No. 98-1152

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

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

BRIEF FOR THE PETITIONERS

SETH P. WAXMAN
Solicitor General
Counsel of Record

DAVID W. OGDEN
Acting Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

WILLIAM B. SCHULTZ
Deputy Assistant Attorney General

IRVING L. GORNSTEIN
Assistant to the Solicitor General

EUGENE THIROLF
DOUGLAS LETTER
GERALD C. KELL
SCOTT R. MCINTOSH
CHRISTINE N. KOHL
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514–2217

MARGARET JANE PORTER
Chief Counsel

KAREN E. SCHIFTER
PATRICIA J. KAEDING
Associate Chief Counsel
Food and Drug Administration
Rockville, MD. 20857

QUESTION PRESENTED

The Federal Food, Drug, and Cosmetic Act authorizes the Food and Drug Administration (FDA) to regulate products as "drugs" or "devices" when they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3). FDA has found that the nicotine in tobacco products is intended by tobacco manufacturers to cause and sustain a user's addiction to nicotine and to act as a sedative, stimulant, and appetite suppressant. The question presented is whether, given that finding, tobacco products are subject to regulation under the Act as "drugs" and "devices."

PARTIES TO THE PROCEEDING

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

The respondents are: Brown and Williamson Tobacco Corp.; Lorillard Tobacco Company; Philip Morris, Incorporated; RJ Reynolds Tobacco Company; Coyne Beahm, Incorporated; 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; Association of National Advertisers, Incorporated; Magazine Publishers of America; the Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-75a) is reported at 153 F.3d 155. The opinion of the district court (Pet. App. 76a-136a) is reported at 966 F. Supp. 1374. The Food and Drug Administration's jurisdictional determination and final rule concerning tobacco products are published at 61 Fed. Reg. 44,396 (1996), and 61 Fed. Reg. 44,619 (1996).[1]

JURISDICTION

The judgment of the court of appeals was entered on August 14, 1998. A petition for rehearing was denied on November 10, 1998. Pet. App. 137a-146a. The petition for a writ of certiorari was filed on January 19, 1999, and was granted on April 26, 1999. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

[1] Copies of the Federal Register notices containing the final rule and jurisdictional determination have been lodged with the Court.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Federal Food, Drug, and Cosmetic Act appear in an appendix to this brief. The tobacco product regulations appear in the appendix to the petition for a writ of certiorari.

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (Act), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, confers authority on the Secretary of Health and Human Services, through the Food and Drug Administration (FDA), to regulate "drugs" and "devices" for the purpose of protecting the public health. See 21 U.S.C. 393(b)(1), (2)(B) and (C). The Act defines "drug" as, *inter alia*, "articles (other than food) intended to affect the structure or any function of the body of man or other animal." 21 U.S.C. 321(g)(1). The Act similarly defines "device" as, *inter alia*, "an instrument, apparatus, * * * contrivance, * * * or other similar or related article, including any component, part, or accessory, * * * 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 * * * and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h)(3).

The Act recognizes that certain products may constitute a combination of a drug and a device. 21 U.S.C. 353(g)(1). FDA may regulate drug/device combination products by using its authority to regulate drugs, its authority to regulate devices, or both. 61 Fed. Reg. 44,400-44,403 (1996). One provision relating to devices authorizes FDA, by regulation, to "require that a device be restricted to sale, distribution, or use * * * upon such * * * conditions as [FDA] may prescribe in such regulation, if, because of its potentiality for

harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. 360j(e)(1).

2. In response to petitions requesting that FDA regulate tobacco products, FDA conducted an extensive investigation, issued a proposed rule and "jurisdictional" analysis, and invited public comment. 60 Fed. Reg. 41,314 (1995). In August 1996, FDA determined that tobacco products constitute a combination of a "drug" and a "device" and issued regulations directed to those products. 61 Fed. Reg. at 44,396; *id.* at 44,619.

FDA based its determination that tobacco products are "drugs" and "devices" on two key findings: (a) extensive scientific documentation establishes that the nicotine in tobacco products "affects the structure or any function of the body" because it causes and sustains addiction, and acts as a sedative, stimulant, and appetite suppressant, 61 Fed. Reg. at 44,630, 44,664-44,685; and (b) those effects are "intended" by the manufacturers of tobacco products. *Id.* at 44,630, 44,686-45,204.

a. In finding that the nicotine in tobacco products affects the structure and function of the body, FDA relied on scientific evidence that nicotine directly affects a part of the brain known as the mesolimbic system, which rewards the repeated consumption of certain pleasurable substances. By increasing the activity of dopamine within that system, nicotine causes the compulsive drug-seeking behavior of drug addiction. 61 Fed. Reg. at 44,700, 44,721. In some circumstances, and in some doses, nicotine in tobacco products acts as a sedative, while in other circumstances and doses, it acts as a stimulant. *Id.* at 44,666. Studies also show that nicotine can cause weight loss. *Ibid.* FDA found that those effects on the structure and function of the body are quintessentially drug-like, identical to those FDA has found in numerous

other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction. *Id.* at 44,632, 44,666-44,670.

b. In finding that the effects of tobacco products on the structure and function of the body are "intended," FDA drew on three categories of evidence.

First, FDA found that nicotine's widely recognized addictive properties make it foreseeable to any reasonable manufacturer that a substantial proportion of users of tobacco products will consume them to satisfy their addiction. 61 Fed. Reg. at 44,701-44,739. FDA also found that nicotine's mood-altering effects and its effects on weight are so well established that a reasonable manufacturer would foresee that tobacco products would be used by a substantial proportion of consumers for those purposes as well. *Id.* at 44,634-44,635, 44,698-44,701, 44,739-44,744. Those findings, FDA determined, are sufficient in themselves to meet the statutory standard of "intended" effects, because "[i]t is a widely accepted legal principle that persons can be held to 'intend' the reasonably foreseeable consequences of their actions." *Id.* at 44,691 (citing, *inter alia*, *Agnew* v. *United States*, 165 U.S. 36, 53 (1897) ("The law presumes that every man intends the legitimate consequence[s] of his own acts.")).

Second, FDA found that consumers do in fact use tobacco products predominantly for pharmacological purposes. 61 Fed. Reg. at 44,635-44,636, 44,807-44,846. As many as 92% of all cigarette smokers and 75% of all young persons who regularly use smokeless tobacco consume those products because they are addicted to the nicotine in them. *Id.* at 44,635-44,636. Indeed, the percentage of smokers addicted to nicotine is higher than the percentage of heroin and cocaine users addicted to those drugs. *Id.* at 44,812-44,813. More than 70% of young daily smokers and 50% of young

daily smokeless tobacco users consume tobacco products to obtain their mood-altering effects. *Id.* at 44,636. As many as one-half of young persons who smoke do so to control their weight. *Ibid.* Although some people also use tobacco products for their taste or because they like the ritual, those purposes are clearly secondary. *Id.* at 44,807, 44,826-44,827. FDA determined that, "[w]here consumers use a product predominantly or nearly exclusively to obtain any of the effects on the structure or function of the body produced by a substance, such evidence would alone be sufficient to establish manufacturer intent." *Id.* at 44,807 (citing *Action on Smoking & Health* v. *Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980)).

Third, FDA relied on statements, research, and actions of the manufacturers themselves, which showed that the manufacturers intend their products to affect the structure and function of the body. 61 Fed. Reg. at 44,847-45,097. That extensive evidence, FDA concluded, satisfies the standard dictionary definitions of "intend," because it shows that manufacturers "have in mind" the pharmacological effects and uses of their tobacco products and "design" them to enhance those effects and uses. *Id.* at 44,851 & n.413 (quoting, *inter alia*, *The American Heritage Dictionary of the English Language* 668 (2d ed. 1991)).

FDA cited recently discovered evidence that the leading tobacco manufacturers have long known that consumers use tobacco products to obtain the pharmacological effects of nicotine. 61 Fed. Reg. at 44,636-44,640, 44,854-44,915. For example, as early as 1969, the vice president for research and development for Philip Morris informed the board of directors that "the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker." *Id.* at 44,855. In the ensuing decades, Philip Morris researchers described a cigarette as "a dispenser for a dose unit of nicotine," *id.* at 44,856,

observed that cigarettes serve as "a narcotic, tranquilizer, or sedative," *id.* at 44,857, characterized nicotine as "a powerful pharmacological agent with multiple sites of action," *ibid.*, and reported that "it is well recognized within the cigarette industry that there is one principal reason why people smoke —to experience the effects of nicotine, a known pharmacologically active constituent in tobacco," *id.* at 44,858.

Similarly, a memorandum from the early 1970s shows that R.J. Reynolds (RJR) scientists regarded nicotine as a "potent" and "habit-forming" drug, considered cigarettes to be "a vehicle for delivery of nicotine," and conceived of the tobacco industry itself as "a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 61 Fed. Reg. at 44,867. The memorandum also stated that "the confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine," and that "what we are really selling [is] nicotine satisfaction." *Id.* at 44,868. RJR researchers later reiterated that "[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body," that "a confirmed smoker attempts to get a certain desired level of nicotine," and that "[t]he nicotine in the blood acts upon the central nervous system and produces in the average smoker a sensation one could describe as either stimulating or relaxing." *Id.* at 44,871.

In the 1960s, a senior advisor to the board of British American Tobacco Company (BATCO), the parent company of Brown & Williamson, stated that "smoking is a habit of addiction," and that "nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect." 61 Fed. Reg. at 44,882. During the same period, Brown & Williamson's general counsel stated that "nicotine is addictive" and that "[w]e are, then, in the business of selling nicotine, an addictive drug." *Id.* at 44,884. BATCO researchers also stated that "puffing behaviour is the means

of providing nicotine dose in a metered fashion." *Id.* at 44,890.

FDA further found that cigarette manufacturers acted on the basis of their statements and research concerning the pharmacological effects of tobacco products. In particular, FDA found that "[m]anufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers." 61 Fed. Reg. at 44,951. Such manipulation is especially evident in low-tar cigarettes, which make up 80% of the cigarette market. *Id.* at 44,951-44,952. As tar levels are reduced, nicotine levels naturally fall. *Id.* at 44,976. To counteract that effect and to provide an active dose of nicotine in low-tar cigarettes, manufacturers use tobacco blends with higher nicotine content, *id.* at 44,954-44,957, ventilation systems that remove more tar than nicotine from smoke, *id.* at 44,963-44,967, and chemical additives that increase the amount of pharmacologically active nicotine in the smoke, *id.* at 44,970-44,971.

FDA likewise found evidence that manufacturers of smokeless tobacco manipulate nicotine deliveries. They market "starter" brands that have a low level of nicotine, so that new users may develop a tolerance for nicotine without experiencing nausea or vomiting. 61 Fed. Reg. at 44,643. They also market regular brands to experienced users that are engineered to deliver the level of nicotine necessary to sustain addiction. *Ibid.* Through marketing and advertising, manufacturers encourage those who have developed a tolerance for starter brands to graduate to regular brands. *Id.* at 45,120.[2]

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[2] FDA also relied on evidence that tobacco manufacturers advertise that tobacco products will provide "satisfaction." 61 Fed. Reg. at 45,172-45,178. FDA found that, to the users of tobacco products, the "promise of 'satisfaction' implies that the product will fulfill their craving for the

Finally, although FDA concluded that each of the three categories of evidence just discussed independently supports its determination that manufacturers intend the pharmacological effects and uses of their tobacco products, the cumulative effect and convergence of the evidence "convincingly establishes that cigarettes and smokeless tobacco are 'intended' to affect the structure and function of the body within the meaning of the Act." 61 Fed. Reg. at 45,203-45,204.

c. Having concluded that tobacco products fall squarely within the "drug" and "device" definitions, FDA next examined the structure of the Act as a whole, prior agency statements concerning its authority to regulate tobacco products, Congress's failure to pass legislation that would have expressly authorized FDA to regulate tobacco products, and Congress's enactment of certain tobacco-specific statutes. After carefully evaluating each of those considerations, FDA concluded that none of them detracts from the conclusion that tobacco products are "drugs" and "devices" under the Act. See, *e.g.*, 61 Fed. Reg. at 44,412-44,413 (structure of the Act); *id.* at 45,219-45,252 (prior statements); *id.* at 45,255-45,259 (unenacted legislation); *id.* at 44,544-44,548, 45,261-45,265 (tobacco-specific statutes).

d. In sum, FDA concluded that the nicotine in tobacco products is a "drug," 61 Fed. Reg. at 45,207, that tobacco products contain "device components" for the delivery of that drug, and that cigarettes and smokeless tobacco therefore are "combination products" under the Act. *Id.* at 45,208-45,216.

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pharmacological effects of nicotine—satisfying their addiction and providing the sought after mood-altering effects of nicotine." *Id.* at 45,175. In effect, "manufacturers use 'satisfaction' as a code-word for the pharmacological effects of nicotine." *Id.* at 45,178.

3. a. FDA next determined that tobacco use is the largest cause of preventable death in the United States. 61 Fed. Reg. at 44,398. Tobacco kills more Americans annually than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires combined. *Ibid.* FDA also found that tobacco use is a "pediatric disease," *id.* at 44,421, because most people who use tobacco as adults began smoking regularly during childhood. If adolescents can be kept tobacco-free, most will never start using tobacco as adults. *Id.* at 44,399. Efforts to prevent childhood tobacco use, however, have not been successful thus far. Approximately one million children begin to smoke every year. *Id.* at 44,568. One of every three young people who become regular smokers will die prematurely from a tobacco-related disease. *Id.* at 44,399.

b. Because most tobacco-related addiction begins in childhood, FDA issued regulations aimed at reducing the use of tobacco products by young people. It adopted access restrictions that, *inter alia*: (1) prohibit the sale of tobacco products to persons under age 18; (2) require retailers to check the identification of persons under age 27; and (3) prohibit vending machine sales and self-service displays of tobacco products except in adult-only locations. 61 Fed. Reg. at 44,616-44,617. FDA also issued regulations requiring tobacco product labeling to bear the established name of the product (*e.g.*, "cigarettes") and the statement, "Nicotine-Delivery Device for Persons 18 or Older." *Id.* at 44,617.

Based on evidence that "advertising plays a material role in the decision of children * * * to engage in tobacco use," 61 Fed. Reg. at 44,489, and internal company documents showing the industry's concerted efforts "to attract young smokers" and "presmokers" through advertising, *id.* at 44,480, FDA concluded that restrictions on the forms of advertising that are most effective in attracting young smokers are necessary to complement the access restrictions. *Id.* at 44,406-44,407. FDA's advertising and promo-

tion restrictions include: (1) a requirement that advertisements appear in black-and-white, text-only format, except in adult publications and adult-only facilities; (2) a ban on outdoor advertising within 1000 feet of schools and public playgrounds; (3) a prohibition on the sale or distribution of hats, t-shirts, and other similar promotional products that bear a tobacco product brand name or logo; and (4) a prohibition on sponsorship of athletic, cultural, or other events in a tobacco brand name. *Id.* at 44,617-44,618. In adopting its access, labeling, and advertising restrictions, FDA invoked its authority under 21 U.S.C. 360j(e)(1) to place conditions on the sale, distribution, and use of a device if FDA determines that "there cannot otherwise be reasonable assurance of its safety and effectiveness."

4. Respondents (tobacco companies, advertisers, and retailers) brought suit in the United States District Court for the Middle District of North Carolina, challenging the validity of FDA's tobacco product regulations. Respondents moved for summary judgment, arguing that: (1) FDA lacks statutory authority to regulate tobacco products that are marketed without claims of therapeutic value; (2) FDA lacks statutory authority to regulate advertising of tobacco products; and (3) FDA's advertising restrictions violate the First Amendment. For purposes of their summary judgment motion, respondents accepted as true the facts found by FDA concerning the effects of tobacco products on the human body, and the intent of the manufacturers to cause those effects. Pet. App. 77a-78a n.1.

The district court granted in part and denied in part respondents' motion for summary judgment. Pet. App. 76a-134a. The district court first held that FDA had lawfully concluded that tobacco products are subject to regulation as "drugs" and "devices." *Id.* at 80a-126a. The court reasoned that, given FDA's finding that tobacco products are intended to cause and sustain addiction and to act as a stimulant,

sedative, and weight regulator, tobacco products fit squarely within the Act's definitions of "drug" and "device." *Id.* at 81a, 104a-116a. The court concluded that FDA's previous statements concerning its authority to regulate tobacco products, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products, and the tobacco-specific statutes enacted after 1938 do not detract from the reasonableness of FDA's conclusion that tobacco products are drugs and devices under the Act. *Id.* at 84a-101a.

The district court upheld FDA's restrictions on minors' access to tobacco products as a valid exercise of FDA's authority under 21 U.S.C. 360j(e)(1) to impose conditions on the "sale, distribution, or use" of "devices." Pet. App. 133a. It also upheld FDA's labeling requirements. *Id.* at 134a. The court concluded, however, that FDA's advertising and promotion restrictions are not authorized by Section 360j(e). *Id.* at 127a-133a. The district court certified all of its rulings for interlocutory appeal, *id.* at 135a, and the court of appeals accepted that certification, *id.* at 11a.

5. a. In a 2-1 decision, a panel of the Fourth Circuit reversed, Pet. App. 1a-75a, holding that "FDA lacks jurisdiction to regulate tobacco products," and that "all of the FDA's August 28, 1996 regulations * * * are thus invalid," *id.* at 11a-12a. The majority acknowledged that the plain meaning of the drug and device provisions "may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices." *Id.* at 19a. The majority determined, however, that FDA could not rely on the definitional provisions, because, in its view, tobacco products do not fit into the Act's overall regulatory scheme. *Id.* at 20a-30a.

The majority concluded that, under 21 U.S.C. 360j(e), FDA has a responsibility to determine that there is a reasonable assurance of safety of a product that it declines to

ban completely from the market. Pet. App. 21a-22a. Because FDA found tobacco products to be dangerous, the majority concluded, FDA's failure to prohibit the sale of such products does not "comply with the terms of the very statutory provision it has chosen as its basis for regulation." *Id.* at 23a. The majority further concluded that, given FDA's finding that tobacco products are not safe, several other provisions of the Act would require FDA to ban the sale of tobacco products, a result the majority found to be in conflict with what it perceived to be Congress's intent. *Id.* at 23a-30a. The majority concluded that "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." *Id.* at 29a-30a. The majority also concluded that FDA's previous statements concerning the circumstances in which it would regulate tobacco products, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products, and the tobacco-specific statutes enacted since 1938 all corroborate that Congress did not intend the original grant of authority to FDA to include regulation of tobacco products. *Id.* at 31a-52a.

b. Judge Hall dissented. Pet. App. 55a-75a. Observing that the "record contains voluminous evidence of the pharmacological effects of nicotine," *id.* at 57a, and that such effects are "intended" by tobacco manufacturers, *id.* at 57a-59a, he concluded that "[t]obacco products fit comfortably into the [Act's] definitions of 'drug' and 'device,'" *id.* at 55a. Judge Hall rejected the majority's view that FDA's failure to prohibit the sale of tobacco products, despite finding them to be dangerous, demonstrates that tobacco products are not covered by the Act. *Id.* at 60a-61a. He reasoned that "*[h]ow* the FDA has chosen to regulate tobacco has no bearing on the question of *whether* the agency has the authority to regulate it at all." *Ibid.* Judge Hall similarly disagreed with

the majority's reliance on FDA's prior decisions and statements regarding its authority to regulate tobacco products. *Id.* at 63a-65a. He pointed out that "an agency can change its view of what action is possible or necessary, particularly when new facts come to light." *Id.* at 64a. Here, he explained, FDA had a strong basis for changing its position because of new evidence that "nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction," and, even more important, because of new evidence that "manufacturers design their products to sustain such addiction." *Id.* at 65a. Judge Hall also disagreed with the majority's reliance on unenacted bills, concluding that any inference that could be drawn from that experience was offset by Congress's inaction following FDA's announcement of its proposed rule to regulate tobacco products. *Id.* at 61a n.1. Finally, Judge Hall concluded that the "tobacco-specific" statutes cited by the majority address narrow subjects and fall far short of showing that Congress intended to prevent FDA from exercising regulatory authority over tobacco products. *Id.* at 65a-70a.

SUMMARY OF ARGUMENT

The Food and Drug Administration reasonably concluded that tobacco products are drugs and devices subject to regulation under the Act. Under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), FDA's conclusion is entitled to controlling weight.

A. The Federal Food, Drug, and Cosmetic Act defines "drug" and "device" to include products "intended to affect the structure or any function of the body," 21 U.S.C. 321(g)(1)(C) and (h)(3), and it does not exempt tobacco products from those definitions. Given FDA's finding that the nicotine in tobacco products is intended by manufacturers to sustain addiction and to act as a sedative, stimulant, and

appetite suppressant, tobacco products plainly qualify as drugs and devices under the Act.

B. Tobacco products also have the classic characteristics of drugs and devices subject to regulation under the Act: They are taken within the human body, they deliver a pharmacologically active substance to the bloodstream, and they have potentially dangerous effects. Moreover, the intended pharmacological effects of tobacco products mirror those of numerous other products that FDA regulates, including tranquilizers, stimulants, weight-loss products, nicotine replacement products, and narcotics used to treat addiction.

Respondents' argument that tobacco products cannot be drugs or devices unless they are accompanied by express claims of therapeutic value is without merit. The text of the Act makes "intended" effects, not "market claims," the decisive factor. When, as here, consumers use a product predominantly for its pharmacological effects, manufacturers know that is why consumers use their products, and manufacturers manipulate the content of the product in order to promote those uses, an intent to affect the structure or function of the body is clearly established. FDA has regulated other products intended to affect the structure or function of the body, despite the absence of explicit market claims, and there is no principled basis for treating tobacco products differently.

C. The court of appeals' view that tobacco products cannot be drugs or devices, because if they were, they would have to be banned, is incorrect. The Act authorizes FDA to permit the continued marketing of drugs and devices, subject to regulation, when it finds that the dangers of banning the product outweigh the benefits. FDA reasonably determined that, with respect to adults, the dangers of banning tobacco from the market outweigh the benefits, because a ban would leave many users with untreatable

symptoms of withdrawal, and would predictably lead to the use of more dangerous black market products. If the Court were to overturn FDA's judgment concerning the risks and benefits of leaving tobacco products on the market, however, that would simply mean that the Act, as presently written, requires tobacco products to be banned. That consequence would in no way undermine FDA's conclusion that tobacco products are intended to affect the structure or function of the body and are therefore drugs and devices subject to regulation under the Act.

D. Until FDA issued the regulations at issue here, the only instances in which it had found that tobacco products were intended to affect the structure or function of the body involved cases in which there were express market claims of therapeutic value. An agency is always free to change its position on an issue, however, as long as it provides a reasoned explanation justifying the change, and FDA provided such a reasoned explanation here. FDA's conclusion that tobacco products are intended to affect the structure or function of the body, regardless of whether manufacturers make express claims of therapeutic value, is based on overwhelming new evidence that nicotine is addictive, that consumers use tobacco products primarily to satisfy addiction and for its mood-altering effects, that manufacturers know that consumers use their products primarily for those purposes, and that manufacturers have engineered their products to deliver pharmacologically active doses of nicotine.

Nor is it significant that Congress has failed to enact bills that would have expressly authorized FDA to regulate tobacco products. The Constitution requires Congress to express its will through enacted legislation, not unenacted bills. Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products therefore has no more bearing on the question presented in this case than does Congress's failure to enact other bills

that would have excluded tobacco products from the reach of the Act.

Finally, the tobacco-specific statutes enacted long after 1938 do not affect the question presented here. Those statutes address narrow issues, such as what warning labels should be placed on cigarette packages. None of those statutes exempts tobacco products from the reach of the Federal Food, Drug, and Cosmetic Act, and none of them remotely implies that FDA altogether lacks authority to regulate tobacco products.

ARGUMENT

THE FOOD AND DRUG ADMINISTRATION VALIDLY DETERMINED THAT TOBACCO PRODUCTS ARE "DRUGS" AND "DEVICES" WITHIN THE MEANING OF THE ACT

After the most extensive rulemaking hearing in its history, the Food and Drug Administration determined that the nicotine in tobacco products is intended by tobacco manufacturers to cause and sustain addiction and to act as a stimulant, sedative, and appetite suppressant. The sole question presented in this case is whether, given that finding, FDA validly determined that tobacco products are subject to regulation as "drugs" and "devices" under the Act.

Because Congress has conferred on FDA the authority to administer the Act, 21 U.S.C. 393(d)(2) (1994 & Supp. III 1997), and to issue regulations to carry out its purposes, 21 U.S.C. 371(a), FDA's conclusion that tobacco products are drugs and devices is subject to review under the standard set forth in *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, unless Congress has "unambiguously expressed [its] intent" and "directly addressed the precise question at issue," the question for a court is whether the agency's view is based on

a "permissible construction" of the Act. *Id.* at 843. That means that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Id.* at 844. Rather, when the agency "fills a gap or defines a term in a way that is reasonable in light of the legislature's revealed design," a court must give the agency's view "controlling weight." *Ibid.* As we now demonstrate, FDA reasonably concluded that tobacco products are subject to regulation under the Act as "drugs" and "devices." The Court should therefore give FDA's interpretation controlling weight.[3]

A. FDA's Interpretation Is Supported By The Plain Language, Structure, And Drafting History Of The Drug And Device Definitions

1. Rather than identifying specific products that FDA may regulate as "drugs" and "devices," Congress enacted

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[3] The court of appeals appeared to question the applicability of *Chevron* for two reasons. First, the court noted (Pet. App. 16a) that, under *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649 (1990), "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority," suggesting that the court believed that such a delegation is absent here. *Adams Fruit* holds that an agency is not entitled to deference when it does not have authority to enforce the statutory provision at issue. *Ibid.* Because Congress has conferred authority on FDA to regulate drugs and devices, *Adams Fruit* is inapplicable here. Second, the Fourth Circuit suggested (Pet. App. 16a) that an agency is entitled to diminished deference when it attempts "to expand the scope of its jurisdiction." As long as an agency is reasonably interpreting a statutory provision it enforces, however, *Chevron* deference applies. It is not relevant whether the agency's proposed interpretation can be said to affect its jurisdiction. *Chevron*, 467 U.S. at 844 (an agency is entitled to deference on the "reach of a statute" it is authorized to enforce). See *Commodity Futures Trading Comm'n* v. *Schor*, 478 U.S. 833, 844-845 (1986); *NLRB* v. *City Disposal Sys., Inc.*, 465 U.S. 822, 830 n.7 (1984); see also *Mississippi Power & Light Co.* v. *Mississippi ex rel. Moore*, 487 U.S. 354, 380-382 (1988) (Scalia, J., concurring) (collecting cases).

comprehensive definitions of those terms. Products that fall within those definitions, unless expressly exempted, are subject to the Act's regulatory regime. The Act defines "drug" as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) *articles (other than food) intended to affect the structure or any function of the body of man or other animals*; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.

21 U.S.C. 321(g)(1) (emphasis added). The Act similarly defines "device" as, *inter alia*, "an instrument, apparatus, * * * contrivance, * * * or other similar or related article, including any component, part, or accessory, * * * intended to affect the structure or any function of the body of man or other animal, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h)(3).

Significantly, the Act does not exempt tobacco from the drug and device definitions. In contrast, the Act does specifically exclude "food" from the very "structure-function" definition of "drug" at issue here, 21 U.S.C. 321(g)(1)(C), and exempts "tobacco" itself from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1). See also 21 U.S.C. 321(i) (exempting "soap" from the definition of "cosmetic"; 21 U.S.C. 321(s) (1994 & Supp. III 1997) (exempting "pesticides" in certain circumstances from the definition of

"food additive"). Congress has also specifically exempted tobacco products from many other laws, including the Federal Hazardous Substances Act, 15 U.S.C. 1261(f)(2), the Fair Packaging and Labeling Act, 15 U.S.C. 1459(a)(1), the Consumer Products Safety Act, 15 U.S.C. 2052(a)(1)(B), the Toxic Substances Control Act, 15 U.S.C. 2602(2)(B)(iii), and the Controlled Substances Act, 21 U.S.C. 802(6). Accordingly, the overwhelming implication from the text and structure of the "drug" and "device" definitions is that tobacco products, like all other products not specifically exempted, are subject to regulation as "drugs" and "devices" if they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3).

2. Given the extensive evidence before FDA, and FDA's findings based on that evidence, tobacco products plainly qualify as "drugs" and "devices" under that statutory standard. The evidence established that: (1) nicotine in tobacco products causes and sustains addiction and acts as a sedative, stimulant, and appetite suppressant; (2) most persons who use tobacco products do so in order to obtain those effects; (3) tobacco manufacturers know that most consumers use their products for those purposes; (4) tobacco manufacturers themselves characterize nicotine as a powerful drug and cigarettes as a vehicle for delivering nicotine; (5) the manufacturers design their products to deliver pharmacologically active doses of nicotine; and (6) the manufacturers market their products with claims that they will provide "satisfaction," a "code-word" for the pharmacological effects of nicotine. See pp. 3-8, *supra*. Based on that compelling evidence, FDA found that the nicotine in tobacco products is intended by manufacturers to cause and sustain addiction, and to act as a sedative, stimulant, and appetite suppressant. In light of that critical finding, tobacco products fit squarely within the "drug" and "device" definitions—they are, without question, "intended to affect the structure or any func-

tion of the body." 21 U.S.C. 321(g)(1)(C) and (h)(3). Thus, the plain language of the Act, which is the starting point in resolving any question of statutory construction, *United States* v. *Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989), provides powerful support for FDA's conclusion that tobacco products are "drugs" and "devices" under the Act.

3. The history of the Act provides additional support for FDA's conclusion. Before the Act was passed in 1938, the Pure Food and Drugs Act defined "drug" to include "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them," and "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." Pure Food and Drugs Act of 1906, ch. 3915, § 6, 34 Stat. 769. In the 1938 Act, Congress expanded the definition of "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man or other animals." § 201, 52 Stat. 1041. The new Act also added a parallel definition of "device." *Ibid.* Congress enacted the new definitions because existing law "contain[ed] serious loopholes" and was "not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions." H.R. Rep. No. 2139, 75th Cong., 3d Sess. 1 (1938). Congress was particularly concerned about dangerous and ineffective weight-loss products that had escaped regulation under the old drug definition. S. Rep. No. 361, 74th Cong., 1st Sess. Pt. 1, at 239 (1935). Congress understood, however, that the Act would reach well beyond weight-loss products and cover other products intended to affect the structure or function of the body. See H.R. Rep. No. 2139, *supra*, at 2 ("Drugs intended for diagnosing illness or for remedying underweight or overweight or for otherwise affecting bodily structure or function are subjected to regulation.").

The drafting history of the drug and device definitions provides compelling evidence that the definitions were intended to have a scope that is as broad as their language prescribes. Early versions of the bill had included "devices intended to affect the structure or function of the body" within the definition of "drug." S. Rep. No. 493, 73d Cong. 2d Sess. 2 (1934). In hearings on one of those bills, a Member of Congress asked the FDA Administrator whether the drug definition would include "ultraviolet lights and various instruments of that sort." Charles W. Dunn, *Federal Food, Drug, and Cosmetic Act*, App. B at 1053 (1938). The Administrator responded that it would, because the portion of the "drug" definition that encompassed "devices" was "admittedly an inclusive, * * * wide definition." *Ibid.* The Administrator added that the definition would also encompass belts used for therapeutic purposes, explaining that "[t]his definition of 'drugs' is all-inclusive." *Id.* App. C at 1126-1127. Members of Congress later expressed concern that the device portion of the drug definition was so broad as to reach shoulder braces, radium belts, electrical devices, bathroom weight scales, hospital air conditioners, and crutches. *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 795-796 (1969) (citing relevant debates). The members did not object to the regulation of such products under the Act; instead, they objected to the characterization of such products as drugs. *Id.* at 796-797. In response to that narrow concern, the bill was amended to remove devices from the drug definition and to create a separate definition of "device" that paralleled the new definition of drug. *Ibid.* That solution eliminated the awkwardness of referring to electric belts and therapeutic lamps as drugs, while preserving the bill's broad scope. *Ibid.*

The statutory background and drafting history of the Act show that Congress understood that the definitions of "drug" and "device" would determine what products would

be subject to regulation under the Act, and that the scope of those definitions was intended to be coextensive with their plain language, reaching many products that had not been subject to regulation before. Accordingly, they firmly support FDA's reliance on the plain language of the "drug" and "device" definitions in concluding that, given their intended pharmacological effects, tobacco products are subject to regulation under the Act.[4]

4. This Court's decision in *Bacto-Unidisk* also provides significant support for FDA's analysis. The question in that case was whether an antibiotic sensitivity disc used to determine which antibiotic should be used in treatment of a particular patient was a "drug" under the Act. 394 U.S. at 784. The disc satisfied the literal definition of "drug," because it was intended for use in the cure, mitigation, or treatment of disease. *Id.* at 792. The lower courts had held, however, that the drug definition should be construed to

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[4] As the court of appeals noted (Pet. App. 32a), there is no discussion in the legislative history of the 1938 Act concerning whether tobacco products would or would not be covered as drugs or devices. But that is hardly surprising. At the time, there was not public evidence that the nicotine in tobacco products was intended by manufacturers to cause and sustain addiction and to act as a sedative, stimulant, and appetite suppressant. Moreover, as the discussion in the text demonstrates, Congress deliberately drafted comprehensive definitions of drug and device, and it is that intent, rather than Congress's understanding of the specific products that would be encompassed by those definitions, that is controlling. See *Oncale* v. *Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) (Since "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed," it is irrelevant whether the members of Congress who enacted Title VII would have regarded male-on-male sexual harassment as a form of discrimination prohibited by Title VII.); *H.J. Inc.* v. *Northwestern Bell Tel. Co.*, 492 U.S. 229, 248 (1989) (While "[t]he occasion for" the enactment of the RICO statute was "the perceived need to combat organized crime," Congress "chose to enact a more general statute."). See also note 7, *infra*.

reach only those products that satisfy the medical definition of a drug. *Ibid.* This Court squarely rejected that interpretation and held that the disc was a "drug" within the meaning of the Act. Relying on the text of the Act and the drafting history discussed above, the Court concluded that "the word 'drug' is a term of art for purposes of the Act, encompassing far more than the strict medical definition of that word." *Id.* at 793. The Court further explained that "[t]he 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." *Id.* at 798. *Bacto-Unidisk* therefore fully supports FDA's reliance on the plain language of the drug and device definitions for its conclusion that, in light of their intended pharmacological effects, tobacco products are drugs and devices under the Act.

B. FDA's Interpretation Is Also Supported By FDA's Prior Regulatory Practice And The Public Health Purposes Of The Act

1. FDA's conclusion that tobacco products are subject to regulation as drugs and devices is also supported by FDA's prior regulatory practice and the public health purposes of the Act. As FDA has explained, the intended pharmacological effects of tobacco products mirror those of numerous other products that FDA regulates, including tranquilizers, stimulants, weight-loss products, and narcotics used to treat addiction. See 61 Fed. Reg. at 44,632, 44,667-44,678. FDA also regulates the sale of other products containing nicotine, such as nicotine patches, nicotine chewing gum, and nicotine nasal spray, and the pharmacological effects of nicotine in tobacco products are far more powerful than those in the other nicotine-containing products. *Id.* at 44,665.

Significantly, moreover, tobacco products have the classic characteristics of drugs and devices subject to regulation under the Act: Tobacco products are taken within the human body, they deliver a pharmacologically active substance to the bloodstream, and they have potentially dangerous effects. 61 Fed. Reg. at 44,628. The resemblance of tobacco products to other products regulated as drugs and devices by the FDA has not escaped the attention of tobacco manufacturers. In their own research, market planning, and deliberations, the manufacturers have referred to the nicotine in tobacco as a drug, to cigarettes as a vehicle for the delivery of nicotine, and to the tobacco industry as a segment of the pharmaceutical industry. See pp. 5-7, *supra*. Because of the similarity between tobacco products and other products regulated by FDA, it is not surprising that FDA has previously regulated tobacco products when it has found sufficient evidence that they were intended to affect the structure or any function of the body, see *United States* v. *354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959), or that they were intended to treat or prevent disease, see *United States* v. *46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953).

2. Respondents have sought to distinguish the products regulated by FDA that have pharmacological effects similar to those of tobacco products on the ground that those products are sold with express therapeutic claims. That distinction, in respondents' view, also explains why it was appropriate for FDA to regulate tobacco products in the two cigarette cases cited above. Under respondents' theory, tobacco products would be subject to FDA regulation only if tobacco manufacturers suddenly decided on a policy of full public disclosure and made express representations that their products cause and satisfy addiction and are intended to be used as a sedative, stimulant, and appetite suppres-

sant. But as long as they refrain from making such claims, respondents argue, tobacco products are not subject to the Act. That remains true, under respondents' theory, even when, as here, there is overwhelming evidence that consumers use tobacco products as sedatives, stimulants, and appetite suppressants and to maintain addiction; that those characteristics of tobacco products are so well known as to render them unquestionably foreseeable to the manufacturers of the products; and that the manufacturers of the products in fact act keenly aware of those effects and uses and manipulate the nicotine content of their products to promote them.

In these circumstances, the pervasive knowledge and conduct on the part of both manufacturers and consumers serve the same function as labeling or other express representations by the manufacturers in identifying the intended effects and uses of the product, thereby rendering any such representations unnecessary. It would be ironic indeed, and contrary to the fundamental public health purposes of the Act, to conclude that a product is altogether excluded from regulation under the comprehensive terms of the Act precisely *because* its basic drug-like qualities are so well documented, widely known, and thoroughly embedded in the behavior of consumers and manufacturers as to render express claims to that effect superfluous. And, not surprisingly, respondents' view that FDA must blind itself to compelling evidence that a product is intended to affect the structure or function of the body simply because a manufacturer has not made any express claims of therapeutic value is at odds with the text of the Act, longstanding FDA regulations, the legislative history of the Medical Devise Amendments of 1976, lower court decisions, and FDA's regulatory practice.

The text of the Act makes "intended" effects, not "market claims," the decisive factor. 21 U.S.C. 321(g)(1)(C) and (h)(3).

While market claims are one important way in which a product's intended effects may be established, they are not the only way. As the present case so clearly shows, other circumstances can establish that a product is intended to affect the structure or function of the body. Nothing in the text of the operative definitions bars FDA from relying on such evidence. Moreover, if Congress had wished to establish the statutory standard respondents propose, it could have used terms such as "promoted to," "labeled to," "advertised to," or "represented to" instead of "intended to." Congress used such terms in other provisions of the Act. 21 U.S.C. 321(n) (misbranding may result from "representations" made in "labeling or advertising"); 21 U.S.C. 352(a) (a drug is misbranded if its "labeling" is false or misleading); 21 U.S.C. 352(c) (a drug is misbranded unless its "advertisements and other descriptive printed matter" contain certain true statements). Congress's failure to use those terms in the drug and device definitions is therefore significant: It shows that Congress understood the difference between intended effects and claimed effects, and that it deliberately chose the more comprehensive "intended to affect" formulation to define the products subject to coverage under the Act. See 61 Fed. Reg. at 45,154-45,155.

Consistent with that understanding, FDA regulations that have been in effect for more than four decades provide that "intended use" (or words to that effect) refer to "the objective intent of the persons legally responsible for labeling," and may be determined not only by "labeling claims" and "advertising matter," but also by (1) other "oral or written statements" made by persons legally responsible for the labeling; (2) "the circumstances surrounding the distribution of the article"; (3) "the circumstances that the article is, with the knowledge of [the responsible persons], * * * offered and used for a purpose for which it is neither labeled nor advertised"; and (4) evidence that "a manufac-

turer knows, or has knowledge of facts that would give him notice" that a drug or device "is to be used" for purposes other than those for which the manufacturer offered the products. 21 C.F.R. 201.128 (drug); 21 C.F.R. 801.4 (device).[5] FDA has further explained that its "objective intent" standard means that FDA will consider all relevant evidence of intent from the perspective of a reasonable fact-finder, and that it is not bound by the intent a manufacturer claims to have. 61 Fed. Reg. at 45,153, 45,184 n.1133. Compare *Posters 'N' Things* v. *United States*, 511 U.S. 513, 519-522 (1994) (holding that the phrase "primarily intended for use [with illegal drugs]," which is the definition of "drug paraphernalia" in 21 U.S.C. 857(d), "is to be understood objectively and refers generally to the item's likely use").

The legislative history of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, in which Congress revised and reenacted the definition of "device" in its current form, see § 3(a)(i)(A), 90 Stat. 575, confirms the soundness of FDA's interpretation of that definition (and the parallel definition of "drug") as not limiting the "intended" effects of a product to those the manufacturer expressly claims. The House Report stated that, although the major new authorities to be conferred on FDA should be limited to devices intended for human use,

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[5] The regulatory definitions quoted in the text, which were first promulgated in 1952 (see 17 Fed. Reg. 6818 (1952)), define "intended use" for purposes of FDA's labeling regulations. The product labeling regulations require adequate labeling for all "intended uses" of a drug or device. See 21 C.F.R. 201.5 (drugs), 801.5 (devices). As FDA explained in its jurisdictional determination concerning tobacco products (61 Fed. Reg. at 44,693 n.23, 45,157), however, it regularly uses the definitions in the product-labeling regulations not only to identify the intended uses of products that are already classified as drugs or devices, but also to determine whether products should be classified as drugs or devices in the first place.

> [t]his is not to say * * * that a manufacturer of a device that is banned by the Secretary [for human use] can escape the ban by labeling the device for veterinary use. The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, *just as he may consider actual use of a product in determining whether or not it is a device.*

H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976) (emphasis added).

Lower courts likewise have agreed that a manufacturer's intent with respect to effects or use may be determined on the basis of all relevant circumstances, including consumer use, not simply a manufacturer's market claims. *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977) (intent may be determined from any relevant source, including consumer use); *United States* v. *An Article * * * Consisting of * * * 216 Cartoned Bottles*, 409 F.2d 734, 739, 742 (2d Cir. 1969) (the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source, including consumer use); *United States* v. *Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985), (manufacturer intent may be derived from any relevant source), cert. denied, 479 U.S. 1086 (1987); *Action on Smoking & Health* v. *Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980) (*ASH*) (consumer use can be relevant in determining manufacturer intent); see also *United States* v. *789 Cases * * * of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285, 1294-1295 (D.P.R. 1992); *United States* v. *An Article of Device * * * "Cameron Spitler Amblyo-Syntonizer"*, 261 F. Supp. 243, 245 (D. Neb. 1966). From a public health perspective, no other result could be justified. The risks to the public health and the appropriateness of regulation under the Act exist regardless of whether intended effects

are established through market claims or by other evidence. See *Bacto-Unidisk*, 394 U.S. at 798 (the Act is to be given a construction "consistent with the Act's overriding purpose to protect the public health").

Finally, in its administration of the Act, FDA has treated products intended to affect the structure or function of the body as drugs or devices, despite the absence of express market claims of therapeutic value. For example, FDA took enforcement action against "caine," a product that contained anesthetic powders and that was often marketed as incense. FDA found that "caine" was intended to be used as a drug, based on a laboratory analysis of its ingredients, its sale in "head shops," and "street" information that it provided a "cheap high." 61 Fed. Reg. at 45,167. Similarly, FDA took enforcement action against "khat," a shrub whose leaves act as a stimulant when chewed or used as tea, even though its vendors did not make any market claims. FDA determined that "khat" was intended for use as a drug based on its actual effects and widely known uses. *Ibid.*

FDA has also treated other products as drugs or devices, despite the absence of explicit market claims. Among other products, FDA has treated as drugs or devices: (1) cosmetics containing hormones based on the absence of any legitimate cosmetic purpose for the hormones; (2) toothpaste containing fluoride because fluoride is widely accepted as an anti-cavity agent and affects the structure of the tooth; (3) thyroid-containing food supplements based on the recognized physiological effects of thyroid products; (4) interferon based on media coverage touting it as a possible miracle cure; (5) novelty condoms based on their likely use as prophylactics; (6) non-corrective tinted contact lenses based on their effects on the eye; (7) sunscreen products based on consumer expectations that they will provide protection against the sun; and (8) tanning booths based on the known effects of ultraviolet rays. 60 Fed. Reg. at 41,528-41,531. In each of the above

cases, FDA found that the product was intended for use as a drug or a device based on the inherent nature of the product, its predominant use or effects, or both. *Id.* at 41,527. There is no principled basis for treating tobacco products differently, especially in light of the compelling evidence that tobacco manufacturers have known for decades that nicotine is addictive and has mood-altering effects and that those are the main reasons that people use tobacco products. Tobacco products should not escape regulation for the protection of the public health simply because tobacco manufacturers refrain from making express claims about the pharmacological effects and uses they so clearly intend and from which they so clearly profit.

C. FDA's Interpretation Is Consistent With The Structure Of The Act As A Whole

The court of appeals rejected FDA's conclusion that tobacco products are drugs and devices in large part because it believed that regulation of tobacco products is inconsistent with the structure of the Act as a whole. The court essentially reasoned as follows: (1) If tobacco products are drugs or devices within the meaning of the Act, the regulatory provisions of the Act would require them to be banned; (2) Congress did not intend for tobacco products to be banned; therefore (3) tobacco products are not drugs and devices. See generally Pet. App. 18a-30a. That analysis is seriously flawed. FDA reasonably concluded that the operative regulatory provisions of the Act do not require a ban of tobacco products. Even if the operative provisions of the Act were to require a ban, however, that would not detract from the reasonableness of FDA's conclusion that tobacco products are drugs and devices.

1. In concluding that tobacco products would have to be banned if they are drugs and devices, the court of appeals cited provisions of the Act that either directly prohibit the

marketing of drugs and devices that FDA has found not to be sufficiently "safe," or contemplate that FDA will prevent or otherwise regulate the marketing of such products.[6] Because FDA determined that tobacco products are dangerous, the court reasoned, those provisions would require tobacco products to be banned if they were "drugs" and "devices." See generally Pet. App. 18a-30a.

In deciding whether a drug or device is sufficiently "safe" within the meaning of the provisions cited by the court of appeals, however, FDA's role is not confined to determining whether the product is unsafe as that term is most commonly used. FDA also generally weighs the risk presented by a product against countervailing health benefits. That balancing of risks and benefits is expressly required when FDA classifies devices into regulatory categories. 21 U.S.C.

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6 See 21 U.S.C. 393(b)(2)(B) and (C) (Supp. III 1997) (FDA shall protect the public health by ensuring that "drugs are safe and effective," and that "there is a reasonable assurance of the safety and effectiveness of devices."); 21 U.S.C. 360j(e)(1) (FDA "may by regulation require that a device be restricted to sale, distribution, or use * * * upon such * * * conditions as [FDA] may prescribe by regulation, if, because of its potentiality for harmful effect * * *, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."); 21 U.S.C. 355(a) and (d) (No person may introduce any "new drug" absent FDA approval, and, if FDA finds that the drug "is unsafe for use," it "shall issue an order refusing to approve the application."); 21 U.S.C. 331(a), 352(j) (The introduction of a "misbranded" drug or device is prohibited, and a drug or device is "misbranded" when "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."); 21 U.S.C. 360c (FDA must classify devices into one of three categories based on what controls are necessary to provide a reasonable assurance of the safety and effectiveness of the device.); 21 U.S.C. 360h(e)(1) (If FDA "finds that there is a reasonable probability that a device * * * would cause serious, adverse health consequences or death," FDA "shall issue an order requiring the appropriate person * * * to immediately cease distribution of such device.").

360c(a)(2)(C) ("the safety and effectiveness of a device 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"). FDA also follows the same general balancing approach in applying and enforcing other provisions of the Act. See *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979). For example, as FDA has explained, several products used in the treatment of cancer are highly toxic and therefore are not "safe" as that term is most commonly understood. 61 Fed. Reg. at 44,413. FDA has nonetheless approved such products for use in cancer treatment after finding that the danger of not treating the cancer outweighs the risks of the drugs. *Ibid.*

FDA applied a similar analysis here. It found that, while "tobacco products are unsafe as that term is conventionally understood," the Act contemplates "consideration of 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." 61 Fed. Reg. at 44,412-44,413. After undertaking that balancing process, FDA concluded that, with respect to adults, "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous" for several reasons. *Id.* at 44,413. First, as a result of withdrawal symptoms, "[t]here could be significant health risks to many of these individuals." *Ibid.* Second, the health care system could be "overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users." *Ibid.* Finally, because of the strength of the addiction and the difficulty of quitting, "a black market and smuggling would develop to supply smokers with these products," and the black market products would likely "be even more dangerous than those currently marketed, in that they could con-

tain even higher levels of tar, nicotine, and toxic additives." *Ibid.* FDA therefore reasonably concluded that, "on balance, an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while permitting the sale to adults seems most appropriate, * * * is consistent with the statutory standard of reasonable assurance of safety[,] and is more effective in achieving public health goals than a ban on all tobacco products." *Ibid.*

The Fourth Circuit rejected FDA's analysis on the ground that FDA had applied the wrong legal standard for determining the safety of a product. In the court's view, the Act requires FDA "to strike a balance between the risks and benefits of the *use* of a product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market." Pet. App. 21a. The statutory text, however, does not impose any such limitation on the agency's discretion. The "benefit to health from the use" of a product, 21 U.S.C. 360c(a)(2)(C), readily encompasses the prevention of the harmful health consequences that would ensue if a product were removed from the market. Tobacco products thus "benefit" the "health" of many users because they relieve otherwise untreatable symptoms of nicotine withdrawal, and because they are safer than black market products that would predictably be used for that purpose if tobacco products could no longer be lawfully marketed to adults.

FDA's interpretation, moreover, best comports with the public health purposes of the Act. From a public health perspective, it would make no sense to require removal of a product from the market when that would cause more harmful health consequences than leaving the product on the market. This Court's decision in *Rutherford* also supports FDA's interpretation. There, the Court affirmed FDA's conclusion that laetrile, while inherently harmless, was unsafe

within the meaning of the Act and should be removed from the market, because its availability could lead persons to reject more beneficial conventional treatments. 442 U.S. at 556. FDA's conclusion here—that the continued marketing of tobacco products to adults should be allowed because their removal could leave those users without treatment alternatives for their addiction and lead them to use more dangerous products—is the mirror image of the analysis approved in *Rutherford*. Thus, FDA's conclusion that the Act does not require tobacco products to be banned is based on a reasonable construction of the Act. Under *Chevron*, the court of appeals should have deferred to it. The court of appeals, however, did not even advert to the question of *Chevron* deference when it rejected FDA's conclusion that the Act does not require it to impose a complete ban on tobacco products. See Pet. App. 20a-30a.

2. Even assuming the regulatory provisions of the Act would require tobacco products to be banned, however, that would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act. As Judge Hall stated in his dissent in this case, "*[h]ow* 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." Pet. App. 60a-61a. See also *Bacto-Unidisk*, 394 U.S. at 792 (while the parties have debated the wisdom of subjecting antibiotic sensitivity disks to premarket review, the only relevant inquiry "is whether the statute's definition of 'drug' authorizes the disc regulations contested here").

The court of appeals' contrary conclusion rests on the premise that a ban on tobacco products would be a consequence that the enacting Congress did not contemplate and that therefore would conflict with Congress's intent, so that, if the regulatory provisions of the Act would require tobacco products to be banned, they cannot be drugs or devices. No

provision of the Act as passed in 1938, however, suggests that a ban on the sale of tobacco products, or indeed any other products—based on powerful evidence that might later came to light establishing the addictive and other intended pharmacological effects of such products—would conflict with congressional intent. Nor is there any other sound basis for reaching that conclusion.

Congress expresses its operative intent in the text of the laws it enacts, see *Oncale*, 523 U.S. at 79-80; *H.J. Inc.*, 492 U.S. at 248, and that intent is not difficult to discern here: When FDA finds that a product is "intended to affect the structure or any function of the body", 21 U.S.C. 321(g)(1)(C) and (h)(3), and that the product is not sufficiently, "safe," 21 U.S.C. 393(b)(2)(B) and (C)—*i.e.*, the risks of the product outweigh its benefits—Congress intended for the product not to be marketed.[7]

If this Court were to overturn FDA's judgment that the risks of tobacco products are outweighed by the countervailing benefits of continued marketing to adults, that would simply mean that the Act, as presently written, requires tobacco products to be banned. That consequence, however, would in no way undermine FDA's conclusion that tobacco products are intended to affect the structure or function of the body and are therefore drugs and devices subject to regulation under the Act. In those circumstances, then, it would properly be for Congress, after weighing the competing considerations, to decide whether the ban that was

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[7] What is dispositive for purposes of statutory construction is the statute itself, not whether the Congress that enacted the statute could have anticipated a specific application of the general standards that it prescribed, or whether that Congress would have desired the particular consequences of one such natural application. "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." *TVA* v. *Hill*, 437 U.S. 153, 185 (1978); accord *Busic* v. *United States*, 446 U.S. 398, 404-405 (1980).

(by hypothesis) required by the Act in its current form should remain in effect, or whether the Act should be amended to permit the continued marketing of cigarettes and other tobacco products, under whatever conditions Congress might then prescribe. That result would not be at all anomalous in the working of a comprehensive, prophylactic statute designed to protect the public health and safety. It is, for example, the way in which the Food, Drug, and Cosmetic Act itself operated and Congress responded after FDA concluded that saccharin is an animal carcinogen, the continued sale of which as a food additive would be unlawful under the Act, a conclusion that was dictated by the Delaney Clause, 21 U.S.C. 348(c)(3). Congress enacted legislation that imposed an 18-month moratorium on FDA's proposed rule. Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451.[8] That moratorium has been extended repeatedly,

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[8] The court of appeals concluded that FDA's regulatory scheme does not comport with three other provisions of the Act. Those additional criticisms are also misguided. FDA's determination that the "primary mode" of tobacco products is that of a "drug" does not mean that FDA must regulate tobacco products as drugs rather than devices. Pet. App. 24a. A finding concerning the primary mode of a combination product only determines which component of FDA will have principal responsibility to conduct premarket review. See 21 U.S.C. 353(g)(1). Regardless of which component has that responsibility, FDA may regulate a combination product by using its authority to regulate drugs, its authority to regulate devices, or both. 61 Fed. Reg. at 44,400-44,403. Nor does 21 U.S.C. 352(f)(1) automatically require tobacco manufacturers to include directions for use on their product labels. Pet. App. 25a-26a. FDA may grant an exemption from that requirement when the information is "not necessary for the protection of public health." 21 U.S.C. 352(f)(1). Because the way in which tobacco products are used is common knowledge, FDA reasonably determined that an exemption was appropriate. 61 Fed. Reg. at 44,465. Finally, 21 U.S.C. 352(f)(2) does not require tobacco manufacturers to include additional warnings for children on the labels of tobacco products. Pet. App. 26a-27a. FDA reasonably concluded that the familiar Surgeon General's warnings required by other federal statutes are sufficient to

and it remains in effect today. See Pub. L. No. 104-180, § 602, 110 Stat. 1594; 21 U.S.C. 348 note.[9]

D. FDA's Prior Statements, Unenacted Tobacco Bills, And Certain Tobacco-Specific Statutes Enacted Long After 1938 Do Not Detract From The Reasonableness Of FDA's Interpretation

In rejecting FDA's conclusion that tobacco products are drugs and devices, the court of appeals also relied on FDA's prior statements concerning its authority to regulate tobacco products, unenacted bills that would have specifically authorized FDA to regulate tobacco products, and certain tobacco-specific statutes enacted long after the Federal Food, Drug, and Cosmetic Act was passed. FDA carefully examined each of those sources and reasonably determined that they do not detract from the conclusion that tobacco products are drugs and devices under the Act.

1. Until FDA issued the regulations at issue here, the only instances in which the agency had found that tobacco products were drugs involved cases in which there were express market claims of therapeutic value. FDA's prior position on the subject was authoritatively expressed in decisions in 1977 and 1980 rejecting petitions filed by Action

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satisfy that provision's requirement that a label bear adequate warnings against use by children. 61 Fed. Reg. at 44,465. In any event, as discussed above, the sole question presented here is whether tobacco products are drugs and devices within the meaning of the Act. Whether FDA is required to take *further* steps, in addition to the regulations it has prescribed, does not have any bearing on the resolution of that question.

[9] Congress responded in a similar manner to the holding in *TVA* v. *Hill*, 437 U.S. 153 (1978), that the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531 *et seq.*, prohibited the completion of the Tellico Dam because the project would destroy the snail darter, by directing the completion of the dam, "notwithstanding" the ESA. See Energy and Water Development Appropriation Act, Pub. L. No. 96-69, 93 Stat. 449. See also *County of Oneida* v. *Oneida Indian Nation*, 470 U.S. 226, 253 (1985).

on Smoking in Health (ASH) to regulate cigarettes as drugs or devices. See J.A. 44-49 (Letter from FDA Commissioner Kennedy to ASH Executive Director Banzhaf (Dec. 5, 1977)); J.A. 50-68 (Letter from FDA Commissioner Goyan to ASH Executive Director Banzhaf (Nov. 25, 1980)). Focusing on those decisions, and some earlier statements made by FDA officials, the court of appeals treated FDA's current position as not warranting deference. Pet. App. 31a-37a. The court of appeals erred both in its understanding of FDA's prior position and in its approach to reviewing FDA's current regulation of tobacco products.

An agency's position on any given issue is not "carved in stone." *Chevron*, 467 U.S. at 863. To fulfill its assigned responsibilities, an agency "must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances,'" *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut.*, 463 U.S. 29, 42 (1983), and "must consider varying interpretations and the wisdom of its policy on a continuing basis." *Chevron*, 467 U.S. at 863-864. For those reasons, and because "the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency," *Smiley* v. *Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996), an agency is always free to change its position on an issue or its interpretation of a statute, as long as it offers a "reasoned analysis" that justifies the change. *Rust* v. *Sullivan*, 500 U.S. 173, 187 (1991); *Chevron*, 467 U.S. at 863-864; *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42.

FDA provided such a "reasoned analysis" here. Specifically, FDA explained that three key developments led to its change in position. *First*, while no major health organization had determined that nicotine was an addictive drug before 1980, by 1994, every leading scientific panel or organization had concluded that nicotine is addictive. 61 Fed. Reg. at 45,228. *Second*, since 1980, scientific evidence has shown

that an overwhelming percentage of users of tobacco products do so to satisfy their addiction and to obtain nicotine's mood-altering effects. *Id.* at 45,233-45,234. In contrast, before 1980, there was no evidence regarding the proportion of users who were addicted, and the evidence was insufficient to conclude that tobacco products were consumed primarily for their pharmacological effects. *Id.* at 45,234-45,235. *Third*, recently released internal industry documents show that tobacco manufacturers have long known that consumers use tobacco products to sustain addiction and for other pharmacological effects, and that manufacturers have deliberately engineered their products to deliver active doses of nicotine. *Id.* at 45,235- 45,236. Almost none of that evidence was publicly available in 1980. *Id.* at 45,237. FDA's finding that tobacco products are intended to affect the structure and function of the body, regardless of whether they are accompanied by express market claims of therapeutic value, is therefore "based on an overwhelming body of new evidence that ha[d] become available since FDA last considered this issue." *Id.* at 45,237. Because FDA provided a reasoned explanation for its change in position, that position is entitled to full *Chevron* deference. *Rust*, 500 U.S. at 186-187; *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42; see also *Smiley*, 517 U.S. at 742.

The court of appeals concluded that FDA's prior decisions not to regulate tobacco products were based on a categorical view that tobacco products cannot be subject to regulation under the Act absent specific health claims, rather than the absence of the kind of evidence of intended effects discussed above. Pet. App. 36a. The court's understanding of the ASH decisions is incorrect. In the 1977 decision, FDA rejected ASH's assertion that cigarettes could be regulated as drugs because consumers use them for their effects on the body, on the ground that ASH's evidence was not sufficient to establish such an intent by the manufacturers or vendors of ciga-

rettes. J.A. 48-49. The government's brief defending FDA's decision in the court of appeals explained that FDA had concluded that cigarettes could not be regulated as drugs "in the absence of health claims by the manufacturers or vendors *or other evidence of the manufacturers' or vendors' intent to affect the bodily structure or functions*." Gov't Br. at 14, *Action on Smoking & Health* v. *Harris*, 655 F.2d 236 (D.C. Cir. 1980) (emphasis added). In affirming FDA's decision, the D.C. Circuit stated that "we do not read [FDA's decision] to mean either that the Commissioner will never consider evidence of consumer intent on this question or that he simply ignored the evidence presented to him in this petition." *ASH*, 655 F.2d at 239. Instead, the petition failed because ASH had failed to "meet the high standard established in cases where the statutory 'intent' is derived from consumer use alone." *Ibid.*

In the 1980 "device" decision, FDA stated that the relevant inquiry under the Act is whether there "is objective evidence that the manufacturer or vendor intends that the article is to affect the structure or a function of the body." J.A. 56. FDA further explained that a finding of such an intent could be based not only on a manufacturer's market claims, but also on "the circumstances surrounding [a product's] distribution," and the "consumer intent in using a product." *Ibid.* FDA determined, however, that ASH's evidence, including ASH's evidence of consumer use, "fails to establish that cigarettes are intended 'to affect the structure or any function of the body.'" J.A. 57; accord J.A. 61-63. FDA's prior rulings on formal petitions to regulate tobacco products therefore rested on the absence of sufficient evidence at the time that such products were intended to affect the structure or function of the body—not on a categorical view that tobacco products can satisfy the drug and device

definitions only if manufacturers make express market claims of therapeutic value.[10]

Even if FDA's prior decisions not to regulate tobacco products could be understood as resting on such a categorical view, however, that would not affect the validity of FDA's

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[10] The court of appeals also relied upon a 1914 opinion letter by FDA's predecessor agency. Pet. App. 32a. That letter, however, *supports* the proposition that labeling claims are not dispositive and that consumer use is relevant to the question of "intent":

> Under the Food and Drugs Act, a drug is defined as any substance, or mixture of substances, intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. It, therefore, follows that tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof.
>
> On the other hand, tobacco and its preparations which are not so labeled *and are used for smoking or chewing or as snuff and not for medicinal purposes* are not subject to the provisions of the act.

USDA Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements ¶ 13, Opinion of Chief of Bureau C.L. Alsberg). As the letter makes clear, labeling can be *sufficient* to establish the requisite intent. But if the absence of labeling were sufficient to negate intent, the italicized ("and are used") clause would have been superfluous. The final sentence of the opinion simply states that tobacco products could escape regulation under the 1906 Act as drugs if they were not labeled to indicate their use for the cure, mitigation, or prevention of disease *and* they were not used for such purposes. See 61 Fed. Reg. at 45,222 n.1160.

The court of appeals also relied on letters or statements by FDA officials to Members of Congress during hearings at various times after the Act was passed in 1938, to the effect that FDA did not have authority to regulate tobacco products as customarily marketed. See, *e.g.*, Pet. App. 32a-34a. Those statements are best understood as reflecting FDA's view on those occasions that there was insufficient evidence that tobacco products as customarily marketed were intended to affect the structure or any function of the body.

present determination that tobacco products are drugs and devices under the Act. An agency is not only free to alter its view of the underlying facts; it is also free to change its view of the appropriate legal standard for evaluating the facts. See *Rust*, 500 U.S. at 186-187. Regardless of whatever uncertainty there might have been about FDA's position in the past, FDA has now unambiguously concluded that the drug and device definitions encompass products that are intended by manufacturers to affect the structure or function of the body, irrespective of whether the manufacturer makes express claims of therapeutic value. FDA has also concluded that there is no basis for creating an exception to that legal standard for tobacco products. Because that interpretation of the Act is supported by a "reasoned analysis," it is entitled to full *Chevron* deference. *Ibid.*

2. Over the years, Congress has failed to enact bills that would have expressly authorized FDA to regulate tobacco products. The court of appeals viewed such congressional inaction as strong evidence that FDA lacks authority to regulate tobacco products under the Act. Pet. App. 37a-39a. Failed legislative proposals, however, do not furnish a sound basis for determining the meaning of a prior statute. See, *e.g.*, *United States* v. *Estate of Romani*, 523 U.S. 517, 533-535 (1998); *Central Bank* v. *First Interstate Bank*, 511 U.S. 164, 187 (1994). The Constitution requires Congress to express its will through enacted legislation, not unenacted bills. *INS* v. *Chadha*, 462 U.S. 919, 945-959 (1983). Congressional inaction also "lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Central Bank*, 511 U.S. at 187 (quoting *Pension Benefit Guar. Corp.* v. *LTV Corp.*, 496 U.S. 633, 650 (1990)). For those reasons, Congress's failure to enact bills that would have expressly authorized FDA to regulate tobacco products has no more bearing on the

question presented in this case than does Congress's failure to enact bills that would have excluded tobacco products from the reach of the Act, *e.g.*, S. Rep. No. 1295, 104th Cong., 1st Sess. (1995); H.R. Rep. No. 2283, 104th Cong., 1st Sess. (1995), or Congress's failure during the past three years to overturn FDA's decision to regulate tobacco products.

The court of appeals' reason for attributing significance to the legislative inaction at issue here is particularly unconvincing. In the court's view, such inaction amounted to congressional "ratification" of FDA's prior statements and decisions that tobacco products are not subject to regulation under the Act. Pet. App. 37a. As we have explained, however, FDA's prior position was based on the absence of sufficient evidence showing that tobacco products were intended by manufacturers to affect the structure or any function of the body. Ratification of that position would not reflect any congressional view on whether tobacco products would be covered by the Act if new evidence established that they *are* intended by manufacturers to be used for sustaining addiction and for sedation, stimulation, and weight control.

More fundamentally, congressional inaction can never affect the authority of an agency under *Chevron* to alter its position on an issue. *Motor Vehicle Manufacturers Ass'n*, *supra*, is controlling on that point. In that case, the Court held that Congress's failure to overturn an agency regulation did not affect the scope of the agency's authority to rescind the regulation. 463 U.S. at 44-45. The Court explained that the standard for reviewing agency action is not "enlarged or diminished by subsequent congressional action," and that "even an unequivocal ratification—short of statutory incorporation— * * * would not connote approval or disapproval of an agency's later decision to rescind the regulation." *Id.* at 45. Under the analysis in *Motor Vehicle Manufacturers Ass'n*, Congress's failure to overturn FDA's prior position

has no bearing on the validity of FDA's present position that tobacco products are drugs or devices under the Act.

3. Since the Surgeon General issued his well-known report in 1964, Congress has enacted several statutes that deal with tobacco products in certain specific respects. See Pet. App. 39a-42a. None of the statutes, however, expressly exempts tobacco products from the reach of the Act. Nor is there any irreconcilable conflict between the subsequent statutes and the conclusion that tobacco products fall within the reach of the Act. *TVA*, 437 U.S. at 189-190 (implied repeal occurs only when there is an irreconcilable conflict between the old and the new laws). Those statutes therefore do not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices under the Act.

a. The Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331 *et seq.*, requires cigarette packaging and advertising to bear specific warnings from the Surgeon General concerning the adverse health effects of smoking. 15 U.S.C. 1333. FCLAA also contains a specific preemption section that provides that "[n]o statement relating to smoking and health, other than the statement required by section 1333 * * *, shall be required on any cigarette package." 15 U.S.C. 1334(a). That statutory text makes clear that FDA may not require warning labels on cigarettes that are different from those required by FCCLA. The text of FCCLA does not remotely suggest, however, that it altogether deprives FDA of any authority to regulate tobacco products. As this Court explained in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), FCLAA "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels."

The court of appeals derived a broader preemptive scope from FCLAA's statement of policy, which is, *inter alia*, "to establish a comprehensive Federal program to deal with

cigarette labeling and advertising with respect to any relationship between smoking and health, whereby * * * commerce and the national economy may be protected to the maximum extent consistent with this declared policy and * * * not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." 15 U.S.C. 1331. From that statement, the court concluded that Congress had a broad purpose to protect the national economy by allowing the continued marketing of cigarettes if the packages bear sufficient warning labels—a goal the court believed would be undermined if tobacco products were "drugs" and "devices" subject to regulation under the Act. Pet. App. 43a-44a.

As we have already explained, however, treatment of tobacco products as drugs or devices does not lead to the conclusion that such products must be banned, and the regulations at issue here permit the continued sale of tobacco products to adults. In any event, FCLAA does not seek to protect the national economy by shielding tobacco products from laws that would restrict their marketing. Instead, as the text of FCLAA's policy statement makes clear, and as its narrow preemption provision confirms, Congress's goal was far more limited: It wanted to "protect[] the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations." *Cipollone*, 505 U.S. at 514; see *Banzhaf* v. *FCC*, 405 F.2d 1082, 1089 (D.C. Cir. 1968) ("[n]othing in the [FCLAA] Act 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"), cert. denied, 396 U.S. 842 (1969). FCLAA does not limit the authority of FDA to ban the sale of tobacco products, any more than it limits the authority of a State to do so (as indeed all States have done with respect to sales to minors,

61 Fed. Reg. at 44,441). The enactment of FCLAA therefore does not affect the validity of FDA's conclusion that tobacco products are drugs and devices under the Act.

b. The Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), 15 U.S.C. 4401 *et seq.*, requires warnings on smokeless tobacco packages that are similar to the warnings required on cigarette packages. 15 U.S.C. 4402(a) and (b). It also contains a similar express preemption provision, which states: "No 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." 15 U.S.C. 4406(a). Like FCCLA, the Smokeless Tobacco Act simply requires certain warning labels on packages and precludes federal agencies, including FDA, from requiring different ones. Like FCCLA, the Smokeless Tobacco Act does not in any way suggest that tobacco products cannot be drugs or devices under the Act.

c. The Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 178, 42 U.S.C. 290aa *et seq.*, direct the Secretary of Health and Human Services to report to Congress every three years on "the health consequences * * * of drug abuse in the United States [and] * * * current research findings made with respect to drug abuse, including current findings on * * * the addictive property of tobacco," and to include the Secretary's recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. 290aa-2(b). Those reporting requirements do not conflict with FDA's conclusion that tobacco products are drugs and devices under the Federal Food, Drug, and Cosmetic Act. As Judge Hall explained, the reporting obligations do no more than acknowledge the important role that the Secretary has in determining policy in the complex field of drug abuse, and require the Secretary

"to ask Congress for any *additional* tools * * * needed to * * * perform that role effectively." Pet. App. 69a.

d. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (ADAMHA), Pub. L. No. 102-321, 106 Stat. 394, created separate block grants for state mental health services and drug and alcohol abuse programs. One condition for receiving a block grant is that a State must have in effect a law making it illegal to sell or distribute tobacco products to children under age 18. 42 U.S.C. 300x-26(a). Neither the ADAMHA as a whole nor that specific requirement implies that FDA has no authority to regulate tobacco products as a drug or a device.

The court of appeals concluded that, if tobacco products are "drugs" or "devices" subject to regulations under the Federal Food, Drug, and Cosmetic Act, then one provision of that Act, 21 U.S.C. 360k(a) "would prohibit States from addressing the problem of youth access," in conflict with the congressional intent evident in ADAMHA. Pet. App. 51a. Under Section 360k(a), a State may not establish "any requirement" with respect to devices that is "different from, or in addition to, any requirement applicable under" the Act. 21 U.S.C. 360k(a)(1). Section 360k(a), however, "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 496-497 (1996) (quoting 21 C.F.R. 808.1(d)(2)). Since ADAMHA's "age 18" restriction is the same as the access restriction imposed by FDA's regulations, the regulations will not prevent States from complying with their block grant obligations under ADAMHA. In fact, by providing an additional level of enforcement against the sale of tobacco products to children, the regulations will "facilitate the end result that Congress sought" in ADAMHA. 61 Fed. Reg. at 44,547.

FDA's regulations could potentially preempt state regulations that impose stricter conditions on the sale of tobacco

products than those set forth in the regulations. But that result does not suggest that there is any inherent or irreconcilable conflict between ADAMHA and FDA's conclusion that tobacco products are covered under the Federal Food, Drug, and Cosmetic Act. ADAMHA does not provide a protective shield for all state regulations of tobacco. It simply establishes one condition for receiving a block grant, and, as noted above, FDA's regulations do not prevent States from complying with that condition. In any event, under 21 U.S.C. 360k(b), States may apply for an exemption from the preemptive force of the Act, and FDA has substantial discretion to grant such an exemption. See 61 Fed. Reg. at 44,550; *Medtronic*, 518 U.S. at 482 n.5, 496. Thus, like the other later-enacted statutes, ADAMHA does not impose any impediment to FDA's thoroughly documented and reasoned conclusion that tobacco products are "drugs" and "devices" within the meaning of the Federal Food, Drug, and Cosmetic Act.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General

DAVID W. OGDEN
Acting Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

WILLIAM B. SCHULTZ
Deputy Assistant Attorney General

IRVING L. GORNSTEIN
Assistant to the Solicitor General

MARGARET JANE PORTER
Chief Counsel

KAREN E. SCHIFTER
PATRICIA J. KAEDING
Associate Chief Counsel
Food and Drug Administration

EUGENE THIROLF
DOUGLAS LETTER
GERALD C. KELL
SCOTT R. MCINTOSH
CHRISTINE N. KOHL
Attorneys

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APPENDIX

1. 21 U.S.C. 321(g)(1) provides as follows:

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

2. 21 U.S.C. 321(h) provides as follows:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) 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.

3. 21 U.S.C. 352(f) and 352(j) provide as follows:

§ 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

* * * * *

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or

device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * * * *

(j) Health-endangering when used as prescribed

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.

4. 21 U.S.C. 353(g) provides as follows:

(g) Regulation of combination products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

5. 21 U.S.C. 355(a) provides as follows:

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

6. 21 U.S.C. 355(d) provides in relevant part as follows:

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; * * * (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; * * * he shall issue an order refusing to approve the application. * * *

7. 21 U.S.C. 360c(a) provides as follows:

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, PREMARKET APPROVAL.—A device which because—

> (i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, 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.

8. 21 U.S.C. 360c(d)(1) provides as follows:

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

9. 21 U.S.C. 360f(a) provides as follows:

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the

deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

10. 21 U.S.C. 360h(e)(1) provides as follows:

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

* * * * *

11. 21 U.S.C. 360j(e) provides as follows:

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(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. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

12. 21 U.S.C. 360k provides as follows:

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

13. 21 U.S.C. 371(a) provides as follows:

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

14. 21 U.S.C. 393(a) & (b) provide as follows:

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and

taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

* * * * *

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use * * *.