This appellate decision is followed by the Supreme Court's affirmation. To go straight to the Supreme Court ruling do a search (Cntrl + F) for "Begin Supreme Court Decision".

U.S. 4th Circuit Court of Appeals

BROWN & WILLIAMSON v FDA

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY, ***Plaintiffs-Appellants***, and COYNE BEAHM, INCORPORATED; LIGGETT GROUP, INCORPORATED, ***Plaintiffs***,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of No.97-1604 Food and Drugs, ***Defendants-Appellees***.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; THE CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator, ***Amici Curiae***.

COYNE BEAHM, INCORPORATED; BROWN & WILLIAMSON TOBACCO CORPORATION; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO

COMPANY; NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED; UNITED STATES TOBACCO COMPANY; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; 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; No. 97-1581 ASSOCIATION OF NATIONAL ADVERTISERS, INCORPORATED; MAGAZINE PUBLISHERS OF AMERICA; THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED; POINT OF PURCHASE ADVERTISING INSTITUTE; LORILLARD TOBACCO COMPANY, ***Plaintiffs-Appellees***, and LIGGETT GROUP, INCORPORATED, ***Plaintiff***.

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, ***Defendants-Appellants***.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator, ***Amici Curiae***.

COYNE BEAHM, INCORPORATED; BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS,

INCORPORATED; RJ REYNOLDS TOBACCO COMPANY; UNITED STATES TOBACCO COMPANY; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL, No. 97-1606
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; THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED; POINT OF PURCHASE ADVERTISING INSTITUTE; NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED, ***Plaintiffs-Appellees***, and LIGGETT GROUP, INCORPORATED, ***Plaintiff***.

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, ***Defendants-Appellants***.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator, ***Amici Curiae***.

NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED, ***Plaintiffs-Appellants***,

v.

DAVID A. KESSLER, Commissioner of the Food & Drug Administration; FOOD & DRUG ADMINISTRATION, ***Defendants-Appellees***,

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF No. 97-1614 IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN CANCER SOCIETY; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION, ("WLF"); MARIO ANDRETTI, DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives, LAUCH FAIRCLOTH, United States Senator, ***Amici Curiae***.

Appeals from the United States District Court for the Middle District of North Carolina, at Greensboro. William L. Osteen, Sr., District Judge. (CA-95-591-2, CA-95-593-2, CA-95-665-6, CA-95-706-2) UNITED STATES TOBACCO COMPANY; BROWN & WILLIAMSON TOBACCO CORPORATION; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL, INCORPORATED; CENTRAL CAROLINA GROCERS, INCORPORATED; J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED, ***Plaintiffs-Appellants***.

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, ***Defendants-Appellees***.

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, United States Representatives; LAUCH FAIRCLOTH, United States Senator, ***Amici Curiae***.

Appeal from the United States District Court for the Middle District of North Carolina, at Winston-Salem. William L. Osteen, Sr., District Judge. (CA-95-665-6)

Argued: June 9, 1998
Decided: August 14, 1998

Before WIDENER, Circuit Judge, HALL, Senior Circuit Judge, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Reversed by published opinion. Judge Widener wrote the opinion, in which Senior Judge Michael joined. Senior Judge Hall wrote a dissenting opinion.

COUNSEL ARGUED: Gerald Cooper Kell, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Government. Richard Melvyn Cooper, WILLIAMS & CONNOLLY, Washington, D.C.; Larry Bruce Sitton, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; John L. Oberdorfer, PATTON BOGGS, L.L.P., Washington, D.C.; William C. McLeod, COLLIER, SHANNON, RILL & SCOTT, Washington, D.C., for Private Parties.

ON BRIEF: Frank W. Hunger, Assistant Attorney General, Walter C. Holton, Jr., United States Attorney, Stephen W. Preston, Deputy Assistant Attorney General, George J. Phillips, Counselor to the Assistant Attorney General, Eugene M. Thirolf, Douglas N. Letter, Scott R. McIntosh, Christine N. Kohl, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Margaret Jane Porter, Chief Counsel, Karen E. Schifter, Patricia J. Kaeding, Associate Chief Counsel, FOOD & DRUG ADMINISTRATION, Rockville, Maryland, for Government. Robert R. Marcus, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; Norwood Robinson, ROBINSON & LAWING, L.L.P., Winston- Salem, North Carolina; John R. Jordan, Jr., JORDAN, PRICE, WALL, GRAY & JONES, Raleigh, North Carolina; John F. Fithian, G. Kendrick Macdowell, PATTON BOGGS, L.L.P., Washington, D.C.; Eric Rowe, PATTON BOGGS, L.L.P., Greensboro, North Carolina; R. Timothy Columbus, Brian A. Dahl, COLLIER, SHANNON, RILL & SCOTT, Washington, D.C.; Ray V. Hartwell, III, Douglas W. Davis, HUNTON & WILLIAMS, Richmond, Virginia, for Private Parties. Hubert H. Humphrey, III, Attorney General, Alan I. Gilbert, Solicitor General, James S. Alexander, Assistant Attorney General, Cheryl Heilman, Assistant Attorney General, STATE OF MINNESOTA, St. Paul, Minnesota, for Amici Curiae State of Minnesota, et al. Allison M. Zieve, David C. Vladeck, Alan B. Morrison, PUBLIC CITIZEN LITIGATION GROUP, Washington, D.C., for Amici Curiae Public Citizen, et al. Dennis B. Fleming, Jr., General Counsel, Michael T. Alexander, Jack Conway, OFFICE OF THE GOVERNOR, Frankfort, Kentucky, for Amicus Curiae Commonwealth of Kentucky. Daniel J. Popeo, David M. Young, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amici Curiae Foundation, et al.

OPINION

WIDENER, Circuit Judge:

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, *et al*.). In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief.1 Plaintiffs then filed a motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the

[1] When the complaint was filed on August 10, 1995, the FDA had only issued a Notice of Proposed Rulemaking. 60 Fed.Reg. 41,314 (1995). Following a comment period, the FDA adopted the proposed rule in modified form. 61 Fed. Reg. 44,396 (1996). Unless noted otherwise, all references in this opinion are to the final version of the rule published in the Federal Register on August 28, 1996. Where italics appear here within a quotation, they have been added for emphasis unless otherwise indicated.

motion in part, the district court held that Congress did not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. *Coyne Beahm, Inc. v. FDA*, 966 F.Supp. 1374, 1388 (M.D.N.C.1997). The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. *Coyne Beahm*, 966 F.Supp. at 1393-1400. Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal.2 *Coyne Beahm*, 966 F.Supp. at 1400-01. The district court certified its order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), *Coyne Beahm*, 966 F.Supp. at 1401, and by order dated May 13, 1997, this court granted the § 1292(b) petitions for immediate appeal filed by two of the plain- tiff groups and the FDA. In addition, the FDA had filed its Notice of Appeal dated May 2, 1997 from the partial injunction granted by the district court. Jurisdiction over the consolidated appeals is proper in this court under 28 U.S.C. §§ 1292(a)(1) and 1292(b).

Because this case arises from a motion for summary judgment, we review the judgment of the district court *de novo*. *Myers v. Finkle*, 950 F.2d 165, 167 (4th Cir. 1991). For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

I. FDA's Asserted Basis for Jurisdiction

The FDA3 has authority to regulate products only if they fall within one of the categories defined by Congress in the Act. 4 In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug 5 and device 6 definitions in the Act. 61 Fed. Reg. at 44,628. According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the

[2] The district court left in place the FDA's proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18, which had already gone into effect. *Coyne Beahm*, 966 F.Supp. at 1400. How- ever, all 50 States have already banned the sale of tobacco to minors under state law. See 61 Fed. Reg. at 44,419 (citing a joint letter from 25 state attorneys general and other comments submitted to the FDA).

[3] On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, we will refer to any legislative delegation as if made directly to the FDA.

[4] The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics. 21 U.S.C. § 321.

[5] The Act defines "drug" in pertinent part as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

[6] In relevant part, "device" is defined as an article which is: intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes
21 U.S.C. § 321(h)(3).

body." 7 61 Fed.Reg. at 44,628, 44,649-650. Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. 61 Fed.Reg. at 44,400. Although finding that tobacco products function primarily as drugs, 61 Fed. Reg. at 45,209-218, the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section, 21 U.S.C. § 360j(e). 8 61 Fed.Reg. at 44,400. The FDA's jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. Jurisdictional Analysis

We begin with the basic proposition that agency power is "not the power to make law. Rather, it is `the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14 (1976) (quoting *Manhattan Gen. Equip. Co. v. Commission*, 297 U.S. 129, 134 (1936)). Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed."9 The district court framed the issue as "whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed." *Coyne Beahm*, 966 F.Supp. at 1380. However, we are of opinion that the issue is correctly framed as whether Congress intended to delegate such jurisdiction to the FDA. See *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (stating that "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority

---

[7] A combination product is described as a product that contains a combination of a drug, device, or biological product. 21 U.S.C. § 353(g). Neither party contends that tobacco products contain any "biological product," as that term is used in the Act. See 42 U.S.C. § 262(I) (defining a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings").

[8] Section 360j(e) provides in relevant part:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use --
> . . .
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.
> 21 U.S.C. § 360j(e).

[9] Plaintiffs use the term "customarily marketed" in their briefs to indicate tobacco products marketed with customary claims such as smoking pleasure as opposed to tobacco products marketed with specific therapeutic claims such as weight loss. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

delegated by Congress"); *INS v. Chadha*, 462 U.S. 919, 953 n.16, 955 n.19 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it; and if that authority is exceeded it is open to judicial review" and "Congress ultimately controls administrative agencies in the legislation that creates them"). This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in *Chevron*, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under *Chevron*, we first consider the intent of Congress because "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842 -43. It is only if the intent of Congress is ambiguous that we defer to a permissible interpretation by the agency. *Chevron*, 467 U.S. at 843. And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990). Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. *Chevron*, 467 U.S. at 843 n.9; see also *Cabell Huntington Hosp., Inc. v. Shalala*, 101 F.3d 984, 986 (4th Cir. 1996) (stating that "[t]he goal of statutory interpretation is to implement congressional intent"). We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. See, e.g., *Adams Fruit Co.*, 494 U.S. at 650 (quoting *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)) (warning that "an agency may not bootstrap itself into an area in which it has no jurisdiction"); *ACLU v. FCC*, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987) (stating that"[w]hen an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue"), *cert. denied*, 485 U.S. 959 (1988); *Hi-Craft Clothing Co. v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981) (noting that "[t]he more intense scrutiny that is appropriate when the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission").

Although the task of statutory construction generally begins with the actual language of the provision in question, *Mead Corp. v. Tilley*, 490 U.S. 714, 722 (1989), the inquiry does not end there.10 The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *United States Nat'l Bank of Or. v. Independent Ins. Agents of America, Inc.*, 508 U.S. 439, 455 (1993) (quoting *United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122, (1849)); see also *Regions Hosp. v. Shalala*, 66 U.S.L.W. 4125, 4129 n.5 (U.S. Feb. 24, 1998) (No. 96-1375); *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989).

[10] In fact, if application of the plain language of a statute "would produce a result demonstrably at odds with the intent of Congress . . . the intent of Congress rather than the strict language controls." *Maryland State Dep't of Educ. v. U.S. Dep't of Veterans Affairs*, 98 F.3d 165, 169 (4th Cir. 1996) (citing *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 242 (1989)), *cert. denied*, 118 S.Ct. 43 (1997).

Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme, *Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 220-221 (1986) (directing courts to examine the language of the statute as a whole); legislative history, *Atherton v. FDIC*, 65 U.S.L.W. 4062, 4067 (U.S. Jan. 14, 1997) (No. 95-928); "the history of evolving congressional regulation in the area," *Dunn v. CFTC*, 65 U.S.L.W. 4141, 4144 (U.S. Feb. 25, 1997) (No. 95- 1181); and a consideration of other relevant statutes, *United States v. Stewart*, 311 U.S. 60, 64 (1940) (explaining that "all acts in pari materia are to be taken together as if they were one law") (italics in original). With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. Intrinsic Evidence

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." *Robinson v. Shell Oil*, 65 U.S.L.W. 4103, 4104 (U.S. Feb. 18, 1997) (No. 95-1376) (quoting *Ron Pair Enter.*, 489 U.S. at 240).

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device.11 See FDA Red Br. at 34 (stating that "the jurisdictional inquiry is at an end with the conclusion that cigarettes and smokeless tobacco are `intended to affect the structure of any function of the body' within the meaning of the Act's drug and device provisions"); see also *Coyne Beahm*, 966 F.Supp. at 1380.

A mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). As noted by the district court, "no court has ever found that a product is `intended for use' or `intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." *Coyne Beahm*, 966 F.Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claims. *Coyne Beahm*, 966 F.Supp. at 1389 n.14.

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. See, e.g., *Robinson*, 65 U.S.L.W. at 4104 (stating that statutory language must be examined by "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995) (instructing that acts of Congress "should not

[11] For example, in its jurisdictional analysis, the district court purported to examine the "Text of the Federal Food, Drug, and Cosmetic Act." *Coyne Beahm*, 966 F.Supp. at 1380. However, the court mentioned only the definitions sections of the statute and ignored the text of all of the mandatory operative provisions of the Act.

be read as a series of unrelated and isolated provisions"); *United States Nat'l Bank*, 508 U.S. at 455 (quoting *United Savings Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd.* 484 U.S. 365, 371 (1988)) (explaining that statutory interpretation is a "holistic endeavor" that must include, at a minimum, an examination of the statute's full text, its structure, and the subject matter). Accordingly, our task is to examine whether tobacco products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold." Statement by FDA Deputy Commissioner William B. Schultz before the Senate Comm. on Labor and Human Resources, 104th Cong., p.8 (2/22/96). In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effective- ness of devices intended for human use." 21 U.S.C. § 393(b)(2)(B), (C). During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of "great pain and suffering from illness such as cancer, respiratory illnesses, and heart disease." 61 Fed.Reg. at 44,412. In addition, the FDA determined that over 400,000 people die each year from tobacco use. 61 Fed. Reg. at 44,412. Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. 21 U.S.C. § 360j(e). According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed.Reg. at 44,412-13. Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. 61 Fed. Reg. at 44,405, 44,412-44,413.

But that test is contrary to the statute. The statutory provision, 21 U.S.C. § 360c(a)(2)(C), provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use ." See also *United States v. Rutherford*, 442 U.S. 544, 556 (1979) (stating that "a drug is unsafe if its potential for inflicting death and physical injury is not offset by the possibility of therapeutic benefit"). According to the language of § 360c(a)(2)(C), the FDA's obligation is to strike a balance between the risks and benefits of the use of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. 21 U.S.C. § 360c(a)(2)(C). Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. 61 Fed.Reg. at 44,413. These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. 21 U.S.C. § 360c(a)(2)(C). According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products

from the market are greater than the risks of leaving them on the market is irrelevant under § 360c(a)(2)(C).

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act. Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. 21 U.S.C. § 360j(e). However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety. Thus, the FDA cannot com- ply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. 21 U.S.C. § 355(a). The Act requires the FDA to disapprove applications for new drugs[12] if the drug is deemed unsafe or if there is not substantial evidence of its effective- ness. 21 U.S.C. § 355(d). This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. 61 Fed. Reg. at 44,412. In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. 60 Fed. Reg. 41,348 (1995) (FDA Proposed Rulemaking). As such, the Act would require the prohibition of the distribution and marketing of tobacco products. 21 U.S.C. §§ 331(d), 355(a).

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. 21 U.S.C. § 353(g)(1). If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. 21 U.S.C.§ 353(g)(1)(A), (B). The FDA concedes that the "primary mode of action" of tobacco products is that of a drug.[13] FDA Red Br. at 26 (citing 61 Fed. Reg. at 45,209-18; 44,400-03). Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug or device that is misbranded. 21 U.S.C. § 331(a). Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. 21 U.S.C. § 352(j). The FDA has concluded that the use of tobacco products is dangerous to health. 61 Fed. Reg. at 44,412. Thus, it is impossible for the labeling of

[12] In relevant part, the Act defines a "new drug" as: Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions pre- scribed, recommended, or suggested in the labeling thereof . . . 21 U.S.C. § 321(p)(1).

[13] Interestingly, the FDA chose to regulate tobacco products as devices even though it has regulated the nicotine products within its jurisdiction - nicotine patches, nicotine gum, and nicotine nasal sprays - as drugs. Approved Drug Products with Therapeutic Equivalence Evaluations, 1762 Food Drug Cosm.L.Rep. (CCH) 3-220, 221 (FDA May 29, 1996).

tobacco products to suggest a nondangerous use. Accordingly, #8E8E # 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include "adequate directions for use." 21 U.S.C. § 352(f)(1). According to the FDA, the requirement of adequate directions for use means "directions under which the lay- man can use a device safely and for the purposes for which it is intended." 61 Fed. Reg. at 44,464. The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the protection of public health." 21 U.S.C. § 352(f). The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. 21 C.F.R. §§ 201.100-201.129, 801.109-801.127 (1996).

The FDA now contends that an exemption for tobacco products is appropriate, 61 Fed. Reg. at 44,410, because everyone knows how to use tobacco products and thus directions are not needed. See 61 Fed. Reg. at 44,465 (stating that tobacco products are "one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge."). However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, 61 Fed. Reg. at 44,412, it is impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its pro- posed regulations, the FDA cited widespread use of tobacco products by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. See 61 Fed. Reg. at 45,238-243 (characterizing youth use of tobacco products as a "pediatric disease"). The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. See 15 U.S.C. § 1333, 4402 (requiring Surgeon General warnings about health risks posed by tobacco products); see also 61 Fed. Reg. at 44,465. The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. 15 U.S.C. §§ 1334(a), 4406(a). Again, the contortions that the FDA has gone through demonstrate that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)-(C). As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Three years after it first introduced the proposed regulations, the FDA has yet to

place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II); see also 61 Fed. Reg. at 44,398, 44,412 (discussing dangers of tobacco use). Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. 21 U.S.C. § 360c(a)(1)(C). The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. 61 Fed. Reg. at 44,412; FDA Red Br. at 45. However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and effectiveness for the product. 21 U.S.C. § 360c(a)(1). As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act requires the FDA to issue an immediate cease- distribution order for all products found to cause "serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1).14 This order begins an agency process that may ultimately result in a recall order for the device. 21 U.S.C. § 360h(e)(2). The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco- related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths." 61 Fed. Reg. at 44,398 (citations omitted). According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order for tobacco products. Nevertheless, the FDA has no intention of com- plying with the requirements of the Act. See 61 Fed. Reg. at 44,419 (stating that the FDA will not ban tobacco products). The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products - a result not intended by Congress. The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA " shall issue an order requiring . . . [the immediate] cease distribution of such device." 21 U.S.C. § 360h(e)(1)(A). However, the FDA contends that "shall" should be interpreted to mean "may." FDA Red Br. at 42-43. Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if "shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban

[14] In relevant part, § 360h(e)(1) provides: If the [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the [FDA] shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device) - (A) to immediately cease distribution of such device;
. . . 21 U.S.C. § 360h(e)(1).

falls out- side the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain its end, not the end contemplated by Congress. Cf. *United States v. Two Plastic Drums*, 984 F.2d 814, 819 (7th Cir. 1993) (rejecting another recent attempt by the FDA to enlarge its jurisdiction and stating that "the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme"). The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951). Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. Extrinsic Evidence

Pursuant to *Chevron's* instruction to employ the traditional tools of statutory construction, we now examine the events surrounding the 1938 passage of the Act as well as subsequent statements and actions by Congress and the FDA. These individual events are like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act. See *MCI Telecomm. Corp. v. AT&T*, 512 U.S. 218, 228 (1994) (stating that relevant time for determining congressional intent on meaning of statute is when controlling statute enacted). As discussed above, the fact that the operative provisions of the Act simply cannot accommodate tobacco products is a clear indication of congressional intent. Cf. *Gustafson*, 513 U.S. at 569 (explaining that an operative provision of the Securities Act of 1933 does not define prospectus, the term at issue, but "does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme"). Subsequent events outside the language of the statute only confirm our understanding of Congress' intent.

1. Historical Actions of the FDA

From 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction. And, as early as 1898, the Supreme Court of Tennessee acknowledged the dangerous nature of tobacco products, characterizing cigarettes as "wholly noxious and deleterious to health," "inherently bad, and bad only," and "widely condemned as pernicious altogether." *Austin v. State*, 48 S.W. 305, 306 (Tenn. 1898).

Yet, the statute preceding the Act, the Pure Food and Drugs Act of 1906, Pub.L.No. 59-384, 34 Stat. 768 (1906), did not mention tobacco. As early as 1914, the FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for "smoking or chewing or as snuff and not for medicinal purposes." Bureau of Chemistry, U.S. Dept. of Agriculture, 13 *Service and Regulatory Announcements* 24 (Apr. 2, 1914). Enacted in 1938, the present Act expanded the definition of drug from the definition provided in the Pure Food and Drugs Act of 1906 and also granted the FDA new authority to regulate "devices." Food, Drug, and Cosmetic Act, Pub.L.No. 75-717, 52 Stat. 1040 (1938). However, neither the Act nor its legislative history mention tobacco products.15

In the 60 years following the passage of the Act, the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the Act. Ever since its beginning in the 1930s, the FDA has taken the position and made statements indicating that the Act did not apply to cigarettes marketed without specific health claims. FDA/Dep't of Justice Brief in *ASH v. Harris* (No.79-1397), at 16. Again, in 1963, an FDA Bureau of Enforcement Guideline stated that "[t]he statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter to Directors of Bureaus and Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), reprinted in Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Sub- comm. of the Senate Comm. on Commerce on S. 1454, 92d Cong. 240 (1972). When Congress later examined the issue of the FDA's jurisdiction during its consideration of tobacco-specific legislation, FDA Commissioner Charles Edwards testified regarding the FDA's lack of authority over cigarettes and stated that "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]."16 Hearings on S. 1454 at 239. The Commissioner took the position that the Federal Cigarette Labeling and Advertising Act, discussed in greater detail below, reinforced that "the regulation of cigarettes is to be the domain of Congress." Hearings on S.1454 at 242. The Commissioner then concluded that "labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by the FDA would be inconsistent with the clear congressional intent." Hearings on S. 1454 at 242.

In 1977, Action on Smoking and Health (ASH), a public health group, petitioned the FDA to regulate cigarettes. ASH claimed that cigarettes were drugs because they contain nicotine which produces addiction in many smokers, and particularly in youth. Citizen Petition,

---

[15] Two of the main supporters of the Act were representatives from the two leading tobacco States - Senator Bailey (D-NC) and Representative Chapman (D-KY). See 83 Cong. Rec. 9094 (1938). In fact, Sen. Bailey and Rep. Chapman were among Senate and House managers of the Act in the Conference Committee. Had there been any indication that the Act might apply to tobacco products, we can only assume that such members of Congress would have expressed opposition to the Act.

[16] The Commissioner cited several cases in support of the FDA's conclusion that it lacked authority over cigarettes as customarily marketed. See, e.g., *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *affirming on opinion below*, 108 F.Supp. 573 (S.D.N.Y. 1952); *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F.Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F.Supp. 336 (D.N.J. 1952).

FDA Docket No. 77P-0185, at 4-11 (5/26/77)[G.Br.Att.77]. In rejecting ASH's petition,17 the FDA cited a 1953 Second Circuit opinion, *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), affirming on opinion below, 108 F.Supp. 573 (S.D.N.Y.1952), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. Specifically, the FDA quoted with approval the following language from the court's opinion:

> The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."

See Letter from FDA Commissioner Donald Kennedy to John F. Banzhaf, III, at 3 (12/5/77)(quoting *Liggett & Myers*, 108 F.Supp. at 577) (stating that the FDA's consistent position has been that cigarettes marketed without health claims by vendors are not drugs within the Act).

In 1978, ASH filed a second petition, claiming that cigarettes were devices under the Act and thus were within the scope of the FDA's jurisdiction. *Citizen Petition*, FDA Docket No. 78P-0338 (Oct. 2, 1978). After reviewing the legislative history of the Act, the FDA stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under [the definition of device]. Therefore, no rulemaking is permissible as a matter of law ." Letter from FDA Com- missioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades, at 12 (11/25/80). In considering the effect of the Medical Device Amendments of 1976 which modified the definition of device to its current formulation, the FDA Commissioner stated:

> Specifically, there 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. It is, therefore, 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. Goyan/Banzhaf Letter, at 3. The FDA's holdings and statements that the Act fails to provide "authority suitable to the regulation of cigarettes" are consistent with part II.A's conclusion, *supra*, that the Act's regulatory scheme simply cannot accommodate tobacco products.

---

[17] A federal appeals court upheld the FDA's denial of jurisdiction. See *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). In upholding the FDA's denial of jurisdiction, the court emphasized the relevance of the remarks of the district court in *Liggett*. In construing the identical language of the definitions in the Federal Trade Commission Act, the *Liggett* court stated: "[s]urely, the legislators did not mean to be as all-inclusive as a literal interpretation of [the definitions] would compel us to be." ASH, 655 F.2d at 240 (quoting *Liggett & Myers*, 108 F.Supp. at 576).

Again in 1989, the FDA Commissioner stated that: "it doesn't look like it is possible to regulate [tobacco products] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Hearings Before the Sub-comm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong., 2d Sess. 409 (1989). The above statements evidence the FDA's position from 1914 until the present rulemaking attempt that, as a matter of law, it did not have jurisdiction to regulate tobacco products as customarily marketed. The FDA's public, consistent, and longstanding interpretation18 of the Act gains even more significance when viewed in conjunction with the actions of Congress during the same time period.

2. Congressional Inaction

We recognize the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation. See *Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (noting that "[a]s a general matter, `we are reluctant to draw inferences from Congress's failure to act'") (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988)). However, under certain circumstances, inaction by Con- gress may be interpreted as legislative ratification of or acquiescence to an agency's position. See *Bob Jones Univ. v. United States*, 461 U.S. 574, 601 (1983) (stating that "[i]n view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the IRS rulings"). In *Bob Jones*, the Court examined Congress' failure to modify two IRS rulings when the public and Congress were well aware of the position of the IRS. *Bob Jones*, 461 U.S. 599 -602. In finding legislative acquiescence to the IRS position, the Court emphasized: extensive hearings held by Congress on the issue; the introduction and failure of numerous bills in Congress introduced to overturn the IRS's interpretation of the Internal Revenue Code; and Congress' awareness of the IRS position when enacting other, related legislation. *Bob Jones*, 461 U.S. at 599 - 601; see also *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137 (1985) (finding legislative acquiescence and explaining that "a refusal by Congress to overrule an agency's construction of legislation" is particularly relevant "where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it").

We are of opinion that the matter before us presents an equally strong case of legislative acquiescence.19 As noted by the district court, Congress has introduced numerous bills that would have granted the FDA jurisdiction over tobacco products. See *Coyne Beahm*, 966 F.Supp. at 1382 (stating that "members of Congress agreed with FDA's assertions that it lacked jurisdiction" and thus introduced bills expressly granting the FDA jurisdiction "in an effort to remedy the situation"). In fact, the district court listed 15 different bills introduced in Congress which would have expressly granted the FDA jurisdiction over tobacco products. *Coyne* Beahm,

[18] We do not mean to suggest that an agency is always irrevocably bound by its prior interpretations of a statute. However, we note that an agency's interpretation of a statutory provision that conflicts with the agency's earlier interpretation is "`entitled to considerably less deference' than a consistently held agency view." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981)). In addition, the evidence of legislative ratification also weighs against the FDA's actions in the present case.

[19] The district court attempted to distinguish the *Bob Jones* and *Riverside Bayview* cases by noting that they involved agency action rather than statements by an agency that it did not have jurisdiction to act. *Coyne Beahm*, 966 F.Supp. at 1383. We fail to see any real distinction and thus find the cases applicable.

966 F.Supp. at 1382. However, none of these bills were enacted. As discussed above, FDA officials have testified at many congressional hearings regarding the FDA's lack of jurisdiction over tobacco products. See also *Coyne Beahm*, 966 F.Supp. at 1381. Thus, Congress has been well aware of the FDA's position that it lacked jurisdiction over tobacco products since 1914. On several occasions, Congress has enacted legislation to deal specifically with the dangers of tobacco products, but has never enacted legislation to overturn the FDA's interpretation of its jurisdiction under the Act. Accordingly, this is not a case where congressional inaction demonstrates "unawareness, pre- occupation, or paralysis." See *Zuber v. Allen*, 396 U.S. 168, 185-86 n.21 (1969). We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.

3. Congress' Tobacco-Specific Legislation

Under Chevron 's instruction to apply the traditional rules of statutory construction, it is also appropriate to consider the provisions of the "whole law, and . . . its object and policy" in ascertaining the will of Congress. *Dole v. United Steelworkers of America*, 494 U.S. 26, 35 (1990) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)). Having examined the Act and prior actions of the FDA and Congress, we now take a closer look at three statutes and related amendments (collectively referred to as the tobacco-specific legislation) enacted by Congress for the purpose of addressing public health concerns about the use of tobacco products. The issue is not, in the words of the stalking horse set up by the government, whether these three statutes partially repeal or amend the Act to withhold jurisdiction over tobacco products from the FDA. FDA Red Br. at 57. Rather, we examine the tobacco-specific legislation as a part of our inquiry into congressional intent. As discussed above, we are of opinion that the statutory text, viewed as a coherent whole, clearly indicates that Congress did not intend the FDA's original jurisdictional grant to include tobacco products. Thus, the sub- sequent enactment of tobacco-specific legislation provides corroborating evidence of established congressional intent.

In January 1964, the publication of the first Surgeon General's report on smoking and health called the federal government's attention to the dangers of tobacco products. Dept. of Health, Education and Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964); see also H.R.Rep.No.289, 91st Cong., 1st Sess., at 5 (characterizing the 1964 Surgeon General's Report as the "principal basis" for regulatory efforts). Shortly thereafter, the House Committee on Interstate and Foreign Commerce initiated a series of hearings regarding the federal government's role in dealing with smoking-related health problems. Committee Chairman, Representative Oren Harris, stated that:

> The purpose of these hearings will be, if we can reach that point, to determine the extent of authority under existing law to deal with the various aspects of this general field, and to determine whether any action of the Congress is warranted in the interest of public health. In other words, we want to find out under our responsibility whether or not legislative action is necessary, and if so, what kind.

Hearings Before the Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess. 23 (1964).

During the course of these hearings, Congress considered and rejected the option of granting the FDA jurisdiction over tobacco products. Of the eleven bills submitted to the Committee, two would have expressly amended the Act to make it applicable to tobacco products. 1964 Hearings at 2-12. These two bills proposed expansion of the Act to cover tobacco products by creating a new category of products subject to FDA jurisdiction. See 1964 Hearings at 4-7 (suggesting creation of new category entitled "smoking products"). These two bills also proposed new operative provisions applicable only to "smoking products."20 1964 Hearings at 4-7. As part of the hearings, Surgeon General Terry was asked whether the Department of Health, Education, and Welfare (HEW), the FDA's parent department, had authority to regulate tobacco products. Dr. Terry's unqualified response was that his department did not believe that it had "such authority in existing laws governing the Public Health Service and Food and Drug Administration." 1964 Hearings at 56. Similar testimony was later provided by the Deputy Commissioner of the FDA. See Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong., 2d Sess. 193 (1965) (statement of Deputy Commissioner Rankin that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); see also 111 Cong. Rec. 13431 (1965). In addition, the Secretary of HEW, Anthony J. Celebrezze, warned the Committee that giving the FDA jurisdiction over tobacco products "might well" lead to a ban and that such a ban would be contrary to the intent of Congress and the will of the American public. See 1964 Hearings at 18 (stating that a ban 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").

Following the hearings and consideration of the various bills, Congress responded to the Surgeon General's report by enacting The Federal Cigarette Labeling and Advertising Act (Cigarette Labeling Act), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331 *et seq.).* In general, the Cigarette Labeling Act required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards. 15 U.S.C. § 1333. The Cigarette Labeling Act also set forth congressional policy regard- ing regulation of tobacco products:

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

[20] The fact that the two proposed bills created a new jurisdictional category and new operative provisions for tobacco products is consistent with our analysis in part II.A, *supra,* which concludes that the current structure of the Act cannot accommodate tobacco products.

> relationship between smoking and health. 15 U.S.C. § 1331. Thus, the express goal of the Cigarette Labeling Act is to warn consumers about the health hazards of smoking while also protecting the national economy.

The district court apparently considered that the plaintiffs claimed that the separate preemption provision of the Cigarette Labeling Act precluded any further regulation of tobacco products except by Congress. See *Coyne Beahm*, 966 F.Supp. at 1385-1386. We do not think that the claim was so broad then, certainly it is not so broad now. While it is true that 15 U.S.C. § 1334, requires that no statement relating to smoking or health other than the statement required by § 1333, shall be required on any cigarette package, that is not a statement excluding other regulation of tobacco products. But the fact that Congress has, some 27 years after the establishment of the FDA in its present form, enacted the Cigarette Labeling Act, is strong evidence that Congress has reserved for itself the regulation of tobacco products rather than delegating that regulation to the FDA.

Congressional policy, as set out in the Cigarette Labeling Act, can- not be harmonized with the FDA's assertion of jurisdiction over tobacco products. First, by enacting the Cigarette Labeling Act rather than other proposed legislation, Congress clearly rejected the proposed regulatory role for the FDA. Next, the Act charges the FDA with protecting the public health, but does not authorize the FDA to consider protection of commerce and the national economy. Thus, by the terms of its enabling statute, the FDA is not capable of complying with Congress' stated policy regarding the regulation of tobacco products. In addition, the congressionally-established regulatory plan of the Cigarette Labeling Act directly contradicts the FDA's mandatory requirements set forth in the Act. As discussed *supra* in part II.A, the Act prohibits the sale or distribution of unsafe devices. See, e.g., 21 U.S.C. §§ 331(a), 352(j). In contrast, the Cigarette Labeling Act recognizes the unsafe and dangerous nature of cigarettes, but permits continued marketing with consumer warnings. 15 U.S.C. §§ 1331, 1333. The decision by Congress to allow continued marketing of unsafe products cannot be reconciled with the operative provisions of the Act, primarily because the Act does not allow FDA consideration of the factors involved in Congress' policy determination. See 15 U.S.C. § 1331(2) (establishing policy of protecting "commerce and the national economy"). Finally, in developing the Cigarette Labeling Act, Congress clearly considered and rejected a role for the FDA. The government does not produce any legislative history to the contrary. The legislative history of the Cigarette Labeling Act is thus important to understanding congressional intent because it reflects the historical context in which the Cigarette Labeling Act was developed. See *Radowich v. United States Att'y,* 658 F.2d 957, 961 (4th Cir.1981) (stating that courts should look at the "clearly expressed intention as expressed without dissent in the legislative history" to be certain that their construction of a statute is consistent with the "manifest purpose as clearly mirrored in the legislative history"). Thus, the Cigarette Labeling Act and the context in which it was enacted provides evidence of Congress' intent that the FDA not have jurisdiction over tobacco products. Subsequent legislation by Congress reinforces our understanding of this expressed congressional intent.

The Cigarette Labeling Act's advertising and labeling regulations originally were set to expire on June 30, 1969. In response, the Federal Communications Commission (FCC) introduced a proposal to ban all television and radio cigarette advertising. 34 Fed. Reg. 1959 (1969). In addition, the Federal Trade Commission (FTC) renewed its proposed rule from 1964. See 34 Fed.Reg. 7917 (1969) (citing health hazards of smoking and proposing warning

statements for cigarette packages and advertisements).21 Again, Congress debated the role of administrative agencies in the regulation of tobacco products. See generally Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong., 1st Sess. (1969). The House Report stated:

> The regulations [proposed by the FCC and the FTC] raise basic constitutional questions and would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities. These activities 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. . . .

Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy . . ., [and] has stated its intention to be the exclusive policymaker on the subject matter . . . . H.R. Rep. No. 289, at 4-5.

Following these debates and hearings, Congress amended the Cigarette Labeling Act by enacting the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970). Basically, the 1969 Act reenacted the Cigarette Labeling Act, but with several amendments.22 Notably, Congress did not amend or replace 15 U.S.C. § 1331, the provision setting out its policy determination regarding the regulation of tobacco products.

Congress showed a continuing interest in the regulation of tobacco products with the Alcohol and Drug Abuse Amendments of 1983, Pub.L.No.98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. §§ 290aa *et seq.*). These amendments require the Secretary of HHS, FDA's parent agency, to submit certain reports to Congress every three years. 42 U.S.C. § 290aa-2(b). The statute directs the Secretary to report to Congress current findings on "the addictive property of tobacco" and to recommend "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C.§ 290aa-2(b)(2)-(3). This statute evidences Congress' awareness of the addictive nature of tobacco products and its intent to retain control over further regulatory action.

In 1984, Congress again amended the Cigarette Labeling Act, but retained the basic regulatory approach established in 1965. See Comprehensive Smoking Education Act (Smoking Education Act), Pub. L. No. 98-474, 98 Stat. 2200 (1984) (amending the Cigarette Labeling Act). The Smoking Education Act required rotating warnings on cigarette packaging and advertising, 15 U.S.C. § 1333; established an Interagency Committee on Smoking and Health, including members from the FTC, the Department of Education, and the Department of Labor, but not from the FDA, 15 U.S.C. § 1341(b); and required annual disclosure of tobacco ingredients to the Secretary of HHS, 15 U.S.C. § 1335a. Quoting U.S. Surgeon General Dr. C. Everett Koop, the House Report recommending this legislation described cigarette smoking as "the most important public issue of our time." H.R. Rep. No. 805, 98th Cong., 2d Sess., at 12 (1984). Consistent with the prior actions of Congress discussed above, the House Report

---

[21] We note that the FDA took no action at this time.

[22] For example, the 1970 amendments changed the wording of the warning to be included on cigarette packages, 15 U.S.C. § 1333; revised § 1334's express preemption provision; and made it unlawful to advertise cigarettes on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 1335.

recognized that "[f]ederal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes." H.R. Rep. 805, at 12.

In 1986, Congress created a similar regulatory program for smoke- less tobacco, but with some additions.23 Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), Pub.L.No.99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C.§§ 4401-4408). In general, the Smokeless Tobacco Act required specific health warnings in smokeless tobacco advertising and on packaging, 15 U.S.C. § 4402(a),(b); authorized the FTC to issue specified regulations regarding the content and form of label warnings, 15 U.S.C. § 4402(c); banned advertising on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 4402(f); and required annual ingredient and nicotine-level reporting to the HHS Secretary, 15 U.S.C. § 4403. In addition, the Smokeless Tobacco Act authorized the Secretary of HHS to develop a program for informing the public of the health hazards caused by use of smokeless tobacco. 15 U.S.C. § 4401(a). Specifically, the Secretary is instructed to make this information available to school systems for educational purposes. 15 U.S.C. § 4401(a)(1)(B). The statute also provided for technical and financial assistance to States for their development of educational programs about the dangers of smokeless tobacco and for establishing 18 as the minimum age for purchasing smokeless tobacco. 15 U.S.C. § 4401(b). 24 Finally, the Smokeless Tobacco Act requires the Secretary of HHS to submit biennial reports to Congress containing "a description of the effects of health education efforts," "an evaluation of the health effects of smokeless tobacco products," and "recommendations for legislation and administrative action." 15 U.S.C. § 4407(a).

Like the Cigarette Labeling Act, the Smokeless Tobacco Act also contains an express preemption provision. See 15 U.S.C. § 4406 (pro- viding that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement"). However, as discussed in relation to the Cigarette Labeling Act, this express preemption provision does not detract from our examination of the statute as a tool for determining congressional intent. In recommending passage of the Smokeless Tobacco Act, the House Report cited particular concerns about the popularity of smokeless tobacco with minors. See S. Rep. No. 209, 99th Cong., at 4 (1985), reprinted in 1986 U.S.C.C.A.N. 7, 10 (stating that "a major reason for the development of a legislative proposal is the alarming incidence of use by children"). Thus, in 1986, Congress considered the very issues that the FDA now purports to address in its proposed regulations.

Within the context of the FDA's repeated stated positions that it had no jurisdiction, Congress enacted comprehensive legislation addressing many of the activities that the FDA now attempts to regulate, based on the same concerns relating to youth use now cited by the FDA. The enactment of the Smokeless Tobacco Act in no way supports a conclusion that Congress intended to give the FDA jurisdiction over tobacco products. To the contrary, the detailed scheme created by Congress evidences its intent to retain authority over regulation of smokeless tobacco. Cf. *Patterson v. McLean Credit Union*, 491 U.S. 164, 181 (1989) (stating that courts "should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the

[23] It is worth noting that Congress adopted a very similar approach to the one taken in the Cigarette Labeling Act, even though it had expressly recognized the addictive nature of tobacco. 42 U.S.C. § 290aa-2(b)(2).

[24] As discussed below, Congress built on the youth education and age limit provisions of the Smokeless Tobacco Act in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub.L.No. 102-321, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26).

detailed remedial scheme constructed in a later statute"). The FDA may not, without empowerment by Congress, construct what it believes is a "better" regulatory scheme. *MCI,* 512 U.S. at 234 . If the FDA believed that additional regulation was needed, the Secretary should have recommended such action to Congress, as directed in the Smokeless Tobacco Act. 15 U.S.C. § 4407(a)(4).

In 1992, Congress again addressed the problem of youth access to tobacco products. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394, focused on regulation at the state level by providing financial incentives to States which enact and enforce access restrictions for individuals under age 18. 42 U.S.C. § 300x-26.25

The 1992 Amendments express clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products. How- ever, the FDA's proposed regulatory scheme would preempt much state regulation in this area, including more stringent regulations than those proposed by the FDA. The Act prohibits States from imposing on devices any requirements "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a). Thus, if the Act applied to tobacco products, § 360k(a) would prohibit States from addressing the problem of youth access. The FDA responds, FDA Red Br. p.67, n.16, that States "might" qualify for exemptions from preemption under § 360k(b). However, the possibility of a discretionary exemption does not take away the inherent conflict between the state regulatory role established by Congress and the FDA's proposed scheme. In developing its regulatory scheme for tobacco products, Congress made a policy determination that state participation was necessary for effective regulation of youth access. Allowing the FDA to override this decision would be contrary to congressional intent.

Over the last 60 years, Congress has enacted numerous statutes and amendments for the regulation of tobacco products. Throughout this period, Congress was well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over tobacco products. Yet, Congress took no steps to overturn the FDA's interpretation of the Act, that it had no jurisdiction over tobacco products as customarily used. In fact, Congress deliberately rejected a role for the FDA during its consideration of various legislation from 1965 through 1993.26 Instead, Congress developed a regulatory scheme whereby it retained the position of policymaker for the industry.27 In addition, it developed a scheme whereby designated agencies would periodically report any new information and recommendations for legislation or regulation to Congress.28 Taken together, these actions by Congress are relevant and

[25] More specifically, States are eligible for the financial incentives only if they: (1) prohibit sales to individuals under age 18, 42 U.S.C. § 300x- 26(a)(1); (2) enforce the prohibition in a way that "can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18," 42 U.S.C. § 300x-26(b)(1); (3) conduct "random, unannounced inspections" of retailers to check compliance, 42 U.S.C. § 300x-26(b)(2)(A); and (4) make annual reports to the HHS Secretary regarding the manner and success of state enforcement activities, 42 U.S.C. § 300x-26(b)(2)(B).

[26] Between 1965 and 1993, at least 13 bills were introduced in Congress which would have given the FDA jurisdiction over tobacco products. None of these bills were enacted.

[27] Although Congress has given the FTC limited authority to regulate advertising related to tobacco products, this power is limited by the tobacco-specific legislation. 15 U.S.C. §§ 1336m, 4404-06.

[28] The HHS, FTC, and Interagency Committee are all directed to make periodic reports to Congress including information on the health effects of tobacco products, the addictive nature of tobacco products, cigarette advertising. See *e.g.,* 15 U.S.C. §§ 1337(a), (b), 1341(a)-(c); 42 U.S.C. § 290aa-2.

corroborative evidence that Congress never intended to give the FDA jurisdiction over tobacco products.

III. Conclusion

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. See *MCI,* 512 U.S. at 234 (stating that "our estimations, and the [FCC's] estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). In rejecting the agency's interpretation of its enabling statute, the MCI Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation . .. which may well be a better regime but is not the one that Congress established." *MCI,* 512 U.S. at 234 . Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is REVERSED. 29

HALL, Circuit Judge, dissenting:

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and "device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

As a consequence of this view, I must also reach those subordinate issues not discussed by the majority. I would affirm the denial of summary judgment to the companies on the issue of

[29] This footnote is added to make clear that the judgment of the district court regarding the construction of 21 U.S.C. § 360j(e), *Coyne Beahm,* 966 F.Supp. at 1399-1400, is vacated. The district court's construction of § 360j(e) was based on its erroneous holding that the FDA had authority to promulgate regulations regarding tobacco products. Had the district court reached the correct conclusion on the jurisdictional issue, there would have been no occasion to address the construction of § 360j(e). Accordingly, we vacate the district court's decision on that issue which is the subject of the government's appeal. We express no opinion on that question, and our decision should not be construed as either agreeing with or disagreeing with the district court's decision on the construction of § 360j(e).

the FDA's choice of the "combination-products" regulatory scheme. I believe, however, that the district court erred in ruling that the FDA cannot, as a matter of statutory law, restrict the advertising of tobacco pursuant to the agency's authority to regulate the "sale" of such products.

I

When reviewing an agency's construction of a statute, we must first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). The usual rule is to enforce the plain language of a statute according to its terms. *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989). Whether the language is plain is "determined by reference to the language itself, the specific context in which the language is used, and the broader con- text of the statute as a whole." *Robinson v. Shell Oil Company*, 519 U.S. 337 , ___, 117 S. Ct. 843, 846 (1997). Here, the language is plain, and the context does not command a result contrary to the plain meaning.

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term `drug' means . . . articles (other than food) intended to affect the structure or function of the body." 21 U.S.C.§ 321(g)(1)(C). While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence elsewhere demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal" meaning of "drug" and "de- vice," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. See 61 Fed. Reg. 44665-66 (1996). Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction, see 61 Fed.Reg. 44634, 44701-39; (2) most consumers do in fact use tobacco products to satisfy addiction, see *id.* at 44233; (3) the manufacturers have long known that consumers use the products for the pharmacological effects, see *id.* at 44849; and (4) the manufacturers design the products to deliver active doses of nicotine, see *id.* at 44951. On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales. *Coyne Beahm*, 966 F.Supp. at 1388-92. In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of "intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. b. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body -- nicotine addiction-- is intended when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "in- tend," and it is ordinarily the one we should use. See *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 & n.7 (D.C.Cir. 1980) [hereinafter *ASH*] (citing as examples *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F.Supp. 847 (D.N.J.1959), in which cigarettes were marketed as weight reduction aids, and *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F.Supp. 336 (D.N.J.1953), in which cigarettes were marketed as helping to prevent respiratory diseases). No other court, however, has been confronted with the type and quantity of evidence collected during the rulemaking process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled sub- stances. It strikes me as patently absurd to contend that cigarettes and smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any `indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.," *Hubbard v. United States*, 514 U.S. 695, 703 (1995) (quoting *BFP v. Resolution Trust Corporation*, 511 U.S. 531, 570 (1994) (Souter, J., dissenting)), quoted in *Dunn v. Commodity Futures Trad- ing Commission*, 117 S.Ct. 913, 916 (1997). The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" *Ron Pair,* 489 U.S. at 243 . In other words, given the plain language used in § 321(g)(1)(C), the question should be whether the intent manifested by the words used -- that tobacco products are "drugs delivery devices" subject to FDA regulation -- is trumped by evidence to the contrary.

The majority seeks to show that the "context" of these readily understood words demonstrates that Congress really meant something else where tobacco is concerned. This search

for context takes us into "the overall regulatory scheme created by Congress" (Maj.op. at 20) and "the history of evolving congressional regulation in the area" (Maj.op. at 19) (citation omitted), the legislative history of the FDCA and related statutes, and even congressional inaction. I will address each avenue explored by the majority.

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of cigarettes is completely at odds with such mandate; ergo, the regulations must be struck down. But whether the regulations contravene the statute is a question wholly apart from whether any regulations could be issued. How the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. See Fed.Reg. 44398-99, 44412-13. It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years.[30]

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute.

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates--and equally clearly, broader than any strict medical definition might otherwise allow. [W]e are all the more convinced that we must give effect to congressional intent in view of the well- accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . . . *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).[31] The majority starts off on the wrong foot when it

[30] Dissent footnote #1: As a corollary to this third point, the majority also relies on congressional refusal to enact legislation that would have expressly given the FDA the authority it now claims. See Maj.op. at 32-34. To whatever extent this inaction may be interpreted as "ratification" of the FDA's prior (no tobacco jurisdiction) position, it would appear that Congress's continued inaction in the face of all that has followed the FDA's announcement of the proposed rule three years ago (see 60 Fed.Reg. 41314) would more than offset any ratification effect to be gleaned from the earlier inaction.

[31] Dissent footnote #2: Justice Frankfurter put it this way: The purposes of this legislation [FDCA] thus touch

asks "whether Congress intended to delegate jurisdiction over tobacco products to the FDA." Maj.op. at 19.

Congress did not "intend" that any particular product be included; as the district court noted, "[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products." *Coyne Beahm v. FDA,* 966 F.Supp. at 1380. An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious -- that the FDCA was not originally directed at tobacco -- gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a "drug" under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate "drugs" and "devices." The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when health claims were made. See Maj. op. at 29-30. The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. See, *e.g., ASH,* 655 F.2d 236. The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

> [i]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 16 (1969). Well, the "cold hard facts" are now in.

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See *Rust v. Sullivan,* 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court added the following caveat:

---

phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. *United States v. Dotterweich,* 320 U.S. 277, 280 (1943).

> Nothing in this opinion should suggest that the[FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.... The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted]. *ASH*, 655 F.2d at 242 n.10.

Under the facts found by the FDA during the rulemaking process, it is now a scientific certainty that nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction; even more important to my mind is the new evidence that the manufacturers design their products to sustain such addiction. The administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open.

The Tobacco Statutes

As products of the democratic process, each tobacco-specific statute is a balance of health, economic, and other concerns. The majority cites this body of legislation as "corroborating evidence of established congressional intent" to withhold jurisdiction over tobacco from the FDA. Maj.op. at 34. Again, I think the majority's approach ignores the fundamental source of intent, the words of the statute itself. Nevertheless, closer examination of these tobacco statutes reveals that they form something less than Congress's "comprehensive program" to address the tobacco problem. Absent a discernable intent to exclude future FDA action,[32] that these statutes were written with knowledge that the FDA foreswore jurisdiction over tobacco does not supply that intent. The first in this series, the Federal Cigarette Labeling and Advertising Act (FCLAA),[33] was enacted in response to the Surgeon General's groundbreaking 1964 report linking smoking to health problems. The companies describe it as a statute that "set the boundaries of the federal regulatory role," "clearly expresses a congressional intent that precludes FDA jurisdiction over tobacco products," "embodied the view that Congress, itself, should retain all policy making authority as to tobacco, even in areas open to regulation," "ratified the established understanding that FDA does not have jurisdiction over tobacco products," "ruled out any later reading of the FDCA as an `implicit' delegation to FDA . . . of authority to decide whether or how to regulate tobacco products and whether to ban them." Companies' Opening br.13, 18-20. An examination of the statute reveals something considerably more modest, something that will not bear anything approaching the weight placed upon it by the companies or the majority. The majority's focus is § 1331, which reads:

[32] Dissent footnote #3: Congress certainly knows how to exempt tobacco. The only mention of tobacco in the FDCA was added in 1994 to explicitly remove tobacco from the new exemption of "dietary supplements" from the definition of "drug." See Pub.L.No. 103-407,§ 3(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)). The criminal laws regarding narcotics incorporate the definition of "drug" found in the FDCA, see 21 U.S.C. § 802(12), but the definition of "controlled substance," which includes "a drug," specifically excludes tobacco. See 21 U.S.C. § 802(6).

[33] Dissent footnote #4: The Comprehensive Smokeless Tobacco Health and Education Act, 15 U.S.C. §§ 4401-4407, more or less mirrors the FCLAA.

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

This is a far cry from a comprehensive federal tobacco program; it is little more than a mild response to one of the earliest official recognitions of an emerging health issue.

The narrowness of the FCLAA was emphasized in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), where the court was con- fronted with a post-FCLAA ruling by the FCC that required radio and television stations that carried cigarette commercials to devote significant broadcast time to permit the case to be made against smoking. Then, as they do today, the tobacco companies argued that the FCLAA embodied a clear congressional intent to preclude intrusions into the regulation of tobacco by any agency. See *id.* at 1088. Judge Bazelon, however, saw things differently:

> [T]here are positive indications that Congress's "comprehensive program" was directed at the relatively narrow specific issue of regulation of "cigarette labeling and advertising." . . . Nothing in the [FCLAA] indicates that Congress had any intent at all with respect to other types of regulation by other agencies-- much less that it specifically meant to foreclose all such regulation. If it meant to do any- thing so dramatic, it might reasonably be expected to have said so directly . . . .

Id. at 1089 (footnotes omitted) (quotations in original). [34] The next thirty years would see several more small steps that, even when considered together, fall far short of a comprehensive program, and even shorter of a demonstration that Congress intended to preclude the exercise of jurisdiction now being asserted by the FDA.

Following the FCLAA, the next step in what the companies characterize as Congress's ongoing program was the Public Health Cigarette Smoking Act of 1969, which amended the FCLAA in response to pro- posed incursions into the field by the FCC and FTC by way of pro- posed regulations that would have restricted tobacco advertising. Again, Congress addressed only advertising, this time in the electronic media, and short-circuited the roles proposed by the agencies for themselves.

Thirteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983, which simply directs the Secretary of HHS to report to Congress every three years on "the health consequences of drug abuse in the United States [and] current research findings made with

---

[34] Dissent footnote #5: In *Cippolone v. Liggett Group, Inc.*, 505 U.S. 504, 514 (1992), the Court described the purposes of the FCLAA as informing the public of the health risks and "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling advertising regulations" [footnote omitted].

respect to drug abuse, including current findings on . . . the addictive property of tobacco" and to include recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b). This does not, as the majority asserts, "evidence[ ] Congress' . . . intent to retain control over further regulatory action." Maj. op. at 39. It is more an acknowledgment that because the HHS (and the FDA), as the experts in the complex field of drug abuse, had and would continue to have a crucial role to play, the Secretary was required to ask Congress for any additional tools it needed get to perform that role effectively.

The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 [ADAMHA], the last brick in the pur- ported congressional tobacco program, provides financial incentives to the States to enforce their own restrictions on access to tobacco by minors. The majority argues that the FDA regulations would conflict with this congressional determination that the States should take an active role in addressing the youth access problem because the FDCA preempts any different restrictions on devices. See 21 U.S.C. § 360k(a). This overstates the case.

ADAMHA restructured block grant programs aimed at substance abuse and mental health services; only a few provisions relate to underage smoking. See 42 U.S.C. § 300x-26. ADAMHA does not demonstrate an intent on Congress's part that the states "take the primary role" in addressing the problem of underage smoking, and it certainly does not "establish" a regulatory role for the states. Maj. op. at 42-43. Although the FDA's proposed regulations would preempt some state laws, the exercise of FDA authority over tobacco would not "prohibit the States from addressing the problem of youth access." *Id.* The proposed rule can co-exist with most of the states' separate laws prohibiting sales to minors and imposing other restrictions on tobacco sales. Even the few more stringent state or local restrictions that are preempted by the FDA's proposed regulations (see 61 Fed.Reg. 44548-50) might qualify for an exemption from preemption, thereby further minimizing conflicts. See 21 U.S.C. § 360k(b). An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other. See *Connecticut Nat'l Bank v. Germain,* 503 U.S. 249, 253 (1992) ("Redundancies across statutes are not unusual events in drafting, and so long as there is no `positive repugnancy' between two laws, a court must give effect to both") (internal citation omitted).

C

Tobacco is different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turn- around in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert -- the FDA -- the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

The FDA's denials that it had any authority over tobacco were certainly part of the background against which Congress passed tobacco- related legislation in the thirty years following the Surgeon General's 1964 report, but this series of statutes is hardly an argument for "legislative ratification" (Maj. op. at 32 n.18) of the FDA's prior position that the agency was

powerless to act. It is agreed, moreover, that an agency is permitted to change its mind, particularly in response to new facts, so the real question is whether all that has gone before -- the tobacco statutes, the consistent denials by the FDA -- is sufficient to demonstrate a clear intent on Congress's part to preclude FDA jurisdiction. The evidence offered by the companies falls far short.

III

Having decided that the FDA has no jurisdiction over tobacco products, the majority had no reason to address whether cigarettes and smokeless tobacco were "devices" and whether the choice of regulatory regime -- as a combination product, pursuant to the device authorities -- was permissible. I agree with and adopt the district court's reasoning on these points entirely. See *Coyne Beahm,* 966 F.Supp. at 1393-97.

IV

Another issue not reached by the majority is whether the FDA may restrict the advertising of tobacco products.35 On this point, I disagree with the district court's conclusion that the advertising regulations exceeded the FDA's statutory authority.

The FDA found that "cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." 61 Fed. Reg. 45239. Minors are particularly vulnerable to Madison Avenue's exhortations, plastered on racing cars and outfield fences, to be cool and smoke, be manly and chew, and the FDA found "compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products." *Id.* at 45247. [36] The FDA chose to attack the problem by attempting to reduce the pressures to start using tobacco in the first place.

The pertinent portion of the of the 1976 Medical Device Amendments, 21 U.S.C. § 360j(e), provides:

> The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . . [by prescription] or upon such other conditions as the Secretary may pre- scribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

The FDA relies on this section as authority for the regulations restricting the advertising of tobacco products, its rationale being that the authority to restrict the "sale" of or to impose "other conditions" on a product includes within it the authority to restrict the means by which such sales are generated.

---

[35] Dissent footnote #6: In view of its ruling on statutory grounds, it was unnecessary for the district court to reach the companies' constitutional objections to the advertising restrictions. *Coyne Beahm,* 966 F.Supp. at 1400 n.33. Because neither party has briefed the First Amendment issue, I do not discuss it here.

[36] Dissent footnote #7: For example, one study cited in the rulemaking record found that "30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking." *Id.* at 45246 (citing Fischer, Schwartz & Richards, *Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe the Camel*, Journal of the American Medical Association, 1991).

Examples of obviously permissible restrictions of the "sale" of a product are regulations regarding where, when, by whom, and to whom a product can be sold. But is a restriction on advertising a restriction of the "sale" of a product? The district court found that the plain meaning of the words precluded advertising restrictions: "Both as ordinarily defined and as used in the phrase `may . . . be restricted to sale, distribution, or use,' the word `sale' does not encompass the advertising or promotion of a product." *Coyne Beahm,* 966 F.Supp. at 1398 (footnote omitted). But even the dictionary entry cited in the district court's opinion defines "sale" as "the act of selling"; the term "sales" is defined as "[a]ctivities involved in the selling of goods and services." *Id.* at n.23. Under a *Chevron* step-two analysis -- "if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute[,]" *Chevron,* 467 U.S. at 843 (footnote omitted) -- we need only find that the agency construction is a reasonable one, not the best one. See *id.* at n.11. I believe the term "sale" is ambiguous enough to encompass the concept of "offer for sale."

The district court also distilled an intent to withhold the authority asserted by the FDA from the use of the terms "offer for sale" and "advertising" elsewhere in 1976 legislation. See *Coyne Beahm,* 966 F.Supp. at 1398-99. However, while the "language and design of the statute as a whole" (*K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988)) might raise a question about the extent of the FDA's authority in this area, it does not mandate a conclusion that Congress intended to foreclose the FDA from imposing advertising restrictions. There is simply no conclusive evidence of intent either way; the phrase is simply ambiguous, both in isolation and with reference to the context in which it is used.

The term "sale, distribution and use," which is used only once in the entire FDCA, can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home. As I have noted above, tobacco is different from the run-of-the-mine drugs and devices in the FDA's bailiwick, and the nature of the differences dictate new approaches to fight the dangers posed. Because the precise approach chosen might not have been considered by the drafters of the statute does not necessarily preclude it. The interpretation is a reasonable one and, therefore, we must defer to the agency.

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.

Begin Supreme Court Decision:

U.S.S.Ct. #98-1152 Argued 12/1/99, Decided 3/21/00.

U.S. Supreme Court

FOOD AND DRUG ADMINISTRATION *et al. v. BROWN & WILLIAMSON TOBACCO CORP. et al.*

certiorari to the united states court of appeals for the fourth circuit

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

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

Held: ***Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed***. Pp. 8-40.

(a) Because this case involves an agency's construction of a statute it administers, the Court's analysis is governed by *Chevron U.S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 , under which a reviewing court must first ask whether Congress has directly spoken to the precise question at issue, *id.*, at 842. If so, the court must give effect to Congress' unambiguously expressed intent. *E.g., id.*, at 843. If not, the court must defer to the agency's

construction of the statute so long as it is permissible. See, *e.g.*, *INS* v. *Aguirre-Aguirre*, 526 U.S. 415, 424 . In determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme. *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 569 . In addition, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See, *e.g.*, *United States* v. *Estate of Romani*, 523 U.S. 517 , 530-531. Finally, the court must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218, 231 . Pp. 8-10.

(b) ***Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction.*** A fundamental precept of the FDCA is that any product regulated by the FDA that remains on the market must be safe and effective for its intended use. See, *e.g.*, §393(b)(2). That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit. *United States* v. *Rutherford*, 442 U.S. 544, 556 . In its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding, see, *e.g.*, §331(a), and device classification, see, *e.g.*, §360e(d)(2)(A), provisions. In fact, based on such provisions, the FDA itself has previously asserted that if tobacco products were within its jurisdiction, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. Congress, however, has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects. See 15 U.S.C. §1331. Thus, an FDA ban would plainly contradict congressional intent. Apparently recognizing this dilemma, the FDA has concluded that tobacco products are actually "safe" under the FDCA because banning them would cause a greater harm to public health than leaving them on the market. But this safety determination--focusing on the relative harms caused by alternative remedial measures--is not a substitute for those required by the FDCA. Various provisions in the Act require the agency to determine that, at least for some consumers, the product's therapeutic benefits outweigh the risks of illness or serious injury. This the FDA cannot do, because tobacco products are unsafe for obtaining any therapeutic benefit. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit. Pp. 10-20.

(c) ***The history of tobacco-specific legislation also demonstrates that Congress has spoken directly to the FDA's authority to regulate tobacco products.*** Since 1965, Congress has enacted six separate statutes addressing the problem of tobacco use and human health. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U.S.C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through any electronic communication medium regulated by the Federal Communications Commission, see §§1335, 4402(f); require the Secretary of HHS to report every

three years to Congress on research findings concerning tobacco's addictive property, 42 U.S.C. §290aa-2(b)(2); and make States' receipt of certain federal block grants contingent on their prohibiting any tobacco product manufacturer, retailer, or distributor from selling or distributing any such product to individuals under age 18, §300x-26(a)(1). This tobacco-specific legislation has created a specific regulatory scheme for addressing the problem of tobacco and health. And it was adopted against the backdrop of the FDA consistently and resolutely stating that it was without authority under the FDCA to regulate tobacco products as customarily marketed. In fact, Congress several times considered and rejected bills that would have given the FDA such authority. Indeed, Congress' actions in this area have evidenced a clear intent to preclude a meaningful policymaking role for any administrative agency. Further, Congress' tobacco legislation prohibits any additional regulation of tobacco product labeling with respect to tobacco's health consequences, a central aspect of regulation under the FDCA. Under these circumstances, it is evident that Congress has ratified the FDA's previous, long-held position that it lacks jurisdiction to regulate tobacco products as customarily marketed. Congress has created a distinct scheme for addressing the subject, and that scheme excludes any role for FDA regulation. Pp. 20-37.

(d) Finally, the Court's inquiry is shaped, at least in some measure, by the nature of the question presented. *Chevron* deference ***is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps.*** See 467 U.S., at 844 . ***In extraordinary cases, however, there may be reason to hesitate*** before concluding that Congress has intended such an implicit delegation. ***This is hardly an ordinary case.*** Contrary to the agency's position from its inception until 1995, the ***FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy.*** In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. ***It is highly unlikely that Congress would leave the determination as to whether the sale of tobacco products would be regulated, or even banned, to the FDA's discretion in so cryptic a fashion.*** See *MCI Telecommunications,* 512 U.S., at 231 . Given tobacco's unique political history, as well as the breadth of the authority that the FDA has asserted, the Court is obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power. Pp. 37-39.

(e) No matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. Courts must take care not to extend a statute's scope beyond the point where Congress indicated it would stop. *E.g., United States* v. *Article of Drug ... Bacto-Unidisk,* 394 U.S. 784, 800 . P. 40. 153 F. 3d 155, affirmed.

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

FOOD AND DRUG ADMINISTRATION, *et al.*, PETITIONERS *v.* BROWN & WILLIAMSON TOBACCO CORPORATION *et al.* on writ of certiorari to the united states court of appeals for the fourth circuit

[March 21, 2000]

Justice O'Connor delivered the opinion of the Court.

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

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

I

The FDCA grants the FDA, as the designee of the Secretary of Health and Human Services, the authority to regulate, among other items, "drugs" and "devices." See 21 U.S.C. §§321(g)-(h), 393 (1994 ed. and Supp. III). The Act defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. §321(g)(1)(C). It defines "device," in part, as "an instrument, apparatus, implement, machine, contrivance, ... or other similar or related article, including any component, part, or accessory, which is ... intended to affect the structure or any function of the body." §321(h). The Act also grants the FDA the authority to regulate so-called "combination products," which "constitute a combination of a drug, device, or biologic product." §353(g)(1). The FDA has construed this provision as giving it the discretion to regulate combination products as drugs, as devices, or as both. See 61 Fed. Reg. 44400 (1996).

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

On August 28, 1996, the FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." *Id., a*t 44396. The FDA determined that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices," and therefore it had jurisdiction under the FDCA to regulate tobacco products as customarily marketed--that is, without manufacturer claims of therapeutic benefit. *Id., a*t 44397, 44402. First, the FDA found that tobacco products " `affect the structure or any function of the body' " because nicotine "has significant pharmacological effects." *Id., a*t 44631. Specifically, nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight. *Id., a*t 44631-44632. Second, the FDA determined that these effects were "intended" under the FDCA because they "are so widely known and foreseeable that [they] may be deemed to have been intended by the manufacturers," *id., a*t 44687; consumers use tobacco products "predominantly or nearly exclusively" to obtain these effects, *id., a*t 44807; and the statements, research, and actions of manufacturers revealed that they "have `designed' cigarettes to provide pharmacologically active doses of nicotine to consumers," *id., a*t 44849. Finally, the agency concluded that cigarettes and smokeless tobacco are "combination products" because, in addition to containing nicotine, they include device components that deliver a controlled amount of nicotine to the body, *id., a*t 45208-45216.

Having resolved the jurisdictional question, the FDA next explained the policy justifications for its regulations, detailing the deleterious health effects associated with tobacco use. It found that tobacco consumption was "the single leading cause of preventable death in the United States." *Id., a*t 44398. According to the FDA, "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." *Ibid.* The agency also determined that the only way to reduce the amount of tobacco-related illness and mortality was to reduce the level of addiction, a goal that could be accomplished only by preventing children and adolescents from starting to use tobacco. *Id., a*t 44398-44399. The FDA found that 82% of adult smokers had their first cigarette before the age of 18, and more than half had already become regular smokers by that age. *Id., a*t 44398 . It also found that children were beginning to smoke at a younger age, that the prevalence of youth smoking had recently increased, and that similar problems existed with respect to smokeless tobacco. *Id., a*t 44398-44399. The FDA accordingly concluded that if "the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely ever to begin." *Id., a*t 44399.

Based on these findings, the FDA promulgated regulations concerning tobacco products' promotion, labeling, and accessibility to children and adolescents. See *id., a*t 44615-44618. The access regulations prohibit the sale of cigarettes or smokeless tobacco to persons younger than 18; require retailers to verify through photo identification the age of all purchasers

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

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

Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed suit in United States District Court for the Middle District of North Carolina challenging the regulations. See *Coyne Beahm, Inc.* v. *FDA,* 966 F. Supp. 1374 (1997). They moved for summary judgment on the grounds that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, the regulations exceeded the FDA's authority under 21 U.S.C. §360j(e), and the advertising restrictions violated the First Amendment. Second Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97-1604 (CA4), Tab No. 40; Third Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97-1604 (CA4), Tab No. 42. The District Court granted respondents' motion in part and denied it in part. 966 F. Supp., at 1400. The court held that the FDCA authorizes the FDA to regulate tobacco products as customarily marketed and that the FDA's access and labeling regulations are permissible, but it also found that the agency's advertising and promotion restrictions exceed its authority under §360j(e). *Id., a*t 1380-1400. The court stayed implementation of the regulations it found valid (except the prohibition on the sale of tobacco products to minors) and certified its order for immediate interlocutory appeal. *Id., a*t 1400-1401.

The Court of Appeals for the Fourth Circuit reversed, holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. See 153 F.3d 155 (1998). Examining the FDCA as a whole, the court concluded that the FDA's regulation of tobacco products would create a number of internal inconsistencies. *Id.,* at 162-167. Various provisions of the Act require the agency to determine that any regulated product is "safe" before it can be

sold or allowed to remain on the market, yet the FDA found in its rulemaking proceeding that tobacco products are "dangerous" and "unsafe." *Id.,* at 164-167. ***Thus, the FDA would apparently have to ban tobacco products, a result the court found clearly contrary to congressional intent.*** *Ibid.* This apparent anomaly, the Court of Appeals concluded, demonstrates that Congress did not intend to give the FDA authority to regulate tobacco. *Id.,* at 167. The court also found that evidence external to the FDCA confirms this conclusion. ***Importantly, the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco***, and Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position. See *id., a*t 168-176. In fact, the court reasoned, Congress has considered and rejected many bills that would have given the agency such authority. See *id., a*t 170-171. This, along with the absence of any intent by the enacting Congress in 1938 to subject tobacco products to regulation under the FDCA, demonstrates that Congress intended to withhold such authority from the FDA. *Id.,* at 167-176. Having resolved the jurisdictional question against the agency, the Court of Appeals did not address whether the regulations exceed the FDA's authority under 21 U.S.C. §360j(e) or violate the First Amendment. See 153 F. 3d, at 176, n. 29.

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

II

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

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. ***Because this case involves an administrative agency's construction of a statute that it administers***, our analysis is governed by *Chevron U.S. A. Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984). Under *Chevron,* a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.,* at 842. If Congress has done so, the inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.,* at 843; see also *United States* v. *Haggar Apparel Co.,* 526 U.S. 380, 392 (1999); *Holly Farms Corp.* v. *NLRB,* 517 U.S. 392, 398 (1996). ***But if Congress has not specifically addressed the question***, a reviewing court must respect the

agency's construction of the statute ***so long as it is permissible***. See *INS* v. *Aguirre-Aguirre*, 526 U.S. 415, 424 (1999); *Auer* v. *Robbins*, 519 U.S. 452, 457 (1997). Such deference is justified because "[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron*, *supra*, at 866, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated, see *Rust* v. *Sullivan*, 500 U.S. 173, 187 (1991).

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning--or ambiguity--of certain words or phrases may only become evident when placed in context. See *Brown* v. *Gardner*, 513 U.S. 115, 118 (1994)("Ambiguity is a creature not of definitional possibilities but of statutory context"). ***It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."*** *Davis* v. *Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989). ***A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme,"*** *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 569 (1995), ***and "fit, if possible, all parts into an harmonious whole,"*** *FTC* v. *Mandel Brothers, Inc.*, 359 U.S. 385, 389 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See *United States* v. *Estate of Romani*, 523 U.S. 517, 530-531 (1998); *United States* v. *Fausto*, 484 U.S. 439, 453 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U.S. 218, 231 (1994).

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

A

Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. See 21 U.S.C. §393(b)(2)(1994 ed., Supp. III)(defining the FDA's mission); More Information for Better Patient Care: Hearing before the Senate Committee on Labor and Human Resources, 104th Cong., 2d Sess., 83 (1996)(statement of FDA Deputy Commissioner Schultz)("A fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold"). This essential purpose pervades the FDCA. For instance, 21 U.S.C. §393(b)(2)(1994 ed., Supp. III) defines the FDA's "mission" to include "protect[ing] the public health by ensuring that ... drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." The FDCA requires premarket approval of any new drug, with some limited exceptions, and states that the FDA "shall issue an order refusing to approve the application" of a new drug if it is not safe and effective for its intended purpose. §§355(d)(1)-(2), (4)-(5). ***If the FDA discovers after approval that a drug is unsafe or ineffective, it "shall, after due notice and opportunity for hearing to the applicant, withdraw approval" of the drug.*** 21 U.S.C. §§355(e)(1)-(3). ***The Act also requires the FDA to classify all devices into one of three categories. §360c(b)(1). Regardless of which category the FDA chooses, there must be a "reasonable assurance of the***

safety and effectiveness of the device." 21 U.S.C. §§360c(a)(1)(A)(i), (B), (C)(1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Even the "restricted device" provision pursuant to which the FDA promulgated the regulations at issue here authorizes the agency to place conditions on the sale or distribution of a device specifically when "there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. §360j(e). ***Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."*** *United States* v. *Rutherford*, 442 U.S. 544, 556 (1979).

In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness." 61 Fed. Reg. 44412 (1996). It found that the consumption of tobacco products "presents extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States." *Id., a*t 44398. ***It stated that "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths," and that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined."*** *Ibid.* ***Indeed, the FDA characterized smoking as "a pediatric disease,"*** *id., a*t 44421, ***because "one out of every three young people who become regular smokers ... will die prematurely as a result,"*** *id., a*t 44399.

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

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See §360c(b)(1). The agency relies on a device's classification in determining the degree of control and regulation necessary to ensure that there is "a reasonable assurance of safety and effectiveness." 61 Fed. Reg. 44412 (1996). The FDA has yet to classify tobacco products. Instead, the regulations at issue here represent so-called "general controls," which the Act entitles the agency to impose in advance of classification. See *id., a*t 44404-44405. Although the FDCA prescribes no deadline for device classification, the FDA has stated that it

will classify tobacco products "in a future rulemaking" as required by the Act. *Id.*, *a*t 44412. ***Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "presen[t] a potential unreasonable risk of illness or injury."*** 21 U.S.C. §360c(a)(1)(C). ***As Class III devices, tobacco products would be subject to the FDCA's premarket approval process.*** See 21 U.S.C. §360c(a)(1)(C)(1994 ed., Supp. III); 21 U.S.C. §360e; 61 Fed. Reg. 44412 (1996). ***Under these provisions, the FDA would be prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof."*** 21 U.S.C. §360e(d)(2)(A). ***In view of the FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.***

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

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." 7 U.S.C. §1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. See Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. 89-92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102-321, §202, 106 Stat. 394. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine's pharmacological effects. See, *e.g.*,U.S. Dept. of Health, Education, and Welfare, U.S. Surgeon General's Advisory Committee, Smoking and Health 25-40, 69-75 (1964)(hereinafter 1964 Surgeon General's Report)(concluding that cigarette smoking causes lung cancer, coronary artery disease, and chronic bronchitis and emphysema, and that nicotine has various pharmacological effects, including stimulation, tranquilization, and appetite suppression); U.S.

Dept. of Health and Human Services, Public Health Service, Health Consequences of Smoking for Women 7-12 (1980)(finding that mortality rates for lung cancer, chronic lung disease, and coronary heart disease are increased for both women and men smokers, and that smoking during pregnancy is associated with significant adverse health effects on the unborn fetus and newborn child); U.S. Dept. of Health and Human Services, Public Health Service, Why People Smoke Cigarettes (1983), in Smoking Prevention Education Act, Hearings on H. R. 1824 before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 32-37 (1983)(hereinafter 1983 House Hearings)(stating that ***smoking is "the most widespread example of drug dependence in our country," and that cigarettes "affect the chemistry of the brain and nervous system***"); U.S. Dept. of Health and Human Services, Public Health Service, The Health Consequences of Smoking: Nicotine Addiction 6-9, 145-239 (1988)(hereinafter 1988 Surgeon General's Report)(concluding that ***tobacco products are addicting in much the same way as heroin and cocaine, and that nicotine is the drug that causes addiction***). Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that "commerce and the national economy may be ... protected to the maximum extent consistent with" consumers "be[ing] adequately informed about any adverse health effects." 15 U.S.C. §1331. Congress' decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy ... to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.

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

It may well be, as the FDA asserts, that "these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products." *Id., a*t 44413. But the FDA's judgment that leaving tobacco products on the market "is more effective in achieving public health goals than a ban," *ibid.*, is no substitute for the specific safety determinations required by the FDCA's various operative provisions. Several provisions in the Act require the FDA to determine that the *product itself* is safe as used by consumers. That is, the

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

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

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

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

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

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

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

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

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

detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect.

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

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

B

In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The "classic judicial task of reconciling many laws enacted over time, and getting them to `make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States* v. *Fausto*, 484 U.S., at 453 . This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States* v. *Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it ha[s] not been expressly amended." 523 U.S., at 530 -531.

Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health. See *supra*, at 14. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U.S.C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission (FCC), see §§1335, 4402(f); require the Secretary of Health and Human Services (HHS) to report every three years to Congress on research findings concerning "the addictive

property of tobacco," 42 U.S.C. §290aa-2(b)(2); and make States' receipt of certain federal block grants contingent on their making it unlawful "for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," §300x-26(a)(1).

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

On January 11, 1964, the Surgeon General released the report of the Advisory Committee on Smoking and Health. That report documented the deleterious health effects of smoking in great detail, concluding, in relevant part, "that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate." 1964 Surgeon General's Report 31. It also identified the pharmacological effects of nicotine, including "stimulation," "tranquilization," and "suppression of appetite." *Id.*, at 74-75. Seven days after the report's release, the Federal Trade Commission (FTC) issued a notice of proposed rulemaking, see 29 Fed. Reg. 530-532 (1964), and in June 1964, the FTC promulgated a final rule requiring cigarette manufacturers "to disclose, clearly and prominently, in all advertising and on every pack, box, carton or other container ... that cigarette smoking is dangerous to health and may cause death from cancer and other diseases," *id., a*t 8325. The rule was to become effective January 1, 1965, but, on a request from Congress, the FTC postponed enforcement for six months. See *Cipollone* v. *Liggett Group, Inc.,* 505 U.S. 504, 513-514 (1992).

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

is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people." 1964 Hearings 18.

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

The FDA's position was also consistent with Congress' specific intent when it enacted the FDCA. Before the Act's adoption in 1938, the FDA's predecessor agency, the Bureau of Chemistry, announced that it lacked authority to regulate tobacco products under the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, unless they were marketed with therapeutic claims. See U.S. Dept. of Agriculture, Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914)(Feb. 1914 Announcements ¶;13, Opinion of Chief of Bureau C.L. Alsberg). In 1929, Congress considered and rejected a bill "[t]o amend the Food and Drugs Act of June 30, 1906, by extending its provisions to tobacco and tobacco products." S. 1468, 71st Cong., 1st Sess., 1. See also 71 Cong. Rec. 2589 (1929)(remarks of Sen. Smoot). And, as the FDA admits, there is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the applicability of the Act to tobacco products. See Brief for Petitioners 22, n. 4. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter. Of course, whether the Congress that enacted the FDCA specifically intended the Act to cover tobacco products is not determinative; ***"it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed."*** *Oncale* v. *Sundowner Offshore Services, Inc.*, 523 U.S. 75, 79 (1998); see also *TVA* v. *Hill*, 437 U.S. 153, 185 (1978)("***It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated***"). Nonetheless, this intent is certainly relevant to understanding the basis for the FDA's representations to Congress and the background against which Congress enacted subsequent tobacco-specific legislation.

Moreover, before enacting the FCLAA in 1965, Congress considered and rejected several proposals to give the FDA the authority to regulate tobacco. In April 1963, Representative Udall introduced a bill "[t]o amend the Federal Food, Drug, and Cosmetic Act so as to make that Act applicable to smoking products." H. R. 5973, 88th Cong., 1st Sess., 1. Two months later, Senator Moss introduced an identical bill in the Senate. S. 1682, 88th Cong., 1st Sess. (1963). In discussing his proposal on the Senate floor, Senator Moss explained that "this amendment simply places smoking products under FDA jurisdiction, along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963). In December 1963, Representative Rhodes introduced another bill that would have amended the FDCA "by striking out `food, drug, device, or cosmetic, each place where it appears therein and inserting in lieu thereof `food, drug, device, cosmetic, or smoking product.' " H. R. 9512, 88th Cong., 1st Sess., § 3 (1963). And in January 1965, five months before passage of the FCLAA, Representative Udall again introduced a bill to

amend the FDCA "to make that Act applicable to smoking products." H.R. 2248, 89th Cong., 1st Sess., 1. None of these proposals became law.

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

Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by ... this Act, shall be required on any cigarette package." *Id.*, § 5(a), 79 Stat. 283. The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today. The labeling requirements currently imposed by the FDCA, which are essentially identical to those in force in 1965, require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers. See 21 U.S.C. § 352; 21 U.S.C. § 352 (1964 ed. and Supp. IV). As discussed earlier, the Act requires that all products bear "adequate directions for use ... as are necessary for the protection of users," 21 U.S.C. § 352(f)(1); 21 U.S.C. § 352(f)(1)(1964 ed.); requires that all products provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," 21 U.S.C. § 352(f)(2); 21 U.S.C. § 352(f)(2)(1964 ed.); and deems a product misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U.S.C. § 352(j); 21 U.S.C. § 352(j)(1964 ed.). In this sense, the FCLAA was--and remains--incompatible with FDA regulation of tobacco products. This is not to say that the FCLAA's preemption provision by itself necessarily foreclosed FDA jurisdiction. See *Cipollone v. Liggett Group, Inc.*, 505 U.S., at 518 -519. But it is an important factor in assessing whether Congress ratified the agency's position--that is, whether Congress adopted a regulatory approach to the problem of tobacco and health that contemplated no role for the FDA.

Further, the FCLAA evidences Congress' intent to preclude *any* administrative agency from exercising significant policymaking authority on the subject of smoking and health. In addition to prohibiting any additional requirements for cigarette labeling, the FCLAA provided that "[n]o statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Pub. L. 89-92, § 5(b), 79 Stat. 283. Thus, in reaction to the FTC's attempt to regulate cigarette labeling and advertising, Congress enacted a statute reserving exclusive control over both subjects to itself.

Subsequent tobacco-specific legislation followed a similar pattern. By the FCLAA's own terms, the prohibition on any additional cigarette labeling or advertising regulations relating to smoking and health was to expire July 1, 1969. See § 10, 79 Stat. 284. In anticipation of the provision's expiration, both the FCC and the FTC proposed rules governing the advertisement of cigarettes. See 34 Fed. Reg. 1959 (1969)(FCC proposed rule to "ban the broadcast of cigarette

commercials by radio and television stations"); *id.*, *a*t 7917 (FTC proposed rule requiring manufacturers to disclose on all packaging and in all print advertising " `that cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases' "). After debating the proper role for administrative agencies in the regulation of tobacco, see generally Cigarette Labeling and Advertising--1969: Hearings before the House Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess., pt. 2 (1969), Congress amended the FCLAA by banning cigarette advertisements "on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission" and strengthening the warning required to appear on cigarette packages. Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, §§ 4, 6, 84 Stat. 88-89. Importantly, Congress extended indefinitely the prohibition on any other regulation of cigarette labeling with respect to smoking and health (again despite the importance of labeling regulation under the FDCA). §5(a), 84 Stat. 88 (codified at 15 U.S.C. § 1334(a)). Moreover, it expressly forbade the FTC from taking any action on its pending rule until July 1, 1971, and it required the FTC, if it decided to proceed with its rule thereafter, to notify Congress at least six months in advance of the rule's becoming effective. § 7(a), 84 Stat. 89. As the chairman of the House committee in which the bill originated stated, "the Congress--the body elected by the people--must make the policy determinations involved in this legislation--and not some agency made up of appointed officials." 116 Cong. Rec. 7920 (1970)(remarks of Rep. Staggers).

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

Meanwhile, the FDA continued to maintain that it lacked jurisdiction under the FDCA to regulate tobacco products as customarily marketed. In 1972, FDA Commissioner Edwards testified before Congress that "cigarettes recommended for smoking pleasure are beyond the

Federal Food, Drug, and Cosmetic Act." 1972 Hearings 239, 242. ***He further stated that the FDA believed that the Public Health Cigarette Smoking Act "demonstrates that the regulation of cigarettes is to be the domain of Congress," and that "labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent.***" *Ibid.*

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

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

Against this backdrop, Congress enacted three additional tobacco-specific statutes over the next four years that incrementally expanded its regulatory scheme for tobacco products. In 1983, Congress adopted the Alcohol and Drug Abuse Amendments, Pub. L. 98-24, 97 Stat. 175 (codified at 42 U.S.C. § 290aa *et seq.*), which require the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco" and to include recommendations for action that the Secretary may deem appropriate. A year later, Congress enacted the Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200, which amended the FCLAA by again modifying the prescribed warning. Notably, during debate on the Senate floor, Senator Hawkins argued that the Act was necessary in part because "[u]nder the Food, Drug and Cosmetic Act, the Congress exempted tobacco products." 130 Cong. Rec. 26953 (1984). And in 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), Pub. L. 99-252, 100 Stat. 30 (codified at 15 U.S.C. § 4401 *et seq.*), which essentially extended the regulatory provisions of the FCLAA to smokeless tobacco products. Like the FCLAA, the CSTHEA provided that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [the Act], shall be required by any Federal agency to appear on any package ... of a smokeless tobacco product." § 7(a), 100 Stat. 34 (codified at 15 U.S.C. § 4406(a)). Thus, as with cigarettes, Congress reserved for itself an aspect of smokeless tobacco regulation that is particularly important to the FDCA's regulatory scheme.

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

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

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

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

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

The dissent also argues that the proper inference to be drawn from Congress' tobacco-specific legislation is "critically ambivalent." *Post*, at 22. We disagree. In that series of statutes, Congress crafted a specific legislative response to the problem of tobacco and health, and it did so with the understanding, based on repeated assertions by the FDA, that the agency has no

authority under the FDCA to regulate tobacco products. Moreover, Congress expressly preempted any other regulation of the labeling of tobacco products concerning their health consequences, even though the oversight of labeling is central to the FDCA's regulatory scheme. And in addressing the subject, Congress consistently evidenced its intent to preclude any federal agency from exercising significant policymaking authority in the area. Under these circumstances, we believe the appropriate inference--that Congress intended to ratify the FDA's prior position that it lacks jurisdiction--is unmistakable.

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

C

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

more likely to have focused upon, and answered, major questions, while leaving interstitial matters to answer themselves in the course of the statute's daily administration").

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

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

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

* * *

By no means do we question the seriousness of the problem that the FDA has sought to address. The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States. Nonetheless, no matter how "important, conspicuous, and controversial" the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, *post*, at 31, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And " `[i]n our anxiety to effectuate the congressional purpose of protecting the public, ***we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop***.' " *United States* v. *Article of*

Drug ... Bacto-Unidisk, 394 U.S. 784, 800 (1969)(quoting *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951)). Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here. For these reasons, the judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.

End opinion of the Court.

Begin dissent.

FOOD AND DRUG ADMINISTRATION, *et al.*, PETITIONERS *v.* BROWN & WILLIAMSON TOBACCO CORPORATION *et al.* on writ of certiorari to the united states court of appeals for the fourth circuit

[March 21, 2000]

Justice Breyer, with whom *Justice Stevens, Justice Souter,* and *Justice Ginsburg* join, dissenting.

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

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

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

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

(1) the FDCA does not "fit" the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy, *ante*, at 19-20; and

(2) Congress has enacted other statutes, which, when viewed in light of the FDA's long history of denying tobacco-related jurisdiction and considered together with Congress' failure

explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco, *ante*, at 33-34.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA's remedial alternatives. See *infra*, at 14-21. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. See *infra*, at 21-26; cf. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U.S.C. § 321 (1994 ed., Supp. III))(statute "shall" *not* "be construed to affect the question of whether" the FDA "has any authority to regulate any tobacco product").

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

I

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

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

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

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

It also added a similar definition in respect to a "device." See § 201(h), 52 Stat. 1041 (codified at 21 U.S.C. §321(h)). As I have mentioned, the literal language of the third definition and the FDCA's general purpose both strongly support a projurisdiction reading of the statute. See *supra*, at 1-2.

The statute's history offers further support. The FDA drafted the new language, and it testified before Congress that the third definition would expand the FDCA's jurisdictional scope significantly. See Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 15-16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107-108 (1979)(hereinafter Leg. Hist.). Indeed, "[t]he purpose" of the new definition was to "make possible the regulation of a

great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions." *Id.,* at 108. While the drafters focused specifically upon the need to give the FDA jurisdiction over "slenderizing" products such as "anti-fat remedies," *ibid.,* they were aware that, in doing so, they had created what was "admittedly an inclusive, a wide definition." *Id.,* at 107. And that broad language was included *deliberately,* so that jurisdiction could be had over " *all* substances and preparations, other than food, and *all* devices intended to affect the structure or any function of the body ... ." *Ibid.* (emphasis added); see also Hearings on S. 2800 before the Senate Committee on Commerce, 73d Cong., 2d Sess. 516 (1934), reprinted in 2 Leg. Hist. 519 (statement of then-FDA Chief Walter Campbell acknowledging that "[t]his definition of `drugs' is all-inclusive").

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

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

That Congress would grant the FDA such broad jurisdictional authority should surprise no one. In 1938, the President and much of Congress believed that federal administrative agencies needed broad authority and would exercise that authority wisely--a view embodied in much Second New Deal legislation. Cf. *Gray* v. *Powell,* 314 U.S. 402, 411-412 (1941)(Congress "could have legislated specifically" but decided "to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable" determination). Thus, at around the same time that it added the relevant language to the FDCA, Congress enacted laws granting other administrative agencies even broader powers to regulate much of the Nation's transportation and communication. See, *e.g.,* Civil Aeronautics Act of 1938, ch. 601, § 401(d)(1), 52 Stat. 987 (Civil Aeronautics Board to regulate airlines within confines of highly general "public convenience and necessity" standard); Motor Carrier Act of 1935, ch. 498, § 204(a)(1), 49 Stat. 546 (Interstate Commerce Commission to establish "reasonable requirements" for trucking); Communications Act of 1934, ch. 652, §201(a), 48 Stat. 1070 (Federal Communications Commission (FCC) to regulate radio, later television, within confines of even broader "public interest" standard). Why would the 1938 New Deal Congress suddenly have hesitated to delegate to so well established an agency as the FDA all of the discretionary authority that a straightforward reading of the relevant statutory language implies?

Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislators might not have expected. Such a possibility is inherent in the very nature of a broad delegation. In 1938, it may well have seemed unlikely that the FDA would ever bring cigarette manufacturers within the FDCA's statutory language by proving that cigarettes produce chemical changes in the body and that the makers "intended" their product chemically to affect the body's "structure" or

"function." Or, back then, it may have seemed unlikely that, even assuming such proof, the FDA actually would exercise its discretion to regulate so popular a product. See R. Kluger, Ashes to Ashes 105 (1997)(in the 1930's "Americans were in love with smoking ...").

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

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

II

A

The tobacco companies contend that the FDCA's words cannot possibly be read to mean what they literally say. The statute defines "device," for example, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article ... intended to affect the structure or any function of the body ... ." 21 U.S.C. § 321(h). Taken literally, this definition might include everything from room air conditioners to thermal pajamas. The companies argue that, to avoid such a result, the meaning of "drug" or "device" should be confined to *medical* or *therapeutic* products, narrowly defined. See Brief for Respondent United States Tobacco Co. 8-9.

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

Most importantly, the statute's language itself supplies a different, more suitable, limitation: that a "drug" must be a *chemical* agent. The FDCA's "device" definition states that an article which affects the structure or function of the body is a "device" only if it "does *not*

achieve its primary intended purposes through chemical action within ... the body," and "is *not* dependent upon being metabolized for the achievement of its primary intended purposes." § 321(h)(emphasis added). One can readily infer from this language that at least an article that *does* achieve its primary purpose through chemical action within the body and that *is* dependent upon being metabolized is a "drug," provided that it otherwise falls within the scope of the "drug" definition. And one need not hypothesize about air conditioners or thermal pajamas to recognize that the chemical nicotine, an important tobacco ingredient, meets this test.

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

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

B

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

The FDCA, however, does not use the word "claimed"; it uses the word "intended." And the FDA long ago issued regulations that say the relevant "intent" can be shown not only by a manufacturer's "expressions," *but also* "by the circumstances surrounding the distribution of

the article." 41 Fed. Reg. 6896 (1976)(codified at 21 CFR §801.4 (1999)); see also 41 Fed. Reg. 6896 (1976)("objective intent" shown if "article is, with the knowledge [of its makers], offered and used" for a particular purpose). Thus, even in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product. See, *e.g.*, 60 Fed. Reg. 41527-41531 (1995)(describing agency's regulation of topical hormones, sunscreens, fluoride, tanning lamps, thyroid in food supplements, novelty condoms--all marketed without express claims); see also O'Reilly, Food and Drug Administration §13.04, at 13-15 ("Sometimes the very nature of the material makes it a drug ...").

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

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

The companies also cannot deny that the evidence of their intent is sufficient to satisfy the statutory word "intended" as the FDA long has interpreted it. In the first place, there was once a time when they actually *did* make express advertising claims regarding tobacco's mood-stabilizing and weight-reducing properties--and historical representations can portend present expectations. In the late 1920's, for example, the American Tobacco Company urged weight-conscious smokers to " `Reach for a Lucky instead of a sweet.' " Kluger, Ashes to Ashes, at 77-78. The advertisements of R J Reynolds (RJR) emphasized mood stability by depicting a pilot remarking that " `It Takes Steady Nerves To Fly the Mail At Night ... . That's why I smoke Camels. And I smoke plenty!' " *Id.*, at 86. RJR also advertised the stimulating quality of cigarettes, stating in one instance that " `You get a Lift with a Camel,' " and, in another, that Camels are " `A Harmless Restoration of the Flow of Natural Body Energy.' " *Id.*, at 87. And claims of medical proof of mildness (and of other beneficial effects) once were commonplace. See, *e.g.*, *id.*, at 93 (Brown & Williamson advertised Kool-brand mentholated cigarettes as "a tonic to hot, tired throats"); *id.*, at 101, 131 (Phillip Morris contended that "[r]ecognized laboratory tests have conclusively proven the advantage of Phillip Morris"); *id.*, at 88 (RJR proclaimed " `For Digestion's sake, smoke Camels! ... Camels make mealtime more pleasant--digestion is stimulated—alkalinity increased' "). Although in recent decades cigarette

manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the companies no longer need to express--that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.

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

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

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

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

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

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

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

And a 1980 manufacturer's study stated that

" `the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the degree of satisfaction required by the smoker.' " *Id.,* at 44936 (Brown & Williamson).

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

C

The majority nonetheless reaches the "inescapable conclusion" that the language and structure of the FDCA as a whole "simply do not fit" the kind of public health problem that tobacco creates. *Ante,* at 20. That is because, in the majority's view, the FDCA requires the FDA to ban outright "dangerous" drugs or devices (such as cigarettes); yet, the FDA concedes that an immediate and total cigarette-sale ban is inappropriate. *Ibid* .

This argument is curious because it leads with similarly "inescapable" force to precisely the opposite conclusion, namely, that the FDA *does* have jurisdiction but that it must ban cigarettes. More importantly, the argument fails to take into account the fact that a statute

interpreted as requiring the FDA to pick a more dangerous over a less dangerous remedy would be a perverse statute, *causing,* rather than preventing, unnecessary harm whenever a total ban is likely the more dangerous response. And one can at least imagine such circumstances.

Suppose, for example, that a commonly used, mildly addictive sleeping pill (or, say, a kind of popular contact lens), plainly within the FDA's jurisdiction, turned out to pose serious health risks for certain consumers. Suppose further that many of those addicted consumers would ignore an immediate total ban, turning to a potentially more dangerous black-market substitute, while a less draconian remedy (say, adequate notice) would wean them gradually away to a safer product. Would the FDCA still *force* the FDA to impose the more dangerous remedy? For the following reasons, I think not.

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

The Court points to other statutory subsections which it believes require the FDA to ban a drug or device entirely, even where an outright ban risks more harm than other regulatory responses. See *ante,* at 12-13. But the cited provisions do no such thing. It is true, as the majority contends, that "the FDCA requires the FDA to place all devices" in "one of three classifications" and that Class III devices require "premarket approval." *Ante,* at 12, 13. But it is not the case that the FDA *must* place cigarettes in Class III because tobacco itself "present[s] a potential unreasonable risk of illness or injury." 21 U.S.C. §360c(a)(1)(C). In fact, Class III applies *only* where *regulation* cannot otherwise "provide reasonable assurance of ... safety."§§ 360c(a)(1)(A), 360c(a)(1)(B)(placing a device in Class I or Class II when regulation can provide that assurance). Thus, the statute plainly allows the FDA to consider the relative, overall "safety" of a device in light of its regulatory alternatives, and where the FDA has chosen the least dangerous path, *i.e.,*the safest path, then it can--and does--provide a "reasonable assurance" of "safety" within the meaning of the statute. A good football helmet provides a reasonable assurance of safety for the player even if the sport itself is still dangerous. And the safest regulatory choice by definition offers a "reasonable" assurance of safety in a world where the other alternatives are yet more dangerous.

In any event, it is not entirely clear from the statute's text that a Class III categorization would require the FDA affirmatively to *withdraw* from the market dangerous devices, such as cigarettes, which are already widely distributed. See, *e.g.,* § 360f(a)(when a device presents an "unreasonable and substantial risk of illness or injury," the Secretary "may" make it "a banned device"); § 360h(a)(when a device "presents an unreasonable risk of substantial harm to the public health," the Secretary "may" require "notification"); § 360h(b)(when a defective device creates an "unreasonable risk" of harm, the Secretary "may" order "repair, replacement, or refund"); cf. O'Reilly, Food and Drug Administration § 18.08, at 18-38 (point of Class III

"premarket approval" is to allow "careful scientific review" of each "truly new" device " *before* it is exposed" to users (emphasis added)).

Noting that the FDCA requires banning a "misbranded" drug, the majority also points to 21 U.S.C. § 352(j), which deems a drug or device "misbranded" if "it is dangerous to health when used" as "prescribed, recommended, or suggested in the labeling." See *ante,* at 12. In addition, the majority mentions § 352(f)(1), which calls a drug or device "misbranded" unless "its labeling bears . . . adequate directions for use" as "are necessary for the protection of users." *Ibid.* But this "misbranding" language is not determinative, for it permits the FDA to conclude that a drug or device is *not* "dangerous to health" and that it *does* have "adequate" directions *when regulated so as to render it as harmless as possible* . And surely the agency can determine that a substance is comparatively "safe" (*not* "dangerous") whenever it would be *less* dangerous to make the product available (subject to regulatory requirements) than suddenly to withdraw it from the market. Any other interpretation risks substantial harm of the sort that my sleeping pill example illustrates. See *supra,* at 14. And nothing in the statute prevents the agency from adopting a view of "safety" that would avoid such harm. Indeed, the FDA already seems to have taken this position when permitting distribution of toxic drugs, such as poisons used for chemotherapy, that are dangerous for the user but are not deemed "dangerous to health" in the relevant sense. See 61 Fed. Reg. 44413 (1996).

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

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

The second reason the FDCA does not require the FDA to select the more dangerous remedy, see *supra,* at 14, is that, despite the majority's assertions to the contrary, the statute does not distinguish among the kinds of health effects that the agency may take into account when assessing safety. The Court insists that the statute only permits the agency to take into account the health risks and benefits of the " *product itself* " as used by individual consumers, *ante,* at 17, and, thus, that the FDA is prohibited from considering that a ban on smoking would lead many smokers to suffer severe withdrawal symptoms or to buy possibly stronger, more dangerous, black market cigarettes--considerations that the majority calls "the aggregate health effects of alternative administrative actions." *Ibid* . But the FDCA expressly *permits* the FDA to take account of comparative safety in precisely this manner. See, *e.g.,* 21 U.S.C. §360h(e)(2)(B)(i)(II)(no device recall if "risk of recal[l]" presents "a greater health risk than" no

recall); §360h(a)(notification "unless" notification "would present a greater danger" than "no such notification").

Moreover, one cannot distinguish in this context between a "specific" health risk incurred by an individual and an "aggregate" risk to a group. *All* relevant risk is, at bottom, risk to an individual; *all* relevant risk attaches to "the product itself"; and *all* relevant risk is "aggregate" in the sense that the agency aggregates health effects in order to determine risk to the individual consumer. If unregulated smoking will kill 4 individuals out of a typical group of 1,000 people, if regulated smoking will kill 1 out of 1,000, and if a smoking ban (because of the black market) will kill 2 out of 1,000; then these three possibilities means that in each group four, one, and two individuals, on average, will die respectively. And the risk to each individual consumer is 4/1000, 1/1000, and 2/1000 respectively. A "specific" risk to an individual consumer and "aggregate" risks are two sides of the same coin; each calls attention to the same set of facts. While there may be a theoretical distinction between the risk of the product itself and the risk related to the presence or absence of an intervening voluntary act (*e.g.,* the search for a replacement on the black market), the majority does not rely upon any such distinction, and the FDA's history of regulating "replacement" drugs such as methadone shows that it has long taken likely actual alternative consumer behavior into account.

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

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes. A different set of words, added to the FDCA in 1958 by the Delaney Amendment, provides that "no [food] additive shall be deemed to be safe if it is found [after appropriate tests] to induce cancer in man or animal." §348(c)(3). The FDA once interpreted this language as requiring it to ban any food additive, no matter how small the amount, that appeared in any food product if that additive was ever found to induce cancer in any animal, no matter how large a dose needed to induce the appearance of a single carcinogenic cell. See H. R. Rep. No. 95-658, p. 7 (1977)(discussing agency's view). The FDA believed that the statute's ban mandate was absolute and prevented it from establishing a level of "safe use" or even to judge whether "the benefits of continued use outweigh the risks involved." *Id.,* at 5. This interpretation--which in principle could have required the ban of everything from herbal teas to mushrooms--actually led the FDA to ban saccharine, see 42 Fed. Reg. 19996 (1977), though this extremely controversial regulatory response never took effect because Congress enacted, and has continually renewed, a law postponing the ban. See Saccharin Study and Labeling Act, Pub. L. 95-203, §3, 91 Stat. 1452; *e.g.,* Pub. L. 102-142, Tit. VI, 105 Stat. 910.

The Court's interpretation of the statutory language before us risks Delaney-type consequences with even less linguistic reason. Even worse, the view the Court advances undermines the FDCA's overall health-protecting purpose by placing the FDA in the strange dilemma of either banning completely a potentially dangerous drug or device or doing nothing at all. Saying that I have misunderstood its conclusion, the majority maintains that the FDA "may clearly regulate many `dangerous' products without banning them." *Ante,* at 19. But it then adds that the FDA *must* ban--rather than otherwise regulate--a drug or device that "cannot be used safely for any therapeutic purpose." *Ibid* . If I misunderstand, it is only because this linchpin of the majority's conclusion remains unexplained. *Why* must a widely-used but unsafe device be withdrawn from the market when that particular remedy threatens the health of many and is thus more dangerous than another regulatory response? It is, indeed, a perverse interpretation that reads the FDCA to require the ban of a device that has no "safe" therapeutic purpose where a ban is the most dangerous remedial alternative.

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

III

In the majority's view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA's exercise of jurisdiction? With one exception, see *infra,* at 24, the majority points to no such provision. Do they somehow repeal the principles of law (discussed in Part II, *supra*) that otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of "partial repeal"). Perhaps the later laws "shape" and "focus" what the 1938 Congress meant a generation earlier. *Ante,* at 20. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation* v. *LTV Corp.,* 496 U.S. 633, 650 (1990)(later history is " `a hazardous basis for inferring the intent of an earlier' Congress" (quoting *United States* v. *Price,* 361 U.S. 304, 313 (1960))). And, while the majority suggests that the subsequent history "control[s] our construction" of the FDCA, see *ante,* at 20 (citation and internal quotation marks omitted), this Court expressly has held that such subsequent views are not "controlling." *Haynes* v. *United States,* 390 U.S. 85, 87-88 , n. 4 (1968); accord, *Southwestern Cable Co.,* 392 U.S., at 170 (such views have " `very little, if any, significance' "); see also *Sullivan* v. *Finkelstein,* 496 U.S. 617, 632 (1990)(S *calia,* J., concurring)("Arguments based on subsequent legislative history ... should not be taken seriously, not even in a footnote.").

Regardless, the later statutes do not support the majority's conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA's jurisdiction, the laws they enacted did not embody any such "no jurisdiction" assumption. And one cannot automatically *infer* an anti-jurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely,

the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. See, *e.g.,* Cigarette Labeling and Advertising--1965: Hearings on H. R. 2248 et al. before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 19 (1965)(hereinafter 1965 Hearings)(statement of Rep. Fino that the proposed legislation would *not* "erode" agency authority). As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) "ratif[ying]" a no-jurisdiction assumption, see *ante,* at 34, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are "equally tenable," *Pension Benefit Guaranty Corp*., *supra,* at 650 (citation and internal quotation marks omitted); *Johnson* v. *Transportation Agency, Santa Clara Cty.*, 480 U.S. 616, 672 (1987)(*Scalia,* J., dissenting), prevents the majority from drawing from the later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco--a circumstance that the majority finds significant. See *ante,* at 21, 24-25, 32-33. But cf. *Southwestern Cable Co., supra,* at 170 (failed requests do not prove agency "did not already possess" authority). In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, *e.g.*,S. 1262, 104th Cong., 1st Sess., §906 (1995)(failed bill seeking to amend FDCA to say that "[n]othing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products"); see also H. R. 516, 105th Cong., 1st Sess., §2 (1997)(similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996)(Georgia legislators unsuccessfully requested that Congress "rescind any action giving the FDA authority" over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995)(failed bill "[t]o prohibit the [FDA] regulation of the sale or use of tobacco"); H. R. 2414, 104th Cong., 1st Sess., §2(a)(1995)(similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

The majority also mentions the speed with which Congress acted to take jurisdiction away from other agencies once they tried to assert it. See *ante,* at 22, 26-29. But such a congressional response again proves nothing. On the one hand, the speedy reply might suggest that Congress somehow resented agency assertions of jurisdiction in an area it desired to reserve for itself--a consideration that supports the majority. On the other hand, Congress' quick reaction with respect to *other* agencies' regulatory efforts contrasts dramatically with its failure to enact any responsive law (at any speed) after the FDA asserted jurisdiction over tobacco more than three years ago. And that contrast supports the opposite conclusion.

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

The majority's historical perspective also appears to be shaped by language in the Federal Cigarette Labeling and Advertising Act (FCLAA), 79 Stat. 282, 15 U.S.C. §1331 *et seq* . See *ante*, at 25-26. The FCLAA requires manufacturers to place on cigarette packages, etc., health warnings such as the following:

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

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

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

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

When the FCLAA's narrow pre-emption provision is set aside, the majority's conclusion that Congress clearly intended for its tobacco-related statutes to be the exclusive "response" to "the problem of tobacco and health," *ante*, at 35, is based on legislative silence. Notwithstanding the views voiced by various legislators, Congress itself has addressed expressly the issue of the FDA's tobacco-related authority only once--and, as I have said, its statement was that the statute was *not* to "be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product." Note following 21 U.S.C. §321 (1994 ed., Supp. III). The proper inference to be drawn from *all* of the post-1965 statutes, then, is one that interprets Congress' general legislative silence consistently with this statement.

IV

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

Until the early 1990's, the FDA expressly maintained that the 1938 statute did not give it the power that it now seeks to assert. It then changed its mind. The majority agrees with me that the FDA's change of positions does not make a significant legal difference. See *ante,* at 34; see also *Chevron*, 467 U.S., at 863 ("An initial agency interpretation is not instantly carved in stone"); accord, *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U.S. 735, 742 (1996)("[C]hange is not invalidating"). Nevertheless, it labels those denials "important context" for drawing an inference about Congress' intent. *Ante,* at 34. In my view, the FDA's change of policy, like the subsequent statutes themselves, does nothing to advance the majority's position.

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

Other agency statements occasionally referred to additional problems. Commissioner Kessler, for example, said that the "enormous social consequences" flowing from a decision to regulate tobacco counseled in favor of obtaining specific Congressional "guidance." 1994 Hearings 69; see also *ante,* at 31 (quoting statement of Health and Human Services Secretary Brandt to the effect that Congress wanted to make the relevant jurisdictional decision). But a fair reading of the FDA's denials suggests that the overwhelming problem was one of proving the requisite manufacturer intent. See *Action on Smoking and Health* v. *Harris,* 655 F. 2d 236, 238-239 (CADC 1980)(FDA "comments" reveal its "understanding" that "the crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent").

What changed? For one thing, the FDA obtained evidence sufficient to prove the necessary "intent" despite the absence of specific "claims." See *supra,* at 12-14. This evidence, which first became available in the early 1990's, permitted the agency to demonstrate that the tobacco companies *knew* nicotine achieved appetite-suppressing, mood-stabilizing, and

habituating effects through chemical (not psychological) means, even at a time when the companies were publicly denying such knowledge.

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

Finally, administration policy changed. Earlier administrations may have hesitated to assert jurisdiction for the reasons prior Commissioners expressed. See *supra*, at 27-28. Commissioners of the current administration simply took a different regulatory attitude.

Nothing in the law prevents the FDA from changing its policy for such reasons. By the mid-1990's, the evidence needed to prove objective intent--even without an express claim--had been found. The emerging scientific consensus about tobacco's adverse, chemically induced, health effects may have convinced the agency that it should spend its resources on this important regulatory effort. As for the change of administrations, I agree with then- *Justice Rehnquist* 's statement in a different case, where he wrote:

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

V

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

First, one might claim that, despite the FDA's legal right to change its mind, its original statements played a critical part in the enactment of the later statutes and now should play a critical part in their interpretation. But the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory "intent" requirement. See, *e.g.*,FDA Enforcement Letter 240 ("The statutory basis for the exclusion of tobacco products from FDA's

jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions ... for food, drug, device or cosmetic"). The statement, "we cannot assert jurisdiction over substance X unless it is treated as a food" would not bar jurisdiction if the agency later establishes that substance X is, and is intended to be, eaten. The FDA's denials of tobacco-related authority sufficiently resemble this kind of statement that they should not make the critical interpretive difference.

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

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

* * *

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

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

The majority also believes that subsequently enacted statutes deprive the FDA of jurisdiction. But the later laws say next to nothing about the FDA's tobacco-related authority. Previous FDA disclaimers of jurisdiction may have helped to form the legislative atmosphere out of which Congress' own tobacco-specific statutes emerged. But a legislative atmosphere is not a

law, unless it is embodied in a statutory word or phrase. And the relevant words and phrases here reveal nothing more than an intent not to change the jurisdictional status quo.

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

Consequently, I dissent.