCLAA: "cigarette labeling and advertising," *id.*

[28] The contention at Pet. Br. 45 that the "FCLAA does not limit the authority of FDA to ban the sale of tobacco products, any more than it limits the authority of a State to do so (as indeed all States have done with respect to sales to minors . . .)" is mistaken. First, a statute stating "the policy of the Congress" clearly binds all federal agencies with respect to all matters within its scope. Second, application of the FCLAA to the States is not at issue here. Third, State age-restrictions (which are not bans) are not affected by § 1331 (which is not a clear statement preempting them); those existing in 1965 remained valid, and the compatibility of such restrictions with § 1331 is confirmed by the ADAMHA Amendments, discussed at pp. 43-44, 46, *infra*.

B. The Tobacco-Specific Statutes Specify How Congress Intends Tobacco Products To Be Regulated with Respect to Health and Related Matters.

Since 1965, Congress has adjusted and expanded its tobacco-specific program to respond to, *inter alia*, the very concerns FDA says are the bases for its late entry into this field. Today, that program includes the following elements:

Health, Warnings, and Adult Autonomy: Rotating health warnings (four for cigarettes, three for smokeless tobacco) are required on packages and in advertisements; the warning program is administered by the FTC, 15 U.S.C. §§ 1333(c), 4402(a)-(d). Manufacturers must disclose to HHS annual lists of ingredients in tobacco products, and HHS is required to report to Congress on any perceived health effects of the ingredients. *Id.* §§ 1335a, 4403. Federal involvement in smoking-related research, education, and liaison with States and private agencies is coordinated by the Interagency Committee on Smoking and Health, whose designated members do not include FDA. *Id.* § 1341(b).

Advertising: Tobacco product advertising is banned on television, radio, and other electronic media subject to FCC regulation. *Id.* §§ 1335, 4402(f). Permitted advertising is regulated by the FTC. *Id.* §§ 45, 1336.

Addiction: HHS is required to report to Congress on "current research findings . . . on . . . the addictive property of tobacco" and to recommend any needed action. 42 U.S.C. § 290aa-2(b)(2)-(3).

Underage Access: Receipt of full federal substance-abuse block grants by the States is conditioned on their adoption and effective enforcement of a minimum age of 18 to purchase tobacco products. *Id.* § 300x-26.

Reports to Congress. Many provisions require reports to Congress for consideration and possible action.[29]

The tobacco-specific statutes, in response to diverse interests, state Congress's policy and constitute its program for how and by whom tobacco products are to be regulated. The care Congress has shown in providing in these statutes for health warnings, advertising restrictions, ingredient disclosure to HHS, incentives for States to prevent underage access, and continuing reports to Congress on all aspects of tobacco and health would make no sense if the FDCA applied to tobacco products. These statutes preclude FDA jurisdiction, which clashes with their policy and detailed program in many ways.[30]

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29 HHS reports to Congress periodically on the health effects of smoking, 15 U.S.C. § 1341(a), (c); current information about the health consequences of smoking, *id.* at § 1337(a); smokeless tobacco, *id.* at § 4407; perceived health effects of ingredients added to tobacco in cigarettes, *id.* at § 1335a; and the "addictive property of tobacco," 42 U.S.C. § 290aa-2(b)(2). The FTC reports to Congress annually on cigarette advertising, 15 U.S.C. § 1337(b). The Interagency Committee on Smoking and Health makes biennial reports to Congress on activities to inform the public of smoking risks. *Id* at § 1341(b), (c). Most of these reports are required to include any recommendations for legislation.

30 The preclusive effect of the tobacco-specific statutes is not limited by 15 U.S.C. §§ 1334, 4406. Nor is our argument based on preemption. Rather, under the cases cited at p. 36, *supra*, we rely on preclusion of a particular statutory interpretation. Moreover, even as to preemption of State action, under *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992), and *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995), the effect of an express preemption provision depends on "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business,

First, "Congress has clearly enunciated its policy on cigarettes in [section 1331] . . . This act . . . demonstrates that the regulation of cigarettes is to be the domain of Congress." *1972 Hearings* 242 (testimony of FDA Comm'r Edwards). Congress has specified regulatory requirements and prohibitions in statutory text at a level of detail typical of regulations. It has not delegated to any federal agency (apart from the FTC with respect to the warning program) any regulatory authority over tobacco products in relation to health, advertising, addiction, or underage access. In accordance with its retention of regulatory authority, Congress repeatedly has required agencies to report any new information that might warrant a change in federal tobacco policy, so that Congress can decide what to do. Fairly read, the statutes incorporate the precedent of 1964: when the Surgeon General's Report appeared, HEW did not act unilaterally, but presented recommendations to Congress.

Second, these detailed tobacco-specific statutes specify how and by whom the labeling and advertising of tobacco products are to be regulated with respect to health. The FCLAA is, after all, the "Federal Cigarette *Labeling* and *Advertising* Act," and section 1331 expressly refers to "a *comprehensive* Federal program to deal with cigarette *labeling* and *advertising* with respect to . . . smoking and health" (emphasis added). The title of the smokeless

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consumers, and the law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996). Thus, preemption of State action beyond the scope of an express provision is permissible. *See, e.g., Boggs v. Boggs*, 520 U.S. 833 (1997). A similar analysis applies to preclusion of federal agency action. Here, the FCLAA's preclusive effect on federal agencies should effectuate the policy stated in § 1331, with which FDA jurisdiction is incompatible. Finally, the special sensitivity as to implied *preemption* reflected in *Cipollone* derives from the constitutionally-protected role of the States in the federal system. *Medtronic*, 518 U.S. at 485. No such sensitivity applies to statutory *preclusion* of an assertion of authority by a federal agency.

tobacco act—Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30 (1986)—expresses congressional intent that it be treated as "comprehensive" with respect to the matters it addresses. Only the FTC and the Justice Department ("DOJ") may administer and enforce these statutes. *See* 15 U.S.C. §§ 1333(c), 4404, 4405 (FTC jurisdiction), 1338-39, 4404(a)(2), 4405 (DOJ enforcement authority). Yet, FDA's claim of jurisdiction would make *it* the lead agency in regulating tobacco product labeling and advertising.

Third, Congress's policy of protecting the national economy while informing consumers of the risks from tobacco use, 15 U.S.C. § 1331, is incompatible with the application of the FDCA to tobacco products. In the regulation of drugs and devices, FDA is not permitted even to consider "commerce and the national economy," and so cannot implement the congressional policy stated, and the complex balance of interests reflected, in section 1331(2). Thus, in regulating cigarettes, FDA must disregard the very policy Congress declared for health-regulation of cigarettes. *Cf. United States v. Hutcheson*, 312 U.S. 219, 233-36 (1941) (policy statement in labor statute precludes proposed interpretation of antitrust statute as applied to union conduct).

Fourth, FDA's claim of jurisdiction also clashes with 15 U.S.C. §§ 1334(a), 4406(a). Even FDA agrees that they bar it from requiring on tobacco product packages any "statement relating to [smoking or use of smokeless tobacco products] and health" other than the ones prescribed by Congress. 61 Fed. Reg. 44,544-45. Yet, regulation of product labels to protect health is critical to the FDCA. *See* 21 U.S.C. § 352; 21 C.F.R. pts. 201, 801. If the FDCA applies to tobacco products, it is

anomalous that FDA cannot exercise as to them that core authority.[31]

Fifth, FDA's designation of tobacco products as "drugs" and "devices" would also make irrelevant 15 U.S.C. §§ 1335a, 4403, which specify procedures and confidentiality for carefully limited disclosures to HHS of information about ingredients in tobacco products. Under the FDCA, much broader disclosures of ingredients would be required, including disclosures to the public, without the special protections in sections 1335a and 4403. *See* 21 U.S.C. §§ 352(e)(1)(A)(ii)-(iii), 355(b)(1)(B)-(C), 360(k), 360e(c)(1)(B); 21 C.F.R. §§ 314.50(d)(1)(ii)(a), 807.92(a)(4), 814.20(b)(4)(ii). FDA could also obtain ingredient information by inspections under 21 U.S.C. § 374(a)(1).

Sixth, FDA's approach to reducing underage use of tobacco products disregards the limits Congress observed in 42 U.S.C. § 300x-26 (the "ADAMHA Amendments").

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[31] To avoid §§ 1334(a) and 4406(a), FDA contends disingenuously that the statement it would require on tobacco products ("Nicotine-Delivery Device for Persons 18 or Older"), 21 C.F.R. § 897.25, does not relate to tobacco and health. *See* 61 Fed. Reg. 44,544. Yet, protecting minors from nicotine addiction is the asserted basis for all of FDA's tobacco regulations. *See id.* at 44,399. The manifest purpose of the statement is to convey to consumers that tobacco products deliver what FDA has found to be an addictive drug, and to warn against what FDA calls a "pediatric disease," *id.* at 45,238. Because FDA does not administer the FCLAA or the CSTHEA, its interpretation of those statutes is not entitled to deference. *See Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990).

The district court erred in holding that FDA's statement is not the type of "cautionary statement[]" required by § 1333 and covered by § 1334(a) because it "merely provides basic information to those coming into contact with the product." Pet. App. 95a-97a. FDA's statement is indistinguishable in character from the "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide." 15 U.S.C. § 1333(a). Both provide factual information relating to a risk.

That statute focuses on restricting sales to minors, whereas FDA also imposes restrictions on advertising—a type of regulation that raises troubling issues of public policy and constitutionality, and that Congress addressed differently in 15 U.S.C. §§ 1335, 4402(f). (Additional conflicts between FDA jurisdiction and the ADAMHA Amendments are discussed at pp. 46-47, *infra.*)

In sum, when all the relevant statutes are read together, the only way they can all make sense is for the FDCA not to cover tobacco products. The tobacco-specific statutes do not merely "address narrow issues," Pet. Br. 16. They are "the later statute[s], the more specific" and "represent[] Congress' detailed judgment," *United States v. Estate of Romani,* 523 U.S. 517, 532 (1998), as to how the federal government shall address tobacco and health. "Absent a text that clearly requires it, [the Court] ought not expand . . . one piece of the regulatory puzzle so dramatically as to make many other pieces misfits." *United States v. Sun-Diamond Growers,* 119 S. Ct. 1402, 1410 (1999).

III. THE CLEAR STATEMENT RULE PROTECTING THE ROLE OF THE STATES IN THE FEDERAL SYSTEM PRECLUDES APPLICATION OF THE FDCA TO TOBACCO PRODUCTS.

"'[I]t is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides'" "the usual constitutional balance of federal and state powers." *Gregory v. Ashcroft,* 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp. v. Scanlon,* 473 U.S. 234, 243 (1985)). *See also, e.g., BFP v. Resolution Trust Corp.,* 511 U.S. 531, 544 (1994).

Here, without a clear authorizing statement by Congress, FDA would upset that balance with respect to regulation of local retail display, handling, and sale of tobacco products. FDA jurisdiction would unavoidably (i) inject federal regulation into an area of local activity

historically regulated by the States exclusively, (ii) preempt contrary State approaches unless FDA, in its discretion, grants waivers, and (iii) create potentially massive new federal penal jurisdiction over improper local sales of tobacco products.

Regulating tobacco retailers and restricting underage access to tobacco products are traditional State functions.

> For a number of years there has been a well-settled opinion that the use of cigarettes especially by persons of immature years was harmful, and the courts have recognized that they were deleterious in their effects. Their sale and use have been regulated and prohibited by legislative bodies, and these measures have been upheld as a proper exercise of the police power.

State v. Nossaman, 107 Kan. 715, 717, 193 P. 347, 348 (1920). *See also, e.g., Gundling v. City of Chicago,* 177 U.S. 183 (1900) (licensure of cigarette retailers); *Illinois Cigarette Serv. Co. v. City of Chicago,* 89 F.2d 610 (7th Cir. 1937) (ban on cigarette vending machines; ordinance also banned sales to minors and sales within 300 feet of schools); *Bernstein v. City of Marshalltown,* 215 Iowa 1168, 248 N.W. 26 (1933) (permit to sell cigarettes); *Nash-Finch Co. v. Beal,* 124 Neb. 835, 248 N.W. 374 (1933) (licensure system to enforce ban on sale of cigarettes to minors); *Macke v. Commonwealth,* 156 Va. 1015, 159 S.E. 148 (1931) (licensure of tobacco retailers; ban on cigarette vending machines); *Brennan v. City of Seattle,* 151 Wash. 665, 276 P. 886 (1929) (ban on cigarette vending machines); *State v. Olson,* 26 N.D. 304, 144 N.W. 661 (1913) (ban on snuff); authorities cited at Opp. Cert. 3.[32] Every State prohibits the sale of to-

[32] Without considering the relevant historical evidence, FDA flatly denied "that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions." 61 Fed. Reg. 44,429.

bacco products to persons below age 18.[33] FDA's regulations would intrude into this zone, *see* 21 C.F.R. §§ 897.14, 897.16(c), and wrest the lead policy-making and enforcement role from the States.

Moreover, under 21 U.S.C. § 360k(a), all State laws that address the retail display, handling, or sale of tobacco products, and that differ from FDA's tobacco regulations, would be preempted.[34] An intent to preempt a traditional police power of the States must be "clear and manifest." *E.g., Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 146 (1963); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Although such an intent is expressed in section 360k as to genuine devices, it is absent as to tobacco products; and, indeed, the ADAMHA Amendments clearly express an intent *not* to preempt. The strategy of the Amendments is twofold: (1) the initiative for restricting underage access to tobacco remains with the States, exercising their traditional police power, and (2) financial incentives are provided to the States to increase the effectiveness of their restrictions. The limited federal role leaves maximum flexibility to the States. *See* 61 Fed. Reg. 1492, 1495 (1996) (preamble to HHS's implementing regulations).

FDA's uniform national program to deal with underage access, however, would divest the States of the very flexibility Congress intended to preserve. It would substitute federal for State initiative: the States would merely implement FDA's program (under contracts with FDA) rather than initiate and implement their own programs. To take any additional steps different from FDA's, they would need FDA's permission.

Finally, under FDA's regulations, every improper sale or failure to verify a purchaser's age in a local convenience store or gas station would be a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. § 331(b) & (k), punishable by federal prosecution, *id.*, § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(f).[35] But "Congress has traditionally been reluctant to define as a federal crime conduct readily denounced as criminal by the States. . . . [W]e will not be quick to assume that Congress has meant to effect a significant change in the sensitive relation between federal and state criminal jurisdiction." *United States v. Bass,* 404 U.S. 336, 349-50 (1971) (rejecting, in absence of clear statement of congressional intent, "the broad construction urged by the Government [, which] renders traditionally local criminal conduct a matter for federal enforcement"). That some State Attorneys General welcome this transfer of responsibility from themselves to FDA does not make it consistent with congressional intent.

IV. FDA'S ASSERTION OF JURISDICTION IS NOT ENTITLED TO DEFERENCE.

The Government's last refuge is a plea for deference under *Chevron U.S.A., Inc. v. NRDC,* 467 U.S. 837 (1984). No such deference is warranted. Congress's intent is clear: tobacco products are to be regulated under

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33 The Substance Abuse and Mental Health Services Administration ("SAMHSA") recently reported to Congress that "[a]ll States are in material compliance with the [ADAMHA Amendments]. They have laws prohibiting the sale or distribution of tobacco to minors, and they are enforcing those laws. . . . All States expect to achieve the goal of a maximum sales-to-minors rate of 20 percent by Federal Fiscal Year (FFY) 2003." SAMHSA, *Synar Regulation Implementation FY 97 State Compliance* 1 (undated).

34 On petition by a State, FDA may, in its discretion, waive preemption. 21 U.S.C. § 360k(b). The preemptive language of § 360k applies to FDA's tobacco regulations only because FDA has chosen to regulate tobacco products as devices. There is no counterpart to § 360k as to drugs.

35 Such violations also could lead to federal court proceedings for seizure of affected products under 21 U.S.C. § 334, and for injunctions under *id.* § 332.

the tobacco-specific statutes, not the FDCA. Moreover, this case deviates from *Chevron* in critical respects.

The issue of statutory interpretation here involves multiple statutes. Only the FDCA is administered by FDA. The tobacco-specific statutes are not, they are more recent, and they address the specific subject at hand. As to them, FDA has no delegated interpretive authority. *See Adams Fruit*, 494 U.S. at 649-50.

The issue does not involve routine interpretation in a field previously regulated. FDA seeks not to fill a gap, but to annex a continent. It is not "defining a term in a way that is reasonable in light of the legislature's revealed design," *NationsBank, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995), but is disregarding Congress's revealed design for regulation of tobacco products and health. As FDA has acknowledged, "the regulation of cigarettes raises societal issues of great complexity and magnitude. It is vital in this context that Congress provide clear direction to the agency." Letter from Comm'r David A. Kessler to Scott Ballin, Esq., 3 (Feb. 25, 1994), *reprinted in Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong. 25, 27 (1994). Despite Congress's decisions in enacting the tobacco-specific statutes, FDA seeks to decide anew *by whom* and *how* tobacco products shall be regulated, and *whether* they may continue to be sold at all. As the court below observed, "this type of decision involving countervailing national policy concerns is just the type of decision for Congress." Pet. App. 22a. Congress did not consider these concerns or make this type of decision as to tobacco products in 1938, and FDA is not entitled to deference to an agency decision masquerading as one by the 1938 Congress. *See generally, e.g., BATF v. FLRA*, 464 U.S. 89, 97 (1983) (no deference to agency's "unauthorized assumption . . . of major

policy decisions properly made by Congress"); *United States v. Haggar Apparel Co.*, 119 S. Ct. 1392, 1400 (1999) (Congress makes "general policy," agency implements it); Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 370-71 (1986) (unlikely that Congress would leave question of great importance and delicacy to agency to decide).

Contrary to Pet. Br. 16, FDA is not entitled to deference on the theory that the question presented is whether the FDCA, which it administers, applies to a particular category of products. The possibility of *Chevron* deference would not arise until *after* the Court at step 1 had determined whether the FDCA or any other statute clearly answers that question. The Government's approach would simply dispense with step 1.

Finally, although "the mere fact that an agency interpretation contradicts a prior agency position is not fatal," *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996), here FDA's new interpretation is contrary to its contemporaneous interpretation, which, for more than half a century, FDA consistently adhered to in administering the FDCA and presented to Congress as critical background to further legislation. That original interpretation has also been upheld by the courts.[36] Consequently, even if *Chevron* applied, FDA's current interpretation should receive little, if any, deference. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993); *see also Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 778 (1999).

The Court, therefore, should address the issue presented outside the *Chevron* framework, and adopt "the better reading of the statute[s] under ordinary principles of con-

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[36] *See ASH v. Harris, supra*; *FTC v. Liggett & Myers Tobacco Co., supra* (interpreting language in Federal Trade Commission Act identical to that in FDCA).

struction." *California Dental Ass'n v. FTC*, 119 S. Ct. 1604, 1610 (1999). Even if *Chevron* applied, however, we have shown that the reading of the FDCA as not reaching tobacco products is not merely the "better" one, but also the one required by Congress's clear intent in both the FDCA and the tobacco-specific statutes.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

RICHARD M. COOPER
Counsel of Record
STEVEN M. UMIN
WILLIAMS & CONNOLLY
725 12th Street, N.W.
Washington, DC 20005
(202) 434-5000
Attorneys for Respondent
R.J. Reynolds Tobacco Company