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 PHILIP MORRIS INCORPORATED & LORILLARD TOBACCO COMPANY

Filed September 10, 1999

QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate tobacco products even though Congress did not intend for FDA to regulate tobacco products when it enacted the Federal Food, Drug, and Cosmetic Act, and Congress—having been repeatedly advised by FDA that it lacks jurisdiction—enacted a series of tobacco-specific statutes addressing tobacco and health, which give no role to FDA and are inconsistent with FDA's assertion of jurisdiction?

RULE 29.6 LISTING

Philip Morris Incorporated

The parent company of Philip Morris Incorporated is Philip Morris Companies, Inc. Philip Morris Incorporated has no nonwholly owned subsidiaries.

Lorillard Tobacco Company

The parent companies of Lorillard Tobacco Company are Lorillard, Inc., and Loews Corporation. Lorillard Tobacco Company has no nonwholly owned subsidiaries.

PARTIES TO THE PROCEEDINGS

The petitioners are: Food and Drug Administration, and Jane E. Henney, Commissioner of Food and Drugs.

The respondents are: Brown and Williamson Tobacco Corporation; Lorillard Tobacco Company; Philip Morris Incorporated; R.J. Reynolds Tobacco Company; Coyne Beahm, Incorporated; National Association of Convenience Stores; ACME Retail, Incorporated; United States Tobacco Company, LP; Conwood Company, LP; National Tobacco Company, LP; Pinkerton Tobacco Company, LP; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated; The American Advertising Federation; American Association of Advertising Agencies; Association of National Advertisers, Incorporated; Magazine Publishers of America; Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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v.

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

BRIEF FOR RESPONDENTS PHILIP MORRIS INCORPORATED & LORILLARD TOBACCO COMPANY

OPINIONS BELOW

The opinions below are identified in the Brief for the Government ("Pet. Br."), and printed in the Appendix to the Petition for Writ of Certiorari ("Pet. App.").

JURISDICTIONAL STATEMENT

This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This case involves the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the Federal Cigarette Labeling and Advertising Act ("FCLAA"), 15 U.S.C. § 1331 *et seq.*, the Comprehensive Smokeless Tobacco Health Education Act

("CSTHEA"), 15 U.S.C. § 4401 *et seq.*, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Amendments"), 42 U.S.C. § 300x-26. These statutes are set forth in the Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App.").

INTRODUCTION

In 1996, FDA declared that it has jurisdiction to regulate tobacco products under the FDCA, and issued regulations governing their labeling, advertising, and retail sale. Respondents challenged FDA's assertion of jurisdiction and its regulations. The district court held that the FDCA authorizes FDA to assert jurisdiction but invalidated FDA's advertising regulations. *See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397-1400 (M.D.N.C. 1997) (Pet. App. 76a). The United States Court of Appeals for the Fourth Circuit reversed on the threshold jurisdictional issue. It held that Congress never intended the FDCA to grant FDA jurisdiction over tobacco products as customarily marketed. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998) (Pet. App. 1a).

The question at issue is whether Congress granted FDA the authority to regulate tobacco products as customarily marketed.[1] The Government argues that this question is answered exclusively by the definition section of the FDCA. The court of appeals expressly disagreed, correctly concluding that this case can be decided only by looking at the statute as a whole and at Congress' historical treatment of tobacco and health. *Brown & Williamson*, Pet. App. at 14a. The Government ignores or trivializes that history. However, that "historical background . . . is essential to a proper interpretation of the Act's present text." *Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 775 (1999). It shows unequivocally that Congress never intended to delegate to FDA the authority to regulate tobacco products, but chose instead to regulate those products itself through a series of tobacco-specific statutes.

[1] The phrase "as customarily marketed" refers to tobacco products with claims of "smoking pleasure" and similar claims, as opposed to health-benefit claims. *See e.g.* Letter from Acting FDA Comm'r Novitch for FDA Comm'r Goyan to Banzhaf, Jt. App. at 54. ("Novitch Letter") (Nov. 25, 1980). All references herein to "tobacco products" are to such products as customarily marketed.

SUMMARY OF ARGUMENT

Not satisfied with Congress' regulation of tobacco products, FDA set out in 1996 to create a new national tobacco policy. It announced that tobacco products fall within the FDCA's definitions of "drug" and "device" based on its finding that such products are "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C) and (h)(3).[2] FDA took this action even though:

(1) When Congress enacted the FDCA in 1938, it did not intend for FDA to regulate tobacco products—such products are not among the several product categories to which the FDCA expressly applies, and Congress did not discuss or debate applying the FDCA to tobacco products;

(2) FDA's contemporaneous construction of the FDCA was that it lacked authority over tobacco products;

(3) Immediately after the 1964 Surgeon General's Report on smoking, FDA once again told Congress that it lacked authority over tobacco products, and advised Con-

[2] The brief filed by R.J. Reynolds Tobacco Company shows that the FDCA as a whole cannot be read to apply to tobacco products. The briefs filed by Brown and Williamson Tobacco Corporation and United States Tobacco Company, *et al.*, demonstrate why tobacco products do not meet these definitions.

gress that granting FDA such authority would likely result in a ban;

(4) Given this understanding, Congress *rejected* proposals to give FDA such authority and instead enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), which requires congressionally-authored warnings on cigarette packages and reserves to Congress authority to address smoking and health;

(5) After enactment of the FCLAA, FDA expressed its understanding that Congress had reserved to itself the authority to regulate health issues regarding tobacco products, an understanding that Congress itself confirmed by exempting such products from the authority of other federal health agencies that had not, as had FDA, already disavowed jurisdiction over those products;

(6) As new information respecting tobacco and health was presented to Congress, it adopted additional legislation specifically regulating the labeling and advertising of tobacco products, and creating incentives for the States to control their retail sale—without providing any role for FDA;

(7) While acting upon tobacco-specific legislation and at other times, Congress considered, but never enacted, legislation to grant FDA authority over tobacco products.

In the face of this history, FDA nonetheless asks this Court to hold that, in 1938, Congress silently—indeed, unwittingly—authorized FDA to regulate and ban tobacco products. This position is contrary to FDA's disavowals of any authority over tobacco products, which it repeatedly communicated to Congress and which were a predicate for Congress' enactment of tobacco-specific statutes.

In these enactments, Congress expressly *reserved to itself* the power to regulate health issues regarding tobacco

products—either directly or by carefully delineating limited, non-policymaking roles for certain federal agencies—but provided no role for FDA. In legislating national tobacco policy, Congress has addressed the same aspects of tobacco-product labeling, advertising and sale that FDA now seeks to regulate by administrative fiat. FDA's assertion of jurisdiction neither fills a gap in the FDCA nor comports with the purpose or operative provisions of that Act. Rather, "[i]t is effectively the introduction of a whole new regime of regulation . . . which . . . is not the one that Congress established." *MCI v. AT&T*, 512 U.S. 218, 234 (1994).

Simply put, FDA's assertion of jurisdiction cannot be reconciled with Congress' policy as embodied in its tobacco-specific legislation. Congress and FDA itself repeatedly have recognized that a principled application of the "drug" or "device" provisions of the FDCA to tobacco products would result in their prohibition because tobacco products could not meet the Act's safety requirement. But a national ban on tobacco products—like many other aspects of FDA's assertion of jurisdiction—would directly and unavoidably conflict with the tobacco-specific legislation enacted by Congress.

The relevant history and these irreconcilable conflicts establish that Congress never intended that tobacco products be subject to the FDCA. In disregarding that intent, FDA has usurped Congress' legislative powers.

ARGUMENT

I. CONGRESS HAS NEVER GIVEN FDA AUTHORITY OVER TOBACCO PRODUCTS, BUT INSTEAD HAS CHOSEN TO REGULATE TOBACCO PRODUCTS IN WAYS THAT ARE FUNDAMENTALLY INCOMPATIBLE WITH FDA JURISDICTION.

FDA defends its assertion of jurisdiction with the remarkable claim that Congress always intended that FDA

could regulate tobacco products under the FDCA. *See* 61 Fed. Reg. 44,396, 45,253 (1996). Yet this claim makes pointless Congress' consideration for many years of who should regulate tobacco products and how. In fact, FDA repeatedly told Congress that the FDCA does not extend to tobacco products. Given this understanding, no fewer than thirty-six bills have been introduced in Congress to grant FDA jurisdiction over tobacco products, reflecting congressional understanding that new legislation would be necessary to confer such jurisdiction. But Congress never enacted such legislation.

Rather, after much discussion, Congress created its *own* legislative program specifically addressing the issue of tobacco and health. This legislation responds to the very concerns FDA relies on to justify its assertion of jurisdiction—youth access, the influence of tobacco advertising, and the pharmacological effects of tobacco products on the body, including nicotine "addiction."

As FDA and the Justice Department acknowledged, "[t]he participants in these [congressional] discussions [on tobacco] . . . would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them." Brief for Gov't Appellee (FDA) (*"FDA/DOJ Brief"*)[3] at 40, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

A. Federal Food and Drug Laws Were Never Intended to Cover Tobacco Products as Customarily Marketed.

The federal food and drug laws—and the view that they do *not* apply to tobacco products—go back nearly 90 years. In 1906, Congress passed the Pure Food and

[3] Respondents have lodged with the Court a compilation of materials referenced herein, excluding judicial decisions, statutes, and regulations.

Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906). Nothing in the language or legislative history of that early legislation indicates that Congress intended it to govern tobacco products. Indeed, FDA's predecessor, the Bureau of Chemistry in the Department of Agriculture, announced that it could *not* regulate tobacco products unless they were marketed with medical claims. Bureau of Chemistry, U.S. Dep't of Agriculture, *Service & Regulatory Announcements, No. 13* (Apr. 2, 1914).

When this announcement was made, concerns about the health effects of tobacco were widespread, and scientific reports already had identified the pharmacological effects of nicotine.[4] Between 1895 and 1921, fourteen states banned cigarettes entirely; and all the others prohibited their sale to minors.[5] This Court upheld such a cigarette ban in *Austin v. Tennessee*, 179 U.S. 343, 348 (1900), observing that the "belief in [the] deleterious effects [of 'cigarettes'] . . . has become very general." *See also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992) (noting that "physicians had suspected a link between smoking and illness for centuries"). A few years later, some members of Congress proposed to amend the 1906 Act to cover tobacco products. *See* S. 1468, 71st Cong. (1929); 71 Cong. Rec. 2589 (1929). But that proposal—like every similar proposal since—was not enacted.

[4] *See, e.g.*, Henningfield & Jasinski, *Pharmacologic Basis for Nicotine Replacement, in* Nicotine Replacement: A Critical Evaluation 35-36 (Pomerleau, *et al.* eds., 1988) ("[P]harmacologic studies of the psysiologic actions of nicotine were well underway by the 19th century. By the beginning of the 20th century, there was little scientific question that nicotine was the pharmacologic mediator of many effects of tobacco sought by its users.").

[5] *See* Nuehring & Markle, *Nicotine and Norms: The Re-Emergence of a Deviant Behavior, in* 21 Social Problems 513, 515 (1974); 1899 Tex. Gen. Laws Ch. 139 § 1 (*codified at* Tex. Penal Code art. 1049 (1911)).

Nor did Congress intend to authorize FDA to regulate tobacco products when it enacted the FDCA in 1938. The FDCA identifies the four categories of products to which it applies: foods, drugs, devices, and cosmetics. Tobacco products are not among them, even though at the time of its enactment tobacco products outsold pharmaceuticals three-to-one, 37% of American adults smoked cigarettes, and tobacco excise taxes accounted for ten percent or more of federal tax revenues.[6] Moreover, the federal government recognized tobacco as a separate sector of the economy. *See, e.g.*, U.S. Dept. of Commerce, *Statistical Abstract of the United States,* 178-9 (1939). If Congress had intended the FDCA's "drug" and "device" provisions to encompass so significant a category as tobacco products, the legislative history surely would reflect it.

But there is *nothing* in the language or legislative history of the Act suggesting this intent. "If Congress intended such a result, its failure even to hint at it is spectacularly odd." *Medtronic v. Lohr,* 518 U.S. 470, 491 (1996). It is "not plausible to interpret the statutory silence as tantamount to an implicit congressional intent" that FDA regulate tobacco products. *Central Bank of Denver v. First Interstate Bank of Denver,* 511 U.S. 164, 185 (1994). Even the Government does not argue that Congress in 1938 envisioned that tobacco products were within the scope of the FDCA, and it concedes that there was "no discussion in the legislative history of the 1938 Act" respecting its potential application to tobacco products. Pet. Br.

[6] U.S. Dep't of Commerce, Bureau of the Census, *Historical Statistics of the United States: Colonial Times to 1970,* 319 (H.R. Doc. No. 93-78, 1973); U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking to Women, A Report of the Surgeon General* 23 (1980); U.S. Dep't of Commerce, Bureau of the Census, *Statistical Abstract of the United States 1938,* at 179 (Table 181) (1939).

at 22, n.4.[7] *Cf, Amoco Prod. Co. v. Southern Ute Indian Tribe,* 119 S. Ct. 1719, 1724-27 (1999) (examining the historical context of the relevant statute).

Had there been any suggestion in 1938 that the FDCA might apply to tobacco products:

> Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history . . . . "In a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change, . . . judges as well as detectives may take into consideration the fact that a watchdog did not bark in the night."

Chisom v. Roemer, 501 U.S. 380, 396, n.23 (1991). Indeed, the Senate and House Conference Committee managers *supporting* passage of the FDCA included Members from the two leading tobacco States—North Carolina and Kentucky. *See* 83 Cong. Rec. 9094 (1938).

Congress' silence cannot be attributed to a lack of legislative interest in tobacco. Since at least the turn of the century, Congress has regulated tobacco products separately from foods, drugs, devices, and cosmetics. *See, e.g.*, Pub. L. No. 57-237, §§ 1-2, 32 Stat. 714 (1902)

[7] Far from creating an "overwhelming implication" that the FDCA covers tobacco products, Pet. Br. at 19, this congressional silence at most reflects Congress' understanding that tobacco products, like other non-medical products, are subject to the FDCA only if manufacturers or vendors make therapeutic claims. *See United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes,* 178 F. Supp. 847, 848-49 (D.N.J. 1959); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes,* 113 F. Supp. 336, 337 (D.N.J. 1953). In the present case, FDA asserted jurisdiction "regardless of whether manufacturers make express claims of therapeutic value," Pet. Br. at 15, and FDA has not alleged that any of the respondents make such claims. 61 Fed. Reg. 44,396, 45,194 (1996).

(cigarette packaging); Pub. L. No. 61-5, §§ 30-35, 36 Stat. 108-11 (1909) (cigarette packaging, marketing, and sale); Pub. L. No. 73-483, §§ 1-13, 48 Stat. 1275 (1934) (cigarette production, marketing, and consumption); Pub. L. No. 74-314, §§ 2-3, 49 Stat. 731 (1935) (cigarette marketing). Congress even passed *separate* tobacco legislation in the same year it passed the FDCA. *See* Pub. L. No. 75-430, 52 Stat. 31 (1938). Thus, it is no surprise that the 1938 Congress "did not endeavor to break away from the traditional understanding," *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 119 S. Ct. 1324, 1327 (1999), that tobacco products are separate from foods, drugs, devices, and cosmetics.

FDA's original understanding that the FDCA does not cover tobacco products reflected its own extensive involvement in drafting the FDCA—preparing the initial bill, testifying on it and successor bills, and explaining to Congress how the "drug" and "device" definitions of the Act would operate.[8] In light of that involvement, in the two decades following enactment of the FDCA, FDA consistently reiterated its understanding and "repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term 'drug' absent

[8] The "original bill leading to the enactment of the [FDCA] . . . was prepared in the U.S. Dept. of Agriculture," which was the parent department of FDA (and FDA's predecessor, the Bureau of Chemistry). Dunn, *Federal Food, Drug, and Cosmetic Act*, 24 (1938). *See e.g., Food, Drugs and Cosmetics: Hearing on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong. 15-16 (1934) (remarks of FDA Chief Campbell regarding meaning of definitions); *Food, Drugs, and Cosmetics, 1934: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516-518 (1934) (same); *Food, Drugs, and Cosmetics, 1935: Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong. 55-56 (1935) (same).

health claims on behalf of the manufacturer or vendor." *FDA/DOJ* Brief at 16, 22 n.19. This history demonstrates that FDA's prior position "that cigarettes are beyond the scope of the [FDCA] absent health claims" "accords with congressional intent in drafting the statute." *Id.* at 14-15.

As the Justice Department explained:

> [C]orrespondence dating from at least as early as 1940, show that [FDA's] interpretation was in accordance with the *contemporaneous construction* of the 1938 Act by the persons charged with its administration.

Id. at 22, n.19 (emphasis added). "This contemporaneous administrative construction of the Act is persuasive evidence of the original" congressional "understanding, especially in light of the extensive role the [agency] played in drafting the statute and explaining its operation to Congress." *United States v. Board of Comm'rs*, 435 U.S. 110, 131 (1978); *see also United States v. American Trucking Ass'ns*, 310 U.S. 534, 549 (1940).

B. In the 1960s, Congress Rejected the Option of Granting FDA Authority to Regulate Tobacco Products, and Instead Enacted Its Own Regulatory Program that Provided No Role for FDA.

Congress addressed the possible health implications of tobacco products in the 1960s. Indeed, Congress was aware of the same concerns now raised by FDA to justify its assertion of jurisdiction: youth access, tobacco advertising, and the pharmacological effects of nicotine, *e.g.*, "addiction."[9] In response to such concerns, Mem-

[9] *See, e.g.*, 109 Cong. Rec. 7,455 (1963) (Rep. Udall expressing concern over reports by "leading medical authorities" of the "harmful, and in fact deadly, effects of cigarette smoking" and "the increasing tempo of advertising in all media designed to lure young people into the use of cigarettes"); 108 Cong. Rec. 10,053 (1962)

bers of Congress again expressed interest in federal regulation of tobacco products, and introduced bills to amend the FDCA to grant FDA jurisdiction over cigarettes.[10] These bills were introduced precisely because it was clear that "smoking products do not come under the protection of the FDA." 109 Cong. Rec. 10,318 (1963) (Sen. Moss). Again, however, Congress did not give FDA jurisdiction over tobacco products.

At the same time, FDA repeated its position that it could not regulate tobacco products unless they were sold with therapeutic claims. In 1963, FDA referred to "the exclusion of tobacco products from FDA's jurisdiction," and stated that: "tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA] for food, drug, device or cosmetic." Letter from FDA Bureau of Enforcement to Directors of Bureaus, Divisions and Directors of Districts (May 24, 1963) *in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92nd Cong. 240 (1972).

In 1964, the Advisory Committee to the Surgeon General on Smoking and Health issued its landmark "Report on Smoking and Health." U.S. Dep't of Health, Education and Welfare, Public Health Service, *Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964) ("1964

(Senator Neuberger noting statement of American Cancer Society official that "smoking is 'truly and in all respects an addiction,'" and that "help is needed to 'prevent new recruitment to smoking among the young'").

10 S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963). Even prior to the 1960s, bills had been introduced to amend the FDCA to grant FDA authority over cigarettes. H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957). None of these bills were enacted.

Surgeon General Report"). The publicity was enormous, and Congress' response was swift. Legislation to permit FDA to regulate tobacco products was proposed, but Congress instead chose an entirely different course—it enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA").

Hearings on the FCLAA commenced in 1964, shortly after the release of the Surgeon General's Report. Chairman Harris of the House Committee on Interstate and Foreign Commerce announced:

> The purpose of these hearings will be . . . to determine the extent of authority under existing law to deal with [the issue of tobacco and health,] and to determine whether any action of the Congress is warranted in the interest of public health.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 88th Cong. 23 (1964) ("*1964 Hearings*").[11] When asked whether the Department of Health, Education and Welfare ("HEW") (FDA's parent) "presently has authority to brand or label the packages of cigarettes or to control the advertising," Surgeon General Terry responded without qualification: "we do not have such authority in existing laws governing the Public Health Service and Food and Drug Administration." *Id.* at 56.

11 There "was no question at the time of the 1964 [Surgeon General's] Report that nicotine was the critical pharmacologic agent for tobacco." U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General*, 10 (1988); *1964 Surgeon General Report*, at 69-75 (discussing scientific research regarding pharmacological effects of nicotine, including "stimulation," "tranquilization" and "suppression of appetite").

Congress specifically considered youth smoking and advertising: "[S]ome 4,500 boys and girls between the ages of 12 and 17 take up the habit each day of the year." *1964 Hearings* at 34; *see also id.* at 16-17, 25-26, 31, 293-94.

Even those Members who believed that FDA should address smoking and health understood that the existing FDCA did not give FDA such authority. Instead, they introduced legislation to *grant* it such authority. *See id.* at 4-7.

However, HEW Secretary Celebrezze opposed those bills on the ground that FDA jurisdiction over cigarettes would likely result in their ban:

> In light of the Advisory Committee's report on smoking and health, this provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th Amendment, would be acceptable to the American people.

Id. at 18. When Chairman Harris later observed that the one remaining bill to give FDA jurisdiction would lead to a tobacco ban, Rep. Udall, its sponsor, said he did not intend that result, and abandoned his bill. *Cigarette Labeling and Advertising—1965: Hearing on H.R. 2248 Before the House Comm. on Interstate and Foreign Commerce,* 89th Cong. 29 (1965) ("*1965 Hearings*").

Shortly thereafter, FDA again testified that it "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Id.* at 193 (statement of FDA Deputy Comm'r Rankin). Although another bill was introduced to give FDA jurisdiction over cigarettes, H.R. 2248, 89th Cong. (1965), it did not pass. Thus, as it debated how best to respond to the Surgeon General's Report, Congress actively considered—then squarely rejected—any FDA involvement.

Instead, Congress enacted the FCLAA and made clear that it was retaining for itself sole authority to balance the important competing societal interests and to determine the appropriate federal regulation of cigarettes:

> *The determination of appropriate remedial action in this area . . . is a responsibility which should be exercised by the Congress* after considering all facets of the problem. The problem has broad implications in the field of public health and health research, and involves potentially far-reaching consequences for a number of sectors of our economy.

H.R. Rep. No. 89-449, 3 (1965) (emphasis added). Indeed, Congress took the step of announcing *in the statutory text* its overriding policy and purpose

> *to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health,* whereby . . . the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect . . . and . . . commerce and the national economy may be . . . protected to the maximum extent consistent with this declared policy . . . .

Pub. L. No. 88-92, § 2, 79 Stat. 282 (1965), *codified at* 15 U.S.C. § 1331 (emphasis added).

Congress' intent to withhold jurisdiction from FDA is further confirmed by the outcome of a broader debate over whether *any* administrative agency should be given any policymaking authority over smoking and health. Arguing for administrative flexibility, the FTC Chairman, the HEW Secretary, and the Surgeon General presented options for delegating new regulatory authority over tobacco to federal agencies. *1965 Hearings* at 38, 78-79. Several Members and witnesses expressed support for that view; others were opposed. *See e.g., id.* at 168-70, 240, 445-46; *Cigarette Labeling and Advertising: Hearings Before the Senate Commerce Comm. on S. 559 and S. 547,* 89th Cong. at 405, 636, 692 (1965); 110 Cong. Rec. 15000-01 (1964).

As Rep. Rogers of Texas, author of the bill that passed the House, 111 Cong. Rec. 13900 (1965), and a Conference Committee member, *id.* at 13913, put the issue:

> [T]he main issue here is who is going to put the reins on the situation involving an industry that is very important in this country at the present time from an economic standpoint, if reins are needed.
>
> * * * *
>
> [M]y bill was introduced for the purpose of laying down a situation that the Congress of this country, made up of the duly elected representatives under the Constitution, are still the ones who are supposed to set policy in this field.

1965 Hearings at 218.

Chairman Harris, manager of the FCLAA in the House, also addressed the "who" question: "I think it is a job for the Congress to do and not an executive agency or a regulatory agency through its own action. . . ." 111 Cong. Rec. 13900 (1965).

Sen. Hartke observed that "much of the time during the hearings" was devoted to considering whether the FTC

> *or any other federal administrative agency* created by Congress should be permitted, [by] expanding authority delegated to it by Congress . . . to *usurp the authority of the Congress* in an area of national importance.

111 Cong. Rec. 13431 (1965) (emphasis added).

The FCLAA thus reflects Congress' decision to reserve to itself the decision-making responsibility for setting national policy respecting tobacco and health. Exclusion of FDA from regulation of cigarettes was indispensable to Congress' program because, as HEW Secretary Celebrezze had told Congress in 1964, FDA jurisdiction probably would lead to a ban. Given that understanding, the FCLAA "clearly bar[s] any expansion," *Northwest Bank Worthington v. Ahlers*, 485 U.S. 197, 206 (1988), of the FDCA to encompass tobacco products.

The policy established in the FCLAA—that cigarettes may be advertised and sold to adults but that smokers must be informed of possible health hazards through warnings drafted by Congress—reflects Congress' balancing of health, consumer liberty, and "commerce and the national economy." FDA's assertion of jurisdiction—which under the FDCA would lead to a ban—would nullify that statutory scheme. Apart from a ban, FDA's authority over product labeling under the FDCA is inconsistent with the FCLAA labeling provisions. *Cf. Int'l Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 567-70 (1979) (enactment of ERISA confirms SEC's lack of authority to reverse its prior understanding and expand its jurisdiction).

C. During the 1970s, FDA Reaffirmed that It Lacked Authority to Regulate Tobacco Products, and Congress Continued to Develop Its Own Regulatory Program, and to Exclude Agency Policymaking, on Tobacco and Health.

In 1969, Congress revisited the FCLAA and again focused on the issues of youth access, tobacco advertising, and "addiction." For example, one Member advised his colleagues, "The statistics indicate that 4,000 children every day are newly hooked on smoking." *Cigarette Labeling and Advertising—1969 (Part 1): Hearings on H.R. 643, H.R. 1237, H.R. 3055, H.R. 6543 Before the House Comm. on Interstate and Foreign Comerce*, 91st Cong. 47 (1969) ("*1969 Hearings*"). John Banzhaf, a founder of Action on Smoking and Health ("ASH"), testified that there was "substantial medical evidence" that "smoking to many people can be as addicting in the physical and medical sense as heroin . . . ." *Id.* at 288.

Congress responded by amending the FCLAA to prohibit broadcast advertisements for tobacco products and by strengthening the warning on cigarette packs. Pub. L. No. 91-222, § 6, 84 Stat. 87, 89 (1970).[12] Congress also

[12] The legislative history of the 1970 Amendments contains numerous comments on the need to discourage underage smoking and

reaffirmed that federal tobacco policy was a matter for Congress—not administrative agencies. The House Report states:

> The regulations [proposed by the FTC and FCC would] . . . cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.
>
> * * * *
>
> Therefore, the committee feels that it is incumbent on the Congress to act on the reported legislation in order to prevent [administrative] intrusion . . . into basic areas of policymaking *which it has reserved to itself.*"

H.R. Rep. No. 91-289, 5 (1969) (emphasis added). Thus, Congress disparaged the "assumption by these agencies of policymaking with respect to a subject matter on which Congress has made policy [and] has stated its intention to be the exclusive policymaker." *Id.*

Two years later, FDA again advised Congress that it had no jurisdiction over tobacco products under the FDCA and that such jurisdiction would necessitate a ban:

> [*C*]*igarettes recommended for smoking pleasure are beyond the* [FDCA]. . . . Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. . . .

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cigarette advertising that appealed to youth. *See 1969 Hearings* 91st Cong. at 44-47, 54, 57, 69, 72-88, 169-70, 193, 224, 229, 263-64, 279, 286-89, 298-302, 314, 356, 373, 381, 430, 447, 451, 467, 471, 476, 484-90, 494, 497, 501-02, 601, 615-18, 625-35, 644-45, 679, 728-29, 737-38, 1201, 1287-88, 1291, 1303-07, 1340-41, 1350, 1371-72, 1376 (1969); *Cigarette Advertising and Labeling: Hearings on H.R. 6543 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong., 33, 47-48, 76-79, 84-87, 98-99, 117, 121-22, 135, 156, 181 (1969).

> [W]e believe [the FCLAA] demonstrates that *the regulation of cigarettes is to be the domain of Congress.* . . . In sum, labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent.

Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before Consumer Subcomm. of the Senate Comm. on Commerce, 92nd Cong. 246 (1972) (emphasis added) (Statement of FDA Comm'r Edwards). FDA further acknowledged that Congress decided in the FCLAA

> that cigarettes should not be banned, that they should be allowed to remain in commerce with the warnings decided on by Congress [and] we have no basis for making any kind of determination *literally contrary to the congressional determination.*

Id. at 245 (Statement of FDA Chief Counsel Hutt). Shortly thereafter, the FDA Chief Counsel, after consultation with the General Counsel of HEW, stated that "a test case [asserting FDA jurisdiction over cigarettes] would be without sound legal basis, and thus should not be instituted." *Id.* at 242 (letter from Chief Counsel Hutt to Sen. Moss).

By the early 1970s, Congress had established, and FDA had acknowledged, two fundamental propositions: First, Congress itself would regulate the health aspects of tobacco products through specific legislation that balanced health concerns with other factors, including the freedom of adults to smoke and the importance of tobacco to the national economy. Second, FDA would have no role in regulating tobacco products. Indeed, FDA's testimony reflects its understanding that, through the FCLAA, Congress had reserved such authority to itself. Thus, FDA's current assertion of jurisdiction over tobacco products

defies Congress' intent that no federal agency shall have authority to fashion federal tobacco and health policy.

Congress' intent to exclude administrative competition in the development of federal tobacco and health policy is expressed not only in the FCLAA; it is also manifest in post-FCLAA product safety statutes that expressly exclude tobacco products.[13] FDA, of course, had made it clear that it could not regulate tobacco products. However, the same assurance could not be provided for a new agency, the Consumer Product Safety Commission ("CPSC"), which Congress created in 1972, pursuant to the Consumer Product Safety Act ("CPSA"), Pub. L. No. 92-573, 86 Stat. 1207 (1972) *codified at* 15 U.S.C. § 2051 *et seq.* So, Congress expressly excluded "tobacco products" from the CPSC's jurisdiction. *Id.* at § 2052(a)(1)(B).[14]

In 1976, Congress twice again precluded the possibility of agency interference with Congress' regulation of tobacco products. The CPSC had been ordered by a U.S.

[13] The Government asserts that the FDCA's failure to expressly exclude tobacco products indicates that Congress never intended to bar FDA from regulating them. Pet. Br. at 19. To the contrary, FDA's repeated testimony to Congress that it lacked authority over tobacco products fully explains why, during this period, Congress did not have to consider amending the FDCA to explicitly exempt tobacco products. The Government's attempt to make affirmative use of the statutes that preclude administrative regulation of tobacco products ignores the unmistakable congressional policy which they embody—that no federal agency may regulate tobacco product health and safety absent specific congressional direction.

[14] The CPSA was the product of competing bills. The House version that prevailed transferred from FDA to the CPSC responsibility over the Federal Hazardous Substances Act, *codified at* 15 U.S.C. § 1261 *et seq.*—which, among other things, provides that a hazardous substance may be banned. 15 U.S.C. § 2052(a)(1)(B). The Senate bill would have created a super product-safety agency built around FDA and the statutes for which it was then responsible—the FDCA and the FHSA. *See* S. Rep. 92-749, 12 (1972).

district court to consider the merits of a petition to ban high-tar cigarettes pursuant to the Federal Hazardous Substances Act ("FHSA"). Before the CPSC acted, Congress amended the FHSA to add an exclusion for tobacco products similar to the one it had adopted in the CPSA four years earlier. FDA understood the message that Congress intended to send, for it later interpreted the exclusion of tobacco products from FHSA as "indicative of the policy of Congress to limit regulatory authority over cigarettes by Federal Agencies." Novitch Letter, Jt. App. at 59.

A few months later, agency jurisdiction over tobacco arose again during Congress' consideration of the Toxic Substances Control Act ("TSCA"), Pub. L. No. 94-469, Title I, § 2, 90 Stat. 2003 (1976), *codified at* 15 U.S.C. § 2601 *et seq.*, which empowers the EPA to regulate and, if appropriate, to ban toxic chemical substances. Uncertain about how the EPA might apply this new authority, Congress excluded "tobacco or any tobacco product" from the TSCA. 15 U.S.C. § 2602(2)(B)(iii).

The import of these actions by Congress is unmistakable: After making FDA's confirmation that the FDCA could not apply to tobacco products a predicate of its own program in the FCLAA, Congress took the additional steps necessary to assure that no other federal agency could usurp Congress' control of federal tobacco and health policy.[15]

The statutory landscape was thus settled by 1976 when Congress passed the Medical Device Amendments to the

[15] The public health acts passed by Congress in the 1970s also demonstrate Congress' continued understanding that tobacco products are separate from those products regulated under the FDCA. *See* 15 U.S.C. § 1261 (separately excluding "tobacco and tobacco products" and food, drugs, devices, and cosmetics from the FHSA); *id.* at § 2052 (separately excluding same product categories from the CPSA); *id.* at § 2602(2)(B) (separately excluding same product categories from the TSCA).

FDCA, Pub. L. No. 94-295, 90 Stat. 539 (1976). Nothing in the text, structure, or history of these amendments even hints that the same Congress that had precluded EPA and the CPSC from regulating tobacco products intended to give FDA the tools to do so. FDA itself stated:

> [*T*]*here is no evidence in the legislative history . . . that Congress intended to include cigarettes within the definition of "device"* nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.
>
> The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking.

Novitch Letter, Jt. App. at 54 (emphasis added). Only a year later, FDA again declared that it had "*no authority to regulate*" cigarettes. 42 Fed. Reg. 19,996, 20,001 (1977) (emphasis added).

In May 1977, ASH petitioned FDA to regulate cigarettes as "drugs" on the ground that they contain nicotine, which ASH contended produces a "physical addiction" in many smokers, including young smokers. *Citizen Petition*, FDA Dkt. No. 77P-0185 at 4-11 (May 26, 1977). This was the same argument ASH had presented to Congress in 1969 prior to its amending the FCLAA—and that FDA now invokes to justify its assertion of jurisdiction.

In fact, most of the arguments FDA now advances as "new" grounds for asserting jurisdiction over cigarettes, *see* 61 Fed. Reg. 44,396, 45,226 (1996), were presented to FDA in ASH's 1977 petition, just as they had been presented to Congress in the 1960s:

- the nicotine in cigarettes is a drug (p. 2);
- "studies have demonstrated that many smokers smoke largely for the physiological effects the drug causes on their body" (p. 2);
- "[n]umerous medical and other studies treat nicotine as a drug no different in many of its effects than heroin and other addictive substances" (p. 2);
- "overwhelming persuasive evidence" shows that "cigarettes are 'intended to affect the functions of the body' by many users as well as by the manufacturers" (p. 2);
- "[n]icotine is an extremely powerful substance exerting powerful effects . . . on the brain, spinal cord, peripheral nervous system, the heart, lungs and various other bodily structures" (p. 6);
- "[s]tudies going back at least to 1940 . . . indicate that for many smokers the act of smoking is merely a convenient and socially accepted manner of administering a carefully-controlled dose of nicotine to the body" (pp. 7-8);
- a "cigarette, is after all, an instrument, apparatus, or contrivance *designed* to administer controlled amounts of nicotine and other substances to the smoker upon demand" (p. 31) (emphasis added); and
- "most children have no trouble acquiring the product" (p. 36).

In rejecting the ASH petition, FDA did not dispute *any* of ASH's factual assertions. Instead, it rejected the petition *as a matter of law* on the ground that such allegations, *even if true,* could not authorize FDA to regulate cigarettes. FDA confirmed that its "interpretation of the [FDCA] . . . *consistently has been that cigarettes are not a drug unless health claims are made by the vendors.*" Letter from FDA Comm'r Kennedy to Banzhaf, Jt. App. at 47 (Dec. 5, 1977) (emphasis added). Accord-

ing to FDA, "citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies *are not evidence* of such intent by the manufacturers or vendors of cigarettes . . ." *Id.*, Jt. App. at 48-49 (citation omitted) (emphasis added).

When ASH challenged in court FDA's rejection of its petition that FDA regulate cigarettes as "contrivance[s] designed to administer controlled amounts of nicotine," *Citizen Petition* at 31, FDA and the Justice Department defended the Agency's determination that it lacked jurisdiction over cigarettes:

> In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.

FDA/DOJ Brief at 14-15. Although "the hazards of smoking, including its addictive effects, were known in 1952," *id.* at 29, n.24, FDA and the Justice Department stated:

> Since at least the issuance of the Surgeon General's Report on smoking in 1964, cigarettes have been at the forefront of discussions of the public health—in Congress, in the Executive Branch, in the news media, and among the public generally. *The participants in these discussions over the past 15 [now 35] years or more would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.*

Id. at 40 (emphasis added).

As FDA and the Justice Department recognized, any change in such a longstanding interpretation would be contrary to clear congressional intent:

> Although it has amended the Act many times, Congress has never acted to disturb the agency's interpretation. In such circumstances, the Supreme Court has recognized Congressional acquiescence in the FDA's construction of the Act.

Id. at 27 n.23 (citation omitted).

These arguments prevailed. *See ASH*, 655 F.2d at 236. The court of appeals expressly endorsed the statutory interpretation that the pharmacological effects of nicotine do *not* provide a basis for FDA jurisdiction. *Id.* at 240.

In 1978, ASH again petitioned FDA, this time arguing that filtered cigarettes are intended to mitigate or prevent disease and thus were medical "devices" under the FDCA. *Citizen Petition*, Dkt. No. 78P-0338 (Oct. 2, 1978). However, FDA concluded that it is

> not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Novitch Letter, Jt. App. at 54. Thus, "[i]nsofar as rulemaking would relate to cigarettes . . . as customarily marketed, . . . *FDA has no jurisdiction* [and] *no rulemaking is permissible as a matter of law.*" *Id.* at 67 (emphasis added). FDA recognized that its lack of jurisdiction was inherent in the FDCA and not due to a lack of evidence or an exercise of administrative discretion.[16]

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[16] While the ASH petitions were before the Agency, five bills were introduced to grant FDA jurisdiction over cigarettes. H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979). None was enacted.

D. During the 1980s and 1990s, Congress Supplemented Its Regulatory Program for Tobacco Products in Ways Squarely Inconsistent with FDA Jurisdiction.

Congress has continued to refine its program for tobacco regulation through legislation *specifically* addressing aspects of a product that even FDA has recognized raises "unique" issues. 61 Fed. Reg. 44,396, 44,404 (1996).

In 1983, Congress required the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco," and to include recommendations for action that the Secretary may deem appropriate. Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, §2(b)(7), 97 Stat. 175, 178 (1983), *codified at* 42 U.S.C. § 290aa *et seq.*

The next year, Congress again amended the FCLAA to modify the prescribed warning for cigarettes, reaffirming that the FTC—not FDA—would continue to administer this requirement. *See* Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984), *amending* 15 U.S.C. § 1331 *et seq.* In the opening hearing, Chairman Waxman of the House Subcommittee on Health and the Environment, a proponent of increased tobacco regulation, remarked:

> The [FDA] is charged with assuring that the public is adequately warned about the health effects of drugs and that hazardous foods and drugs are removed from the market. *Yet, no Federal agency has jurisdiction over cigarettes. . . . The responsibility to regulate the cigarette industry falls to the Congress.*

Smoking Prevention Education Act: Hearings on H.R. 1824 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong. 1 (1983) (emphasis added).

Assistant Secretary for Health Brandt, speaking on behalf of FDA, agreed: "[T]he issue of regulation of tobacco . . . is *something that Congress has reserved to itself*, and we do not . . . have the authority to regulate nor are we seeking such authority." *Id.* at 74 (emphasis added). Dr. Brandt repeated this understanding to the Senate: "Our view is that the Congress has assumed the responsibility of regulating . . . cigarettes." *Smoking Prevention Health and Education Act of 1983: Hearings on S. 772 Before the Comm. on Labor and Human Resources*, 98th Cong. 56 (1983).

The House committee with jurisdiction over FDA agreed: "Federal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes . . . ." H.R. Rep. No. 98-805, 12 (1984).

As part of these FCLAA amendments, Congress also required cigarette manufacturers to "annually provide the Secretary [of HHS] with a list of the ingredients added to tobacco in the manufacture of cigarettes . . . ." 15 U.S.C. § 1335a(a). This section—which authorizes the Secretary to report directly to Congress on the health effects of those ingredients—reflected Congress' concern that

> [a]t the present time, cigarette manufacturers are not statutorily required to disclose to any agency or department of the federal government any of the ingredients they place in cigarettes during the manufacturing process.

H.R. Rep. No. 98-805, 21 (1984). This statement shows that FDA lacks jurisdiction over tobacco products.

In 1986, Congress enlarged its national tobacco program when it passed the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30 (1986), *codified at* 15 U.S.C. § 4401 *et seq.*, relying in part on the fact that "FDA claims [that]

it does not have the authority to regulate the sale of smokeless tobacco." *Tobacco Issues: Hearings on H.R. 2835, H.R. 760, H.R. 2950, and H.R. 3078, Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 106 (1985) (statement of Rep. Synar). The CSTHEA bans broadcast advertising of smokeless tobacco products, establishes a mandatory warning format, and authorizes the FTC—not FDA—to issue implementing regulations. 15 U.S.C. §§ 4401-08. The CSTHEA thus rests on the same fundamental policy embodied in the FCLAA—that informed adults should be permitted to decide whether or not to use tobacco products.[17]

In 1988, the Surgeon General declared that nicotine is "addictive". U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General* (1988); *see also* U.S. Dep't of Health and Human Services, Public Health Service, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General*, 10 (1989) ("1989 Surgeon General Report").

Rep. Durbin brought the "addiction" issue to the attention of the House:

> Congress declares war on addictive drugs, yet we virtually ignore one of the greatest causes of addiction in America: Tobacco. We regulate food and drugs to protect the health of our citizens, but we *specifically exempt* the cause of 350,000 American deaths each year: Tobacco. . . . *The Congress should change the Food, Drug and Cosmetic Act to define nicotine as a drug.* That would make all tobacco products subject to regulation by the FDA, *allowing us to restrict sales to children* . . . .

134 Cong. Rec. 11,261 (1988) (emphasis added).[18]

The next year, two bills were introduced in both Houses to amend the FDCA to give FDA jurisdiction over tobacco products. *See* H.R. 1494, 101st Cong. (1989); S. 769, 101st Cong. (1989). Again, Congress did not enact either of them even though their proponents argued that the issues of youth smoking and "addiction"—the same issues that FDA itself now advances—called for expanded FDA jurisdiction:

> [E]very day, more than 3,000 American teenagers—or 60 percent of all new smokers—start smoking. Yet . . . tobacco products are largely exempted from the laws we have established to protect the public from unsafe consumer products. All of this despite that fact that we now know without question that cigarettes and other tobacco products containing nicotine are highly addictive.

135 Cong. Rec. 6,550 (1989) (statement of Rep. Durbin).

Even after the Surgeon General reported in 1988 that nicotine in tobacco products is addictive, FDA Commis-

[17] In 1987, Congress failed to enact yet another bill that would have expanded FDA jurisdiction to cover tobacco products. *See* H.R. 3294, 100th Cong. (1987).

[18] Respondents' history of Congress' consideration of tobacco product legislation between 1964 and 1988 is consistent with that of the Surgeon General:

> Following the 1964 Surgeon General's Report, Congress considered a number of bills to regulate tobacco [including] amending the FFDCA to place cigarettes under the authority of the FDA. Because there was no known safe level for tar, nicotine or other tobacco constituents, regulation would have likely resulted in prohibition. . . . Instead, following considerable debate [Congress enacted the FCLAA]

1989 Surgeon General Report at 605, 612-613 (noting further that, rather than "allowing regulation by Federal agencies, Congress in most cases reserved to itself jurisdiction over tobacco products. . . .").

sioner Young testified that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." *Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 100th Cong. 409 (1989). Rep. Durbin agreed: "I think the legal interpretation is fairly clear that tobacco is not included in your legislative mandate." *Id.*

Commissioner Young's reaffirmation of FDA's long-held view that it does not have jurisdiction over cigarettes prompted some Members of Congress to call for new statutory restrictions on cigarette advertising. In 1990, for example, Rep. Waxman sponsored a bill that would have made it a federal offense to distribute free tobacco-product samples, sponsor sporting events using cigarette brand names, or advertise in anything other than a black-and-white format. *See* H.R. 5041, 101st Cong. (1990). The House Commerce Committee did not report the proposed legislation, yet these same unenacted restrictions are now found in FDA's current regulations. *See* 21 C.F.R. §§ 897.16(d), 897.34(c), 897.32.[19]

In response to such concerns about youth and tobacco, Congress expanded its tobacco program in 1992 by enacting the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 ("ADAMHA Amendments"). Pub. L. No. 102-321, Title II, § 202, 106 Stat. 394, *codified at* 42 U.S.C. § 300x-26. Through these Amendments, Congress determined that the States—not the federal government—should remain responsible for re-

[19] These restrictions were rejected by the same Congress that enacted the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511-30 (1990), which FDA claims supports its authority to impose some of the same restrictions in the guise of regulating tobacco products as "devices."

stricting underage access to tobacco products: The federal government creates incentives for the States to pursue their traditional role of regulating the retail sale of tobacco products by withholding funds from States that fail to enact or adequately enforce their own laws prohibiting tobacco product sales to minors.[20]

In the ADAMHA Amendments, Congress sought to preserve State flexibility and declined to "force a particular standard upon all states," 58 Fed. Reg. 45,156, 45,161 (1993) (proposed implementing regulations).

> [E]ach State should have the flexibility to enforce its laws in a manner that can reasonably be expected to reduce availability of tobacco products to minors in light of that State's own unique circumstances.

61 Fed. Reg. 1492, 1495. (1996). Yet, soon after the ADAMHA regulations were finalized, FDA seized jurisdiction and announced its own uniform national tobacco-access requirements, thereby supplanting Congress' program.

E. Following the 1994 Elections, FDA Abruptly Decided to Regulate Tobacco Products Without Congressional Authorization.

In 1994, FDA announced that it would "work with Congress" to consider whether the Agency could assert jurisdiction over cigarettes as "drugs." FDA expressly recognized that it was "vital" that "Congress provide clear direction to the agency" because "the regulation of cigarettes raises societal issues of great complexity and mag-

[20] In 1992, legislation was also introduced—H.R. 4350 and S. 2298, 102d Cong. (1992)—to expand FDA jurisdiction by creating a new regulatory category for tobacco products. Rep. Synar observed that FDA "is powerless to do anything" about tobacco products. 138 Cong. Rec. 4028-29 (1992). Again, in 1993, two more bills were introduced that would have expanded FDA jurisdiction to include tobacco products. H.R. 2147 and S. 672, 103d Cong. (1993). None of these bills passed.

nitude." Letter from FDA Comm'r Kessler to Ballin (Feb. 25, 1994), in *Regulation of Tobacco Products (Part I), Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce,* 103rd Cong. 3, 25 (1994) ("*1994 Hearings*"). *See also 1994 Hearings* at 73 (statement of Comm'r Kessler seeking "guidance from the Congress").

FDA quickly lost interest in working with Congress following the November 1994 election that resulted in a change in the political control of Congress. One day after that election, the Agency announced that "FDA will make" the decision on its jurisdiction over tobacco products. Letter from FDA Assoc. Comm'r Thompson to Rep. Lancaster 2 (Nov. 10, 1994).[21] Thereafter, without any direction—much less authorization—from Congress, FDA asserted jurisdiction over tobacco products.[22] FDA Deputy Commissioner Shultz candidly described this decision as "historic" precisely "because it provided an opportunity for taking decisive action on tobacco without requiring action by Congress." Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 Pace L. Rev. 27, 29 (1997).

FDA's excuse for its abrupt about face is its contention that it has unearthed "new facts" showing that nicotine is an addictive drug.[23] Even if those "new facts" had legal

[21] While FDA reconsidered asserting jurisdiction over tobacco products, Congress excluded them from the definition of "dietary supplement," which otherwise included any "botanical product," in the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417 § 3, 108 Stat. 4325, 4327 (1994). The exclusion was unnecessary, but it precluded FDA from using the DSHEA to reach tobacco products as dietary supplements.

[22] Two months before FDA proposed its tobacco rule, a bill was introduced to give FDA new authority to regulate tobacco products. H.R. 1853, 104th Cong. (1995). The bill was not enacted.

[23] Under FDA's new interpretation of "drug", neither "addiction" nor any other particular pharmacological effect is necessary for FDA jurisdiction. Any kind of physical effect on the body would suffice, including the many kinds of adverse effects ascribed to tobacco products in the 1964 Surgeon General's Report.

relevance, which they do not, FDA's explanation does not withstand scrutiny. Pharmacological effects of nicotine have been well known for decades. Indeed, they were known in 1938 when Congress enacted the FDCA, were catalogued in the 1964 Surgeon General's Report, and were extensively discussed in the 1979 report by the National Institute of Drug Abuse which concluded that cigarettes are addictive. *See* notes 4 and 11, *supra*; National Institute on Drug Abuse, *The Behavioral Aspects of Smoking* (1979), *reprinted in* Dep't of Health, Education, and Welfare, Public Health Service, *Smoking and Health, A Report of the Surgeon General,* ch. 15 (1979). These facts are not new.[24] The only thing new is FDA's willingness to ignore statutory restraints.

F. Congress Continues to Address Smoking and Health Issues.

In the last Congress, legislation to grant FDA jurisdiction over tobacco products was considered on the

[24] FDA acknowledged that the "long history of tobacco and nicotine use for pharmacological purposes" was "well known to the tobacco industry," an acknowledgement it based on a study *published* in 1965. 60 Fed. Reg. 41,314, 41,621 n.240 (1995). FDA also relied on many other *published studies* about the tobacco industry's knowledge of pharmacological effects of nicotine from the 1950s through the 1970s. *See* 61 Fed. Reg. 44,396, 44,895-912, 44,952-53 (1996). Given FDA's claim that foreseeability of pharmacological effects has always established the requisite intended use of a product to affect the structure or function of the body, Pet. Br. at 4, the basis for FDA's current theory of jurisdiction has existed for many decades.

The Government asserts that "basic drug-like qualities [of tobacco products] are so well documented, widely known and thoroughly embedded in the behavior of consumers and manufacturers," that express claims to that effect would be "superfluous." Pet. Br. at 25. Apparently, FDA's argument is that until 1995 everyone was aware of these facts except FDA.

Senate floor and in House hearings. 144 Cong. Rec. S5001 through *id.* at S6481 (daily eds. May 18 through June 17, 1998) (S. 1415, 105th Cong. (1988)) (the "McCain Bill," as modified and printed in the Cong. Rec., 144 Cong. Rec. at S. 5034-84 (daily ed. May 19, 1998)); *The Tobacco Settlement (Parts 1-3): Hearings Before the Subcomm. on Health and Environment of the House Comm. on Commerce,* 105th Cong. (1997-98). The President's 1999 State of the Union Address called for such legislation in the current Congress. 145 Cong. Rec. H260 (daily ed. Jan. 19, 1999). Thus, whether to grant FDA jurisdiction over tobacco products remains before Congress.[25] Since 1996, fifteen bills have been introduced to grant FDA such jurisdiction.[26] Each of these bills would have granted FDA jurisdiction either by creating a new

[25] The Government contends that the entire history of Congress' consideration and rejection of bills to give FDA jurisdiction over tobacco products is no more meaningful than Congress' inaction since FDA asserted jurisdiction. Pet. Br. at 42-43. To the contrary, Congress' "failure" to enact bills to overturn FDA's recent assertion of jurisdiction is easily understood given the immediate judicial challenge to that assertion, the district court's stay of FDA's regulations except for the youth access provisions, the subsequent appellate ruling and this Court's grant of certiorari. Moreover, in 1997, Congress expressly disavowed any intent to affect this case when it provided funding for those FDA regulations not stayed by the district court: "The [Senate] Committee [on Appropriations] is aware of the ongoing litigation. . . . *The Committee emphasizes that its action is in no way to be construed as concurring or disagreeing with any court ruling regarding FDA's authority . . . .*" S. Rep. No. 105-51, 105th Cong. 117 (1997) (emphasis added); see also S. Rep. No. 105-212, 105th Cong. 124 (1998) (same for FY '99); S. Rep. No. 106-80, 106th Cong. 127 (1999) (same for FY '00). Properly, the Government does not seek to draw any inference from the appropriation. *See TVA v. Hill,* 437 U.S. 153, 190 (1978).

[26] S. 527, S. 1414, S. 1415, S. 1492, H.R. 762, H.R. 1244, H.R. 3028 (all 105th Cong. (1997)); S. 1530, S. 1638, S. 1648, S. 1889, H.R. 3474, H.R. 3738, H.R. 3868, H.R. 3889 (all 105th Cong. (1998)).

regulatory scheme exclusively for tobacco products or by modifying the FDCA's standards for safety and effectiveness. *None* of these bills accepted FDA's view that the FDCA, as it stands, fits tobacco products. Rather, these bills reflect the Members' continued understanding that application of the FDCA to tobacco products would require a ban.

Congress has amended the FDCA 57 times in the past 60 years, but has never granted FDA jurisdiction over tobacco products.[27] If Congress had wanted to confer such jurisdiction on FDA, it would have said so by now. Even when interpreting a public health protection statute, as is the FDCA, "we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases . . . of Jam v. United States,* 340 U.S. 593, 600 (1951).

II. THE RELEVANT STATUTES AND THEIR HISTORY DEMONSTRATE THAT FDA LACKS JURISDICTION OVER TOBACCO PRODUCTS.

Both FDA's general assertion of authority and its tobacco regulations are incompatible with Congress' tobacco-specific legislation. The *only* way that the FDCA can be reconciled with the FCLAA, the CSTHEA, and the ADAMHA Amendments is to conclude that the FDCA does not cover tobacco products. In this context, statutes such as these should "be taken together, as if they were one law." *United States v. Stewart,* 311 U.S. 60, 64 (1940); *Hubbard v. United States,* 514 U.S. 695, 701 (1995). FDA's demand that this Court resolve this case exclusively on the basis of FDA's expansive reading of the definitions in the FDCA is, therefore, legally indefensible.

[27] *See* Walsh, Federal Food, Drug, and Cosmetic Act with Amendments iii-iv (amendments through 1980); 21 U.S.C. § 301 Historical & Statutory Notes 33-34 (West Supp. 1998) (amendments since 1980).

> The classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

United States v. Fausto, 484 U.S. 439, 453 (1988). Thus, the "proper inquiry is how best to harmonize", *United States v. Estate of Romani*, 118 S. Ct. 1478, 1486 (1998), the FDCA with the tobacco-specific legislation.

It is well settled that subsequently enacted and more specific statutes (like the tobacco-specific statutes) prevail over earlier and more general statutes (like the FDCA). Such later and more specific statutes preclude efforts 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 Union No. 639*, 362 U.S. 274, 291-92 (1960). Not only do "precisely targeted" statutes prevail over the more general when there are "numerous other regulations and statutes littering" the field, but a general statute should not be expanded "so dramatically as to make many other pieces misfits." *United States v. Sun-Diamond Growers of California*, 119 S. Ct. 1402, 1410 (1999).[28]

[28] The Government cites *TVA v. Hill*, 437 U.S. at 189-90, for the proposition that an "implied repeal occurs only when there is an irreconcilable conflict between the old and the new laws," and asserts that there is no "irreconcilable conflict" between Congress' tobacco-specific statutes "and the conclusion that tobacco products fall within the reach of the Act." Pet. Br. at 44. Respondents do not argue that any portion of the FDCA has been implicitly repealed by Congress' tobacco-specific statutes. Rather, the argument is that those statutes preclude FDA's novel construction of the FDCA. Thus, the standards for an implied repeal are irrelevant. *See Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 438 (1989) (rejecting implied repeal argument and noting that passage by Congress of a later statute precludes an expansive construction of an earlier statute). In any event, there *are* numerous irreconcilable conflicts between FDA's assertion of jurisdiction and Congress' tobacco-specific statutes.

The regulatory program established by Congress' tobacco-specific statutes, premised on the absence of FDA jurisdiction, reflects a political compromise that carefully balances economic interests, personal freedom, and principles of federalism with public health and other interests, including the need to reduce youth access to tobacco. This compromise marks the place where "'opposing social and political forces have come to rest.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979). FDA regulation of tobacco products is fundamentally at odds with Congress' program and would shatter that political balance.

A. FDA's Claim of Authority to Regulate Tobacco Products Is Incompatible with the Federal Cigarette Labeling and Advertising Act.

FDA's claim of authority over tobacco products cannot be reconciled with the policy and regulatory program Congress established in the FCLAA. In statutory text, the FCLAA announces:

> 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 ad-

vertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331.

The Government improperly recharacterizes these purposes as simply seeking to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations." Pet. Br. at 45 (quoting FCLAA § 1331(2)(B)). This contention ignores the far broader purposes reflected in the other paragraphs of § 1331 and the operative provisions of the FCLAA. These include maintaining the primacy of Congress in establishing national policy with respect to smoking and health, and protecting commerce and the national economy consistent with the policy of informing consumers about the health risks associated with cigarettes. Congress' purpose to protect commerce while informing consumers, *codified at* § 1331(2)(A), necessarily precludes any federal agency from banning cigarettes.

Even FDA acknowledges that it lacks the statutory tools and the expertise to take account of these economic and political factors.[29] FDA is not authorized to protect "commerce and the national economy." Its role is limited to carrying out the mandate of its governing statute—a mandate that requires it to ban any drug or device not found to be both "safe" and "effective." *See* 21 U.S.C. §§ 355 (d)-(e), 360c(a)(2)(A)-(C), 360e(d)-(e). However, safety is one of several elements in Congress' complex political balance. Indeed, Congress determined in 1970 that cigarettes are "dangerous," Pub. L. No. 91-222, § 4, 84 Stat. 87 (1970), and accordingly, has prescribed specific warnings, 15 U.S.C. § 1333, but rejected a ban.

[29] "FDA medical officers should not be considering economic issues as part of their safety and efficacy reviews. . . . Although some people look to FDA to resolve those difficult dilemmas, FDA does not have the expertise to decide them." FDA Comm'r Kessler, *Remarks at the Symposium on Pharmacoeconomics* (Oct. 22, 1993).

The very grounds used by FDA to justify its attempt to regulate tobacco products without banning them—notwithstanding its finding that they are unsafe—show how far the Agency has overreached. FDA explains that the health care system could be "overwhelmed" by the need to treat addicted smokers if tobacco products were banned, and that in these circumstances "a black market and smuggling would develop to supply smokers." 61 Fed. Reg. 44,396, 44,413 (1996). But FDA has no expertise with respect to these issues—and no authority under the FDCA to consider them.[30]

Lacking suitable authority, FDA has sought to invent its own tobacco law to avoid a head-on collision with Congress' tobacco-specific statutes.[31] The court of appeals properly recognized this "transparent action by the FDA [as] obvious sophistry," taken "to attain its end, not the end contemplated by Congress." *Brown & Williamson*, Pet. App. at 24a, 30a. Notwithstanding FDA's inventions, a principled application of the FDCA would create numerous irreconcilable conflicts with the FCLAA:

[30] FDA's efforts to address "unique problems of medical judgment, law enforcement and public policy . . . cannot justify a federal agency of specifically delimited jurisdiction from implementing equally unique control solutions not authorized by Congress." *American Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharm. Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam) (FDA's methadone distribution regulations "must be first passed upon by Congress").

[31] FDA's construction of the FDCA and the tobacco-specific statutes reads out of them their legislatively established "intelligible principle[s]," *J.W. Hampton Jr., & Co. v. United States*, 276 U.S. 394, 404-410 (1928) (Taft, C. J.): tobacco products are not immediately banned under the FDCA even though found "unsafe," nor regulated as Congress intended under the tobacco-specific statutes. FDA therefore would lack any congressional direction regarding how to regulate tobacco products. "A construction of the statute that avoids this kind of open-ended grant should certainly be favored." *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1979) (plurality opinion).

Authority to Ban. As the court of appeals recognized: "A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress." *Id.* at 29a.[32] Under the FDCA, a drug or device is "misbranded" and may not be sold if it is "dangerous to health when used in the dosage or manner, . . . recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j). Yet FDA has found that cigarettes, when used in the recommended manner (*i.e.*, smoked), are "dangerous to health," 61 Fed. Reg. 44,396, 44,412 (1996), and are "the single leading cause of preventable death in the United States." *Id.* at 44,398. Thus, if the FDCA actually applied to tobacco products, they would have to be banned.[33]

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[32] To bolster its argument that FDA may ban tobacco products, the Government conflates two issues: the preemptive effect of the FCLAA on state law; and the preclusive effect of the FCLAA on federal agencies. Pet. Br. at 45. But substantially different legal standards govern these separate issues, in part, due to the "strong presumption" against preemption, *Cipollone*, 505 U.S. at 523, "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485. *Cipollone* concerned the preemptive effect on state law of 15 U.S.C. § 1334. *Cipollone*, 505 U.S. at 517. Unlike *Cipollone*, this case involves the preclusive effect of the FCLAA on a federal agency; it cannot be decided by only reading § 1334.

[33] FDA's position is that tobacco products are "devices" that deliver the "drug" nicotine. But if FDA finds that there is a reasonable probability that a device will cause serious adverse health consequences, it "shall issue an order requiring the appropriate person . . . to immediately cease distribution of the device." 21 U.S.C. § 360h(e)(1). Moreover, any drug that is not "generally recognized" as safe may not be marketed unless FDA approves the drug as having been shown to be safe. 21 U.S.C. §§ 321(p), 355(b), 331(d). The Director of FDA's Center for Drug Evaluation and Research has noted that "for a drug that's going to be sold over-the-counter . . . there has to be a very high certainty that the drug is very safe." Woodcock, *When Is a Medical Product Too*

But banning tobacco products is manifestly inconsistent with Congress' intent. Congress has repeatedly refused to give FDA jurisdiction over tobacco products precisely *because* it would lead to a ban. Congress has never delegated that decision to any administrative agency—and certainly not to FDA, whose repeated denials of such authority were a predicate for Congress' own legislative program.

Labeling Authority. The FCLAA and the CSTHEA expressly preclude FDA or any other agency from requiring any statement on tobacco product labeling with respect to tobacco and health except as prescribed by Congress. 15 U.S.C. §§ 1334(a), 4406(a).[34] Yet regulation of product labeling is a core feature of FDA authority over "drugs" and "devices." *See generally,* 21 U.S.C. § 352. Indeed, the FDCA explicitly requires health warnings on drugs and devices. For example, a "drug" or "device" is "misbranded" if its labeling does not include "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Given that FDA called the use of tobacco products a "pediatric disease," 61 Fed. Reg. 44,396, 45,238 (1996), and concluded that tobacco products are "dangerous", *id.* at 44,412, FDA *must* require such warnings if tobacco products are "drugs" or "devices." But it is precluded from doing so by the FCLAA and the CSTHEA. To avoid the conflict without acknowledging it, FDA announced that the current congressionally-prescribed warn-

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Risky? An Interview with FDA's Top Drug Official, FDA Consumer, The Magazine of the U.S. Food and Drug Administration, Sept.-Oct. 1999, at 10 ("FDA Consumer (Sept.-Oct. 1999)").

[34] Nothing in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), suggests the contrary. *Banzhaf* concerned regulation of broadcasters—not cigarette manufacturers—and did not require statements on tobacco product packages concerning smoking and health.

ings satisfy the FDCA. *Id.* at 44,465. But if FDA genuinely believed those warnings were truly "adequate," its regulations would be unnecessary.

Further, under the FDCA, a "drug" or "device" is misbranded unless its labeling contains "adequate directions" for safe use. 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5, 801.5. Given FDA's findings, no such directions could possibly be written for tobacco products. But, even if such directions were possible, FDA could not require them consistent with the FCLAA because they would be in addition to the congressionally-prescribed warnings.

Finally, FDA's tobacco-product regulations would require all product packages to carry the health-based "intended use" statement: "Nicotine Delivery Device for Persons 18 or Older." 21 C.F.R. §§ 897.25, 897.32(c). To seek to avoid a conflict with the FCLAA and the CSTHEA labeling preclusions, FDA contends that this warning about nicotine is somehow unrelated to "smoking and health." 61 Fed. Reg. 44,396, 44,544 (1996). But the very basis of FDA's rulemaking is the health effects of nicotine "delivery" by tobacco products.

Package Inserts. FDA also claims authority to require that package inserts "contain health information and information about the chemicals added to cigarettes and smokeless tobacco." 61 Fed. Reg. 44,396, 44,465 (1996). FDA argues that the FCLAA does not preclude such package inserts because inserts would be "in"—not "on"—cigarette packages. *Id.* FDA was forced to adopt this absurd view of FCLAA preclusion given its desire to assert jurisdiction over tobacco products.

Ingredients. Congress determined that the health effects of cigarette ingredients are to be evaluated *by HHS* and reported *to Congress.* 15 U.S.C. § 1335a. Nevertheless, under FDA's regulation of tobacco products as "devices," *FDA* would evaluate—and sometimes could prescribe—their ingredients, *see* 21 U.S.C. §§ 360d(a)(2)(A), 360, 360e(c)(1)(B), thus usurping Congress' authority.

Moreover, the FCLAA mandates that cigarette manufacturers disclose to HHS the identity of all cigarette ingredients, which HHS must treat "as trade secret or confidential information," 15 U.S.C. § 1335a(b)(2)(A), and store "in a locked cabinet or file." *Id.* at § 1335a (b)(1)(C). By contrast, under the FDCA, a drug is misbranded unless its label includes "the established name and quantity . . . of each active ingredient" as well as "the established name of each inactive ingredient . . . ." 21 U.S.C. § 352(e)(1)(A)(ii, iii). In fact, FDA claims authority "to require labeling or listing of other substances present or delivered by cigarettes." 61 Fed. Reg. 44,396, 44,463 (1996). However, such requirement would result in the public disclosure of the very information that Congress protected from disclosure.

In sum, it is impossible to harmonize FDA's asserted authority over tobacco products with the regulatory program in the FCLAA. Rather, the court of appeals found that FDA has sought "to maneuver around the obstacles created by the operative provisions of the" FDCA, *Brown & Williamson,* Pet. App. at 29a; and "[c]ongressional policy . . . cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products." *Id.* at 44a. This disharmony permits only one conclusion: Congress has not granted FDA such authority.

B. FDA's Assertion of Federal Control over Retail Sales Conflicts With Congress' Legislation to Foster and Support Restrictions on Youth Access to Tobacco Products at the State Level.

FDA's one-size-fits-all program conflicts with the purpose of the ADAMHA Amendments, which contemplate

varying approaches from one State to another. Indeed, the FDCA preempts the States from imposing "requirements" that are different from or in addition to FDA's. *See* 21 U.S.C. § 360k. Thus, if the FDCA applies to tobacco products, Section 360k would prohibit the States from establishing any youth-access restrictions and enforcement procedures that differ from FDA's regulations, even if those restrictions were specifically designed to fit local circumstances.[35] FDA's regulations would thus wrest the lead enforcement role from the States contrary to Congress' intent. 21 C.F.R. § 897.14. The regulations also transform every improper sale of a tobacco product by a local merchant into a federal offense, *see* 21 U.S.C. §§ 331(a), 333(f)(3); 21 C.F.R. § 897.1(b), expanding the scope of federal criminal jurisdiction without congressional authorization.

III. FDA MAY NOT SEIZE AUTHORITY OVER TOBACCO PRODUCTS FROM CONGRESS.

As the court of appeals observed: "At its core, this case is about who has the power to make this type of major policy decision." *Brown & Williamson*, Pet. App. at 53a.[36] Congress has repeatedly enacted tobacco-specific legislation to address the health risks associated with tobacco products—including those relied upon by FDA as the basis of its asserted jurisdiction. In so doing, Congress answered the "who" question, and established a policy *against* FDA jurisdiction. As the D.C. Circuit stated in *ASH v. Harris*, "[i]f the [FDCA] requires expansion [to cover cigarettes], that is the job of Congress." *ASH*, 635 F.2d at 243. The court of appeals agreed that "this type of decision involving countervailing national policy concerns is just the type of decision left for Congress." *Brown & Williamson*, Pet. App. at 22a.

[35] FDA, in its discretion, may waive the FDCA preemption. But in triggering that authority, FDA has shifted primary authority from the States (and Congress) to itself.

[36] FDA recently recognized its inability to modify the fundamental policy underlying the FDCA: If there is "more that can be done" beyond "enforcing the standards and approach called for in our statute," to achieve a "*a balance [that is] correct according to society*," "*[t]hat's really a general consensus rather than our call.*" FDA Consumer (Sept.-Oct. 1999) at 11.

As we have shown, Congress did not intend to grant FDA authority over tobacco products when it enacted the FDCA. For over 60 years, FDA denied that it had such authority until it reversed course in its 1995-1996 rulemaking.[37] FDA communicated its lack of jurisdiction to Congress repeatedly, forcefully and authoritatively—in testimony and official correspondence from senior Agency officials and their Cabinet-level superiors.

FDA's conduct was consistent with its statements. Immediately after the 1964 Surgeon General's Report, the FTC proposed a rule to require health warnings in cigarette advertising. *See* 29 Fed. Reg. 530 (1964). FDA did nothing. Nor did it respond to *any* of the Surgeon General's numerous subsequent reports on tobacco and health. It knew it had no jurisdiction. In such circumstances, both "established practice" and "the want of assertion of power by those who presumably would be alert to exercise it" are "significant in determining whether such power was actually conferred." *BankAmerica Corp. v. United States*, 462 U.S. 122, 131 (1983).

Congress understood and concurred with FDA's view that the FDCA does not extend to tobacco products. *See United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979) (legislative intent "correctly discerned" when Congress was aware of FDA interpretation and did not "alter

[37] Contrary to the Government's contention, FDA's prior position was not based on an absence of sufficient evidence regarding the "intended use" of tobacco products. Pet. Br. at 43. Rather, FDA asserted that, as a matter of law and congressional intent, it lacked authority over tobacco products absent health claims. *See, e.g.*, Novitch Letter, Jt. App. at 54, 67; *see also id.* at 47.

that interpretation although it . . . amended the statute").[38] Further, Congress repeatedly declined to pass legislation to grant FDA jurisdiction over tobacco products. "Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the [agency's] rulings." *Bob Jones Univ. v. United States*, 461 U.S. 574, 601 (1983).

> [A] refusal by Congress to overrule an agency's construction of legislation is at least some evidence of the reasonableness of that construction, particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it.

United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137 (1985).

The evidence of Congress' awareness of, and failure to overturn, FDA's longstanding interpretation, is far more compelling than the evidence in previous cases where this Court relied upon such facts. Here, the unenacted bills are unusually numerous (36) and span nearly 70 years (1929-1998), and thus reflect consistent congressional understanding of, and acquiescence in, the existing state of the law over a very long period.[39] Just last year, the

[38] The Government argues that *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29 (1983), precludes effective congressional ratification of FDA's longstanding statutory interpretation. Pet. Br. at 43. *State Farm*, however, involved an agency's policy judgment on a matter delegated to it to decide, not its interpretation of a statute. *State Farm* held only the former immune to congressional ratification, 463 U.S. at 45, not the latter.

[39] The Government notes that congressional will is expressed through enacted legislation, not unenacted bills. Pet. Br. at 42. Respondents agree. However, the purpose and meaning of the statutes Congress *did* enact, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments, as well as Congress' intent in enacting those statutes, are brightly illuminated by the competing alternatives before Congress. In a further effort to avoid the force of this history, the Government asserts that "[c]ongressional inaction also 'lacks persuasive significance because several equally tenable inferences may be drawn from such action, including the inference that the existing legislation already incorporated the offered change.'" *Id.* The historical evidence here shows that any such inference is untenable: Congress plainly understood that FDA lacked authority to regulate tobacco products.

Senate debated for three weeks the merits of comprehensive tobacco legislation, including extensive provisions which would have established FDA regulatory authority, and similar legislation was considered by the House Committee on Commerce.

Indeed, Congress' recognition that FDA lacks authority was a predicate for Congress' tobacco-specific legislation. Congress "believed that it was filling a regulatory void," *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 570 (1979), when it created its tobacco-specific statutes, a belief which the FDA "actively encouraged." *Id.* The enactment of legislation that "implicitly recognizes" the construction of a statute is "persuasive of legislative recognition" that the "construction is the correct one." *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 488-489 (1940); *see also United States v. American Trucking Ass'ns*, 310 U.S. 534, 550 (1940). Now that Congress has installed a statutory regime for tobacco, it is far too late for FDA to conjure up a contrary interpretation of its jurisdiction. *Cf. Morton v. Ruiz*, 415 U.S. 199, 237 (1974) ("too late now" for agency to change interpretation after it consistently "led Congress to believe that interpretation"); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 289 (1974) (agency "not now free" to change its interpretation of statute).

Thus, Congress ratified FDA's prior construction of the FDCA when it enacted the FCLAA. In reserving to itself the authority to regulate tobacco products, and in constructing its own comprehensive regulatory scheme for

such products, Congress relied upon its own conclusion—buttressed by FDA's statements—that FDA lacked authority over tobacco products and would not take any action to negate or undermine Congress' specific enactments. Congress' tobacco-specific statutes therefore preclude FDA's new construction of the FDCA. *See CFTC v. Schor*, 478 U.S. 833, 846 (1986) (finding ratification "virtually conclusive" when "Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation. . . ."); *see also* Eskridge, *Interpreting Legislative Inaction*, 87 Mich L. Rev. 67, 110-11 (1988) (finding the strongest case for presuming correctness of a prior agency statutory interpretation is a "building block interpretation," *i.e.*, "an authoritative settled interpretation . . . upon which public decisionmakers have (apparently) relied in developing further legal rules").

Simply put, FDA has appropriated Congress' constitutional authority to make major national policy. This Court has been especially skeptical of administrative interpretations that would forge new, major policies that must be resolved by Congress:

> Reviewing courts are not obliged to stand aside and rubberstamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute. Such review is always properly within the judicial province, and the courts would abdicate their responsibility if they did not fully review such administrative decisions. . . . [Where the review is] of a judgment as to the proper balance to be struck between competing interests, "[t]he deference owed to an expert [agency] cannot be allowed to slip into a judicial inertia *which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress.*"

NLRB v. Brown, 380 U.S. 278, 291-2 (1965) (quoting *American Ship Bldg. Co. v. NLRB*, 380 U.S. 300, 318 (1965)) (emphasis added); *see also BATF v. FLRA*, 464 U.S. 89, 97 (1983).

Here, "the thread between these regulations and any grant of authority by the Congress is so strained that it would do violence to established principles of separation of powers," *Chrysler Corp. v. Brown*, 441 U.S. at 307-308, to credit FDA's assertion of jurisdiction "with the 'binding effect of law.' " *Id.* at 308.

CONCLUSION

Accordingly, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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