No. 98-1152

In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

SETH P. WAXMAN
Solicitor General
Counsel of Record

FRANK W. HUNGER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

IRVING L. GORNSTEIN
Assistant to the Solicitor General

EUGENE THIROLF
DOUGLAS LETTER
GERALD C. KELL
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 contained in tobacco products is a highly addictive substance that causes significant mood-altering effects, and that tobacco products are intended by tobacco manufacturers to have substantial effects on the structure and functioning of the human body, including satisfying a user's addiction and acting as a sedative, stimulant, and appetite suppressant. The question presented is whether, given FDA's findings, 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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Miscellaneous—Continued: Page

In the Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-1152

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Food and Drug Administration, *et al.*, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-75a)[1] is reported at 153 F.3d 155. The opinion of the district court (App. 76a-136a) is reported at 966 F. Supp. 1374.

JURISDICTION

The judgment of the court of appeals was entered on August 14, 1998. A petition for rehearing was denied on November 10, 1998. App. 137a-146a. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

[1] "App." refers to the separately-bound appendix to this petition.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Federal Food, Drug, and Cosmetic Act and the tobacco product regulations are reproduced in the appendix to this petition. App. 148a-163a.

STATEMENT

1. This case concerns the authority of the Secretary of Health and Human Services, through the Food and Drug Administration (FDA), to regulate cigarettes and smokeless tobacco (tobacco products) as "drugs" and "devices" under the Federal Food, Drug, and Cosmetic Act (Act), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.* Before that Act was passed in 1938, the Pure Food and Drug Act defined a "drug" to include "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 Drug Act of 1906, ch. 3915, § 6, 24 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; see 21 U.S.C. 321(g)(1)(c). Congress also authorized FDA to regulate "device[s]." § 201, 52 Stat. 1041. The term "device" is now defined to mean, *inter alia*, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, 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." 21 U.S.C. 321(h). In expanding the operative definitions in 1938, "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." *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

The Act recognizes that certain products may constitute "a combination of a drug, device, or biological product." 21 U.S.C. 353(g)(1). FDA may regulate drug/device combination products using its drug authorities, device authorities, or both. 61 Fed. Reg. 44,396, 44,400-44,403 (1996) (explaining the basis for that conclusion).

The Act delegates broad authority to FDA to regulate "drugs" and "devices" for the purpose of protecting the public health. Of particular relevance here, FDA "may by regulation 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). In making findings with respect to safety and effectiveness, FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C); see 21 C.F.R. 860.7(d)(1); 61 Fed. Reg. at 44,412-44,413.

2. In response to petitions filed by public health organizations 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 are "drugs" and "devices" under the Act and, accordingly, issued regulations directed to those products. 61 Fed. Reg. at 44,396-44,397.

FDA based its determination that tobacco products are "drugs" and "devices" on two key findings. First, based on extensive scientific documentation, FDA found 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 suppres-

sant. 61 Fed. Reg. at 44,630, 44,664-44,685. Second, FDA found that those effects are clearly "intended" by the manufacturers of tobacco products. *Id.* at 44,630, 44,686-45,204, 45,227, 45,233-45,236. The evidence before the agency included much material that was only recently uncovered through FDA's investigation, congressional hearings, and disclosures by tobacco company officials and employees.

a. In finding that nicotine affects the structure and function of the body, FDA relied on scientific evidence showing that the nicotine in tobacco products produces chemical reactions in the brain that motivate repeated, compulsive use and create dependence in the user. 61 Fed. Reg. at 44,666. In particular, 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 the neurotransmitter dopamine within that system, nicotine causes the compulsive drug-seeking behavior of drug addiction. *Id.* at 44,700. In some cases, nicotine in tobacco products acts as a sedative, while in other cases, it acts as a stimulant. *Ibid.* Clinical and animal studies also indicate 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 other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction (*e.g.*, methadone). *Id.* at 44,632, 44,666-44,670.

b. FDA based its conclusion that nicotine's effects on the structure and function of the body are "intended" by manufacturers on findings that: (1) a reasonable manufacturer could foresee that consumers will use tobacco products to satisfy their nicotine addiction; (2) consumers use tobacco products because they are addicted to them and because they want to obtain their mood-altering effects; (3) manufac-

turers know that consumers use tobacco products primarily for those reasons; and (4) manufacturers have carefully engineered tobacco products to deliver pharmacologically active doses of nicotine. 61 Fed. Reg. at 44,630, 44,686-45,204, 45,227, 45,233-45,236.

FDA pointed to extensive, recently-discovered evidence that supports each of those findings. For example, internal industry memoranda from the early 1970s show that R.J. Reynolds 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. R.J. Reynolds researchers also recognized in the 1970s that "[t]he confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine," *id.* at 44,868, and that "[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body," *id.* at 44,871. That knowledge was communicated to the highest levels of the tobacco companies; as early as 1969, Philip Morris's vice president for research and development notified his board of directors that "the ultimate explanation for the perpetuated cigaret[te] habit resides in the pharmacological effect of smoke upon the body of the smoker." *Id.* at 44,856.

FDA also found evidence 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 manufacturers use "nicotine-rich tobacco blends in low-tar cigarettes," "filtration and ventilation technologies that selectively remove more tar [than nicotine] from smoke," and "chemical additives that increase the percentage of 'free' nicotine in cigarette smoke." *Ibid.* FDA found evidence that smokeless tobacco manufacturers also

manipulate nicotine deliveries. *Id.* at 45,108. FDA quoted company documents revealing that senior industry officials and researchers expressly conceived of cigarettes and smokeless tobacco as "a dispenser for a dose unit of nicotine," *id.* at 44,856, "*a vehicle for delivery of nicotine*, designed to deliver the nicotine in a generally acceptable and attractive form," *id.* at 44,868, and the "*means of providing nicotine dose in a metered fashion*," *id.* at 44,890.

c. Based on the record evidence, 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 are "combination products." *Id.* at 45,208-45,216.

3. a. Having concluded that tobacco products fall within its regulatory authority, FDA determined that such regulation is consistent with the agency's mission to protect the public health because of the serious threat to public health caused by tobacco use. 61 Fed. Reg. at 44,398. The evidence in FDA's rulemaking record shows that tobacco use is the largest cause of preventable death in the United States; more than 400,000 deaths result each year from illnesses such as cancer, respiratory illnesses, and heart disease that are caused by tobacco use. Tobacco alone kills more Americans annually than AIDS, alcohol, car accidents, homicides, suicides, illegal drugs, and fires combined. The average tobacco user loses 15 years of his or her life. *Id.* at 44,571.

FDA found that tobacco use is a "pediatric disease," 61 Fed. Reg. at 44,421, because most people who use tobacco as adults began smoking regularly during childhood, and childhood initiation leads to addiction. Nearly all first use of tobacco occurs before high school graduation. If adolescents can be kept tobacco-free, most will never start using tobacco. *Id.* at 44,399, 44,421. Efforts to prevent childhood tobacco use, however, have not been successful thus far. Every year,

approximately one million children and adolescents begin to smoke, *id.* at 44,398, 44,568, and the rate of youth tobacco use is increasing, *id.* at 44,399. Tragically, one of every three young people who become regular smokers will eventually die prematurely from a tobacco-related disease. *Id.* at 44,399, 44,568.

b. Because of the evidence that most tobacco-related addiction begins in childhood, FDA directed its initial regulatory efforts to reducing the use of tobacco products by young people. It adopted access restrictions that: (1) prohibit the sale of cigarettes and smokeless 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 cigarettes and smokeless tobacco except in adult-only locations. 61 Fed. Reg. at 44,616-44,617.

Based on evidence that "cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use," 61 Fed. Reg. at 44,489, and internal company documents that show the industry's intent "to attract young smokers and so-called presmokers" through advertising, *id.* at 44,480, FDA also concluded that advertising restrictions are necessary to complement the access restrictions. *Id.* at 44,406-44,407 ("The effectiveness of the restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions."). FDA's advertising 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 by tobacco companies and distributors of hats, t-shirts, and other non-tobacco products, such as promotional items, that bear a tobacco product

brand name or logo; and (4) a prohibition on sponsoring athletic, cultural, or other events in a tobacco brand name. *Id.* at 44,617-44,618.

In adopting the complementary access and advertising restrictions, FDA invoked its authority under 21 U.S.C. 360j(e) 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." FDA relied on that authority because tobacco products are "combination products" for which FDA has discretion to use its drug authorities, its device authorities, or both. 61 Fed. Reg. at 44,400-44,403.

c. FDA considered, but rejected, a ban on the sale of tobacco products to adults. FDA noted that, because of illnesses caused by cigarettes and smokeless tobacco, those products are "unsafe, as that term is conventionally understood." 61 Fed. Reg. at 44,412. But FDA further noted that, as reflected in the Act and judicial decisions construing it, the determination whether there is a "reasonable assurance of safety" within the meaning of the Act "involves 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." *Id.* at 44,412-44,413. For several reasons, 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." *Id.* at 44,413. First, "there 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.* Third, 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 contain even higher levels of tar, nicotine, and toxic additives." *Ibid.*

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 regulations. Respondents moved for summary judgment, arguing that: (1) Congress has withheld from FDA any authority to regulate cigarettes and smokeless tobacco, as marketed by respondents; (2) the Act does not authorize FDA to regulate advertising of cigarettes and smokeless tobacco; and (3) the restrictions that FDA placed on advertising and promotion of cigarettes and smokeless tobacco violate the First Amendment. For purposes of its 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. App. 76a-78a.

The district court denied summary judgment to respondents on the issue of whether tobacco products are covered by the Act and the validity of the access regulations, but granted their motion with respect to the advertising regulations. App. 76a-136a. The district court first held that FDA had lawfully concluded that tobacco products are subject to regulation under the Act as "drugs" and "devices." *Id.* at 80a-126a. The court rejected respondents' contention that the Act applies only to products that have a medical purpose. The court noted (*id.* at 102a-103a & n.13) that the Act separately covers products intended for use "in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. 321(g)(1)(B) and (h)(2); and it explained that, because the definitions on which the FDA relied expressly include all products intended to affect the "structure or any function of the human body," the "plain language" of the Act does not

limit its reach to only those drugs and devices that have a medical purpose. See App. 113a-116a.

The district court also held that FDA had properly determined that tobacco products are "intended" to affect the structure or function of the human body within the meaning of the Act. App. 104a-113a. The court rejected respondents' contention that FDA's general regulations interpreting and implementing the Act's "intended use" standard limit evidence of intended use to explicit representations by manufacturers concerning the therapeutic or other effects of the product. The court pointed out that the regulations provide as well for consideration of consumer use and a manufacturer's knowledge of such use. See *id.* at 109a-110a & n.15 (quoting 21 C.F.R. 201.128 and 21 C.F.R. 801.4). In addition, the district court noted that a number of courts, as well as the House Report on the Medical Device Amendments of 1976 (see H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976)), had stated that FDA could rely on evidence other than manufacturers' representations, such as evidence of consumer use. *Id.* at 107a-108a, 110-112a.

Because it found that cigarettes and smokeless tobacco fall within the Act's definitions of "drug" and "device," the district court concluded that those products would be excluded from the Act's coverage only if respondents established that "Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the [Act]." App. 81a. The court found no such clear intent. *Id.* at 80a-101a. In particular, it rejected respondents' contention that other statutes enacted after 1938, including the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.*, establish a congressional intent to withhold jurisdiction from FDA to regulate tobacco products. App. 92a-101a. The court similarly rejected respondents' contention that FDA's prior decisions not to regulate most tobacco products and

statements to Congress that tobacco products were not covered by the Act unless manufacturers made therapeutic claims for them showed that Congress had withheld jurisdiction. The court explained that FDA was entitled to revisit the question in light of the new evidence concerning the addictive and other effects of tobacco products and the intended use of tobacco products to achieve those effects. *Id.* at 84a-92a.

After concluding that FDA had properly exercised jurisdiction over tobacco products, the district court held that FDA had authority under 21 U.S.C. 360j(e) to issue restrictions on access by minors to tobacco products. It therefore upheld the regulations' access restrictions. App. at 133a. Declining to reach the First Amendment issue (*id.* at 134a n.33), the district court ruled, however, that FDA's advertising restrictions are not authorized by the provision of the Act allowing FDA to impose conditions on the "sale, distribution, or use" of "devices." *Id.* at 127a-133a. The district court certified all of its rulings for interlocutory appeal, *id.* at 135a-136a, and the court of appeals accepted that certification, *id.* at 11a.[2]

5. a. In a 2-1 decision, a panel of the Fourth Circuit reversed, App. 1a-75a, holding that "FDA lacks jurisdiction to regulate tobacco products" and that "all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid," *id.* at 11a-12a. The panel majority disagreed with the district court's framing of the issue as whether, in light of the broad definition of "drug" and "device," Congress nonetheless intended to withhold from FDA jurisdiction to regulate tobacco products. *Id.* at 15a. Rather, the majority

[2] In light of its rulings, the district court permitted the access restrictions prohibiting the sale of tobacco products to children under the age of 18 and the requirement for photographic identification for persons under the age of 27 to remain in effect. The court stayed implementation of the other access restrictions, which had not yet taken effect. App. 135a.

viewed the relevant question as "whether Congress intended to give the FDA jurisdiction over tobacco products as customarily marketed." *Id.* at 14a.[3] The majority noted that, under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress," and that "only if the intent of Congress is ambiguous [do] we defer to a permissible interpretation by the agency." App. 15a-16a. The majority also stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority," *id.* at 16a (quoting *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649 (1990)), so that "no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority," *ibid.* The majority believed that a particularly searching inquiry was necessary because FDA was "attempting to expand the scope of its jurisdiction." *Id.* at 16a-17a.

To ascertain Congress's intent, the majority looked first to the Act's definitions and concluded that the plain meaning of those provisions "may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices." App. 19a. The majority concluded, however, that FDA could not rely on the definitional provisions, because, in its view, tobacco products do not fit into the overall regulatory scheme created by Congress. *Id.* at 22a.

The majority concluded that, under the provision of the Act upon which FDA had relied in issuing its regulations, 21

---

[3] The court used the term "customarily marketed" to refer to tobacco products marketed with claims concerning smoking pleasure and the like, rather than therapeutic claims, such as weight loss. App. 14a-15a n.9. The lower courts have sustained FDA's authority to regulate cigarette products that are marketed with express claims of therapeutic value, and respondents concede that such authority exists. See *id.* at 80a n.3.

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. App. 22a. Because FDA had found tobacco products to be dangerous, the majority concluded, "FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation." *Id.* at 23a. For substantially the same reason, the majority concluded that FDA's regulatory approach failed to satisfy several other provisions of the Act. *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 examined what it termed "extrinsic evidence" of congressional intent. App. 31a-52a. First, the majority concluded, on the basis of its review of various statements by FDA, see *id.* at 31a-37a, that "[f]rom 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction." *Id.* at 31a. The majority next concluded that Congress's failure to enact bills that would have given FDA authority over tobacco products "provide[s] strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products." *Id.* at 39a. And, it concluded that four tobacco-specific statutes enacted since 1964 provide "corroborating evidence" that Congress did not intend the FDA's original jurisdictional grant to include "tobacco products." *Id.* at 40a; see generally *id.* at 39a-52a.

b. Judge Hall dissented. App. 55a-75a. He concluded that "[t]obacco products fit comfortably into the [Act's] definitions of 'drug' and 'device,'" and, even if the "search for legislative intent [is expanded] beyond the words of the statute, the evidence falls far short of demonstrating that

Congress intended to deny or withdraw jurisdiction over tobacco from the FDA." *Id.* at 55a. He noted that "[t]he majority devote[d] approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim" and essentially "conced[ed] that tobacco products fit the [Act's] 'literal' definition of drug." *Id.* at 56a.

Judge Hall rejected the majority's view that, since FDA has a mandate to prevent the marketing of a drug found to be unsafe and tobacco products are unsafe, the regulations at issue must be inconsistent with that mandate, because they do not ban the continued sale of tobacco products to adults. App. 60a-61a. He concluded that "*[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. * * * It is no argument to say that the FDA can do nothing because it could have done more." *Ibid.*

Judge Hall also concluded that "[t]he majority starts off on the wrong foot when it asks 'whether Congress intended to delegate jurisdiction over tobacco products to the FDA,'" because "Congress did not 'intend' that any particular product be included." App. 62a. Rather, "[t]he operative congressional intent * * * was simply to confer broad discretionary powers on the FDA to regulate 'drugs' and 'devices'" through definitions that were "written broadly enough to accommodate both new products and evolving knowledge about existing ones." *Id.* at 63a.

Judge Hall similarly disagreed with the majority's reliance on FDA's prior decisions and statements regarding the regulation of tobacco products. App. 63a. 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. 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 jurisdiction over tobacco products. *Id.* at 65a-70a.[4]

The Fourth Circuit denied FDA's petition for rehearing. App. 137a-146a. Judge Hall would have granted panel rehearing, and Judges Michael, Motz, and Murnaghan would have granted rehearing en banc. *Id.* at 145a-146a. Four active judges were disqualified from the case. *Id.* at 146a.

REASONS FOR GRANTING THE PETITION

A divided court of appeals has ruled that FDA has no authority to regulate tobacco products, and it has invalidated the most important public health and safety rulemaking that FDA has conducted in the past fifty years. The panel reached that conclusion notwithstanding FDA's thoroughly documented findings, based on extensive evidence in the record, that the nicotine in tobacco products is intended to cause substantial effects on the human body, including satisfying a user's addiction and acting as a sedative, stimulant, and appetite suppressant.

The panel's ruling is based on a fundamentally flawed approach to the interpretation of the Federal Food, Drug, and Cosmetic Act, and it drifts far afield from the kind of analysis of administrative action required by this Court's decision in *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Unless reversed by this Court, the panel's ruling will deprive the public of an unparalleled opportunity to prevent millions of children from

[4] Judge Hall also concluded that FDA has authority to regulate tobacco products as "combination product[s]" and to restrict tobacco product advertising under its "device" authority. App. 71a-74a.

beginning a highly addictive habit that often leads to premature death. FDA regulations currently in effect, but invalidated by the court of appeals, are already restricting youth access to tobacco products. The public health suffers in a substantial way as each month passes and FDA's other tobacco product regulations relating to access and advertising remain blocked by court order. The recent agreement between five tobacco companies and 46 States settling financial claims by the States to compensate them for the health-care costs of tobacco use (see note 9, *infra*), does not diminish the public health significance of FDA's regulatory program. To the contrary, it vividly confirms the serious public health consequences of tobacco use. Review by this Court is therefore warranted to resolve the question whether, given FDA's thoroughly documented findings about the intended pharmacological effects of tobacco products on the human body, tobacco products are "drugs" and "devices" covered by the Act.

A. The panel majority in this case held that "FDA lacks jurisdiction to regulate tobacco products." App. 11a-12a. Under that ruling, unless tobacco manufacturers market their products with "specific therapeutic claims such as weight loss," *id.* at 15a n.9, FDA is completely without authority over such products. The panel's holding is based on a serious misreading of the Act and a fundamental misapplication of basic administrative law principles.

1. The Act sets forth a standard for whether a product is subject to regulation as a "drug." That standard is uniformly applicable to all products not expressly exempted. It provides that the term "drug" not only includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also includes, *inter alia*, "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. 321(g)(1). The Act similarly sets forth a standard for

whether a product is a "device" that is uniformly applicable to all products not expressly exempted. The Act provides that a "device" is, *inter alia*, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, * * * intended to affect the structure or any function of the body of man or other animals * * * and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. 321(h).

This Court has held 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." *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Moreover, while the Act specifically excludes certain products from particular product categories—soap is excluded from the definition of "cosmetic," 21 U.S.C. 321(i), and tobacco itself is excluded from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1)—the Act does not exclude tobacco products from the definition of "drug" or "device." Thus, tobacco products, like all other products containing nicotine, are subject to regulation under the Act if they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h).

Applying that statutory standard, FDA concluded that tobacco products fall within the statutory standards for both "drug" and "device." FDA's conclusion is based on an overwhelming factual record showing that: (1) the 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 achieve those effects; (3) tobacco manufacturers know that consumers use their products for those purposes; and (4) tobacco manufacturers design their products to deliver pharmacologically active doses of nicotine. Given that evidence, FDA

reasonably concluded that tobacco products are "intended" to "affect the structure or any function of the body" and are, therefore, subject to regulation under the Act. 21 U.S.C. 321(g)(1) and (h).

Indeed, it is difficult to see how FDA could have come to a different conclusion based on the record before it. As FDA pointed out, in light of its findings, tobacco products cannot be distinguished meaningfully from other products that FDA regulates, such as stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction. 61 Fed. Reg. at 44,632, 44,666-44,670.

It is not necessary for present purposes, however, for the Court to decide whether the text of the Act, as applied to the evidence in the rulemaking record, *compels* the conclusion that tobacco products are "drugs" and "devices" subject to regulation under the Act. Congress assigned to FDA the responsibility to implement the statutory scheme by determining which products satisfy the statutory standards in light of the evidence pertaining to each particular product. Accordingly, FDA's interpretation and application of the complex statutory framework at issue in this case lies at the very core of agency action that is entitled to deference under *Chevron*, 467 U.S. at 842-845. 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. At the very least, in view of FDA's thoroughly documented findings, FDA reached the "reasonable" conclusion that tobacco products fall within the coverage of the Act. The panel majority was therefore required by *Chevron* to defer to FDA's conclusion.[5]

---

[5] A different conclusion could be reached only if an express market claim were the sole ground on which FDA could determine the intended use of a product. Under that interpretation of the Act, tobacco products would be subject to regulation only if manufacturers made specific market claims that their products satisfy addiction, and act as a stimulant, seda-

2. The court of appeals' holding that FDA lacks authority to regulate tobacco products, notwithstanding the plain statutory text and compelling factual record before FDA, rests on a series of legal errors. Those errors fall into three categories.

a. First, the panel started with the wrong question when it asked "whether Congress intended to give the FDA jurisdiction over tobacco products." App. 15a. As Judge Hall noted in dissent, "Congress did not 'intend' that any particular product be included." *Id.* at 62a. Instead, it enacted general definitions of "drug" and "device" so that FDA—applying its accumulated scientific and administrative expertise to both newly developed products and expanded medical knowledge concerning existing products—could decide whether a particular product is subject to regulation based on the evidence before it. *Id.* at 62a-63a. Accordingly, the relevant question in this case is not whether Congress in-

---

tive, and appetite suppressant. As FDA found, however, the text of the Act provides no basis for imposing such a market-claim limitation; it makes "intended uses," not "market claims" or "manufacturer representations," the decisive factor. See 21 C.F.R. 201.128 (describing the evidence relevant to determining intent for drug products); 21 C.F.R. 801.4 (equivalent provision for devices). An express market claim is one important source of evidence concerning intended use. But, as the present case demonstrates, an intended use can be established through other means. From a public health perspective, moreover, it would make no sense to conclude that tobacco products are subject to regulation when manufacturers make specific market claims that their products satisfy addiction and act as stimulants and sedatives, but are not subject to regulation when manufacturers, knowing that consumers use their products for those purposes, engineer their products in order to produce those effects but refrain from making express market claims. At the very least, FDA's judgment that the Act allows intent to be established on the basis of evidence other than express market claims is reasonable and therefore entitled to *Chevron* deference. Significantly, the court of appeals in this case did not hold that FDA could rely only on market claims in determining the intended use of products. App. 19a-20a.

tended to delegate authority to FDA over tobacco products in particular or in the abstract, but whether Congress intended to delegate authority to FDA to regulate tobacco products (along with any other products not expressly exempted) in the event that FDA found that they are "intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1) and (h). The answer to that question is clearly yes, since that is the standard that Congress established, and Congress did not exempt tobacco products from review under that standard.

Once the question is correctly posed, moreover, it is evident that the court of appeals seriously erred in basing its conclusion that FDA lacks jurisdiction over tobacco products on (i) its own view that the Act lacks regulatory provisions that are appropriate for tobacco products, (ii) unenacted bills proposed after 1938 that would have given FDA authority to regulate tobacco products, and (iii) tobacco-specific laws enacted since 1964 that address different issues. Those materials do not provide a principled basis on which to hold that Congress intended to prevent FDA from regulating tobacco products altogether should it find, based on compelling evidence of the sort before FDA in 1996, that tobacco products are intended to affect the structure or any function of the body.[6]

b. Second, the court of appeals' decision rests on fundamental misconceptions concerning *Chevron* deference. The court of appeals stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority," App. 16a (quoting *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649 (1990)), so that "no deference is due the FDA's construction of the Act unless it is acting

---

[6] Furthermore, as we explain in greater detail below (see pp. 22-27, *infra*), those justifications offered by the court of appeals for its contrary holding are without merit even on their own terms.

within the bounds of its congressionally-established authority," App. 16a. That statement implies that, before applying the analysis required by *Chevron* to the question whether FDA has authority over tobacco products, a court must first determine independently whether Congress has delegated to FDA the authority to regulate tobacco products. That approach is circular and would drain *Chevron* of any meaning. The holding in *Adams Fruit*, that a precondition to deference under *Chevron* is a "congressional delegation of administrative authority," simply means that Congress must have delegated authority to the agency to enforce the statutory provision whose meaning is at issue. *Adams Fruit*, 494 U.S. at 650; *Chevron*, 467 U.S. at 842-845. Here, Congress *has* clearly delegated authority to FDA to enforce provisions of the Act that depend on the meaning of the terms "drug" and "device." FDA therefore is unquestionably entitled to *Chevron* deference on the meaning and scope of those terms.

Adams Fruit, on which the majority below relied, addressed a completely different situation. The question in that case was whether state workers' compensation laws bar private rights of action under the Migrant and Seasonal Agricultural Worker Protection Act, 29 U.S.C. 1801 *et seq.* The Court declined to give deference to a regulation of the Department of Labor on that question because the private right of action was administered by the courts and not by the Department of Labor. The Court explained that, because Congress had established "an enforcement scheme independent of the Executive and provided aggrieved farmworkers with direct recourse to federal court where their rights under the statute are violated[,] * * * it would be inappropriate to consult executive interpretations * * * to resolve ambiguities surrounding the scope of [the] judicially enforceable remedy." 494 U.S. at 650. Since the question presented here involves the scope of FDA's authority under

the very law Congress directed it to administer, *Adams Fruit* is inapposite here.

The court of appeals' analysis of the issue under *Chevron* was also affected by its characterization of FDA's action as "attempting to expand the scope of its jurisdiction." App. 16a. As long as an agency is reasonably interpreting a provision it enforces, however, *Chevron* deference applies. It is simply not relevant whether the agency's proposed interpretation can be said to affect its jurisdiction. *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). A contrary rule of interpretation would be unworkable, for *Chevron* deference would then be rendered of little or no force whenever FDA sought to regulate any of the vast range of food and drug products that are introduced each year.

The panel's holding in this case thus cannot be reconciled with a proper application of *Chevron*. In light of FDA's findings concerning the intended effects of tobacco products, and the plain language of the only directly relevant provisions of the Act—the "drug" and "device" definitions—FDA acted reasonably in concluding that tobacco products are subject to regulation under the Act.

c. Third, to the extent that the court of appeals concluded that Congress clearly intended to preclude FDA from regulating tobacco products, that conclusion conflicts with the plain language of the controlling definitions of "drug" and "device." It also ignores the absence of any exemption from those definitions for tobacco products, an absence made all the more telling by Congress's decision to enact an express exemption for tobacco from the Act's definition of "dietary supplement." See 21 U.S.C. 321(ff)(1). And, as we shall now

explain, the panel's conclusion is also unsupported by the materials upon which it relied.

The panel concluded that, because FDA found tobacco products to be dangerous, it would be required by 21 U.S.C. 360j(e) to prohibit the sale of tobacco products to adults as well as children if those products are covered by the Act. App. 21a-23a. For that reason, the panel believed, FDA "cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation." *Id.* at 23a. The Act, however, does not require FDA to consider only the risks of tobacco products. Instead, the Act and implementing regulations authorize FDA to weigh the health risks of permitting continued sales of tobacco products to adults against the health risks of prohibiting such sales. 61 Fed. Reg. at 44,412-44,413 (discussing 21 U.S.C. 360c(a)(2)(C) and 21 C.F.R. 860.7(d)(1)). After engaging in that weighing process, FDA concluded that, with respect to adults, "[t]he sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous." *Id.* at 44,413. That public health policy conclusion was well-founded, and the panel majority should not have second-guessed it. As FDA found, prohibiting adult access to tobacco products "could [create] significant health risks" for persons addicted to such products. 61 Fed. Reg. at 44,413. 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.* Equally important, because of the strength of nicotine addiction, and the difficulty of quitting, "a black market and smuggling would develop to supply smokers with these products," and it is likely that those products "would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives." *Ibid.* In deciding upon its

regulatory approach, FDA properly took those serious health risks into account.

At the very least, FDA's regulatory approach under 21 U.S.C. 360j(e) is reasonable, and it therefore should have been sustained under *Chevron*. But the panel majority did not even consider the question of *Chevron* deference when it rejected FDA's decision to allow continued sales to adults once FDA concluded that tobacco products are subject to regulation under the Act. See App. 21a-22a. In any event, as Judge Hall pointed out in dissent, "[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[.] It is no argument to say that the FDA can do nothing because it could have done more." *Id.* at 60a-61a (emphasis omitted).[7]

The panel majority also relied on prior statements by FDA that it did not have jurisdiction to regulate tobacco products unless manufacturers made therapeutic claims about the products' effect on the body. App. 32a-37a. That reliance was misplaced both as a matter of fact and as a matter of law. In the first place, the court of appeals was simply wrong in regarding the 1996 regulations as an abrupt change from a consistent prior position that tobacco products would be subject to regulation under the Act only if manufacturers made express health or therapeutic claims in marketing them. That notion is refuted by FDA's most recent rejection of a petition to regulate tobacco products

---

[7] The panel majority's belief that there were other "internal inconsistencies" (App. 23a) in FDA's approach under the Act stemmed directly from its basic disagreement with FDA's consideration of the substantial personal and public health risks that would be caused by a complete ban on the sale of all tobacco products. On each of those subsidiary points, moreover, the court once again failed even to advert to its duty to accord *Chevron* deference to FDA's reasonable interpretation of the particular statutory provisions involved. See App. 23a-30a.

prior to 1996—the petition filed by Action on Smoking and Health (ASH) in 1978. In response to ASH's request that FDA regulate filtered cigarettes as devices because they were intended to mitigate disease, the Commissioner stated:

> ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition * * *. *We agree*. However, * * * ASH has not established that consumers use attached cigarette filters * * * to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

Letter from FDA Commissioner Goyan to ASH Executive Director Banzhaf 8-9 (Nov. 25, 1980) (reprinted in 61 Fed. Reg. at 45,224) (emphasis added). In addition, as Judge Hall explained, an agency is always free to change its view on an issue, and that is particularly true "when new facts come to light." App. 64a. See *Rust* v. *Sullivan*, 500 U.S. 173, 186-187 (1991) (recognizing legitimacy of agency change of position). Indeed, the District of Columbia Circuit made that very point in sustaining FDA's denial of an earlier petition filed by ASH in 1977, making clear that FDA "is clearly free to revise its interpretations" if it "provide[s] a reasoned explanation for its action." *Action on Smoking & Health* v. *Harris*, 655 F.2d 236, 242 n.10 (1980). Significantly, the D.C. Circuit also made it clear that manufacturers' claims are *not* the only basis on which intended use of cigarettes could be established and that consumer use of a product *can* be a relevant factor in determining its intended use. See *id.* at 239-240.[8]

---

[8] It is also significant that the D.C. Circuit specifically noted that it did not understand the Commissioner's rejection of ASH's 1977 petition to mean that he would consider only manufacturer representations and would decline to consider evidence of consumer intent. 655 F.2d at 239.

Prior to the present proceeding, FDA simply did not have clear and compelling evidence that nicotine is extremely addictive, that consumers use tobacco products because they are addicted to the products and want to obtain their mood-altering and other effects, that manufacturers know that consumers use tobacco products primarily for those reasons, and that manufacturers have deliberately and carefully engineered tobacco products to deliver pharmacologically active doses of nicotine. 61 Fed. Reg. at 44,630, 44,686-45,204, 45,227, 45,233-45,236; see also App. 65a. As Judge Hall noted, "[t]he administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open." App. 65a.

The court of appeals also deemed it significant that Congress did not enact certain proposed bills that would have specifically given FDA authority to regulate tobacco products. App. 37a-40a. Failed legislative proposals, however, do not furnish a sound basis for determining the meaning of a prior statute. *Central Bank of Denver* v. *First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994); *United States* v. *Estate of Romani*, 118 S. Ct. 1478, 1487-1488 (1998); *id.* at 1488-1489 (Scalia, J., concurring in part and concurring in the judgment). The Constitution requires Congress to express its will through enacted bills, not through unenacted ones. *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. In any event, such post-enactment inaction in the Legislative Branch cannot undermine the respect owed an agency's reasonable interpretation of the statute under *Chevron*. The court of appeals therefore erred in relying on unenacted bills here.

Finally, the panel majority relied on "tobacco-specific" legislation, such as the Federal Cigarette Labeling and Advertising Act (Labeling Act), 15 U.S.C. 1331 *et seq.*, the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4401 *et seq.*, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 92-321, 106 Stat. 394, 42 U.S.C. 300x-26. App. 40a-53a. Those Acts all address narrow issues, such as what warning labels must be put on tobacco products. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (narrowly construing the preemptive force of the Labeling Act). They do not come close to instructing FDA to refrain from *any* regulation of tobacco products even if it finds, based on compelling evidence of the sort before it in 1996, that tobacco products are intended to affect the structure or any function of the body. The suggestion by the court below (App. 44a) that those Acts show that "Congress has reserved for itself the regulation of tobacco products, rather than delegating that regulation to the FDA," is perplexing. The only way for Congress to accomplish that result would be by passing a law that repealed FDA's authority under the Federal Food, Drug, and Cosmetic Act with respect to tobacco products. And even the panel majority did not suggest that the "tobacco-specific" laws it cited did that. *Id.* at 40a, 44a.

d. In sum, when the standard that Congress has selected for determining whether a product is a drug or a device is applied to the extensive evidence before FDA, it is clear that FDA acted reasonably in concluding that tobacco products are subject to regulation under the Act as "drugs" and "devices." This Court should grant certiorari to review the panel's contrary conclusion.

B. The question presented in this case is of urgent public importance. FDA has determined that most persons who become addicted to tobacco products begin using those products when they are children, and youth tobacco use has

been on the rise. Every year, approximately one million children and adolescents begin to smoke, and one out of every three such persons will eventually die prematurely from a tobacco-related disease. 61 Fed. Reg. at 44,568. FDA's regulatory program is aimed at reversing that trend by preventing minors from beginning to use tobacco products. *Id.* at 44,399. Specifically, FDA's program is designed "to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco," and "to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions." *Id.* at 44,406. Unless this Court grants review, an unparalleled opportunity to curb tobacco use by children and to reduce the disease and death associated with such use will be lost.

As much promise as the current regulatory program holds, the significance of this case extends well beyond that particular program. The court of appeals not only has invalidated the current program; it has held that FDA may not issue *any* regulations with respect to tobacco products as currently marketed. For example, even if FDA determined that a particular tobacco ingredient resulted in health hazards not previously known or associated with tobacco use, or that a particular kind of filter would significantly reduce the health risks associated with cigarette use, FDA would lack authority to take action to mandate product modifications. Under the court of appeals' decision, FDA is powerless to adopt any measures designed to reduce the health risks associated with tobacco products as currently marketed, no matter how efficacious such measures might be.

The public has a vital interest in obtaining a resolution by this Court of the question whether FDA has authority to regulate tobacco products. The present case involves all major participants in the industry, including manufacturers, advertisers, and retailers; there will be no better vehicle for

resolving the issue. The parties below thoroughly canvassed the relevant legal sources, and the three opinions below (the panel majority opinion, Judge Hall's dissent, and the district court opinion) fairly stake out the two sides.

FDA regards the question of statutory authority presented in this case as one of the most important questions it has faced since the enactment of the Federal Food, Drug, and Cosmetic Act in 1938. Because the court below incorrectly resolved the issue, and because that issue is of overriding public importance, this Court's review is warranted.[9]

---

[9] The recent agreement between the Nation's five largest tobacco companies and 46 States settling financial claims by the States does not affect the importance of the question presented in this case. To the contrary, the very magnitude of the payments to be made by the manufacturers confirms the serious health consequences of tobacco use. Moreover, the agreement is designed primarily to compensate States for the health-care costs incurred as a result of tobacco use; it is not a public-health measure as such. There are some restrictions on advertising included in the agreement. Because the agreement is concerned primarily with financial compensation rather than public health, however, it includes as private signatories only five tobacco manufacturers, not the thousands of other entities involved in the distribution and sale of tobacco products; it does not contain comprehensive measures to limit youth access to tobacco products; it does not comprehensively address forms and aspects of advertising that are particularly effective in enticing children to begin tobacco use; it does not contain enforcement mechanisms beyond actions by individual States to enforce the agreement; it does not contain any provision regarding manufacturing practices or review and disclosure of ingredients; and it does not reserve for the States the option to seek additional civil relief from the companies. Thus, while the agreement serves important purposes, it does not serve—and was not intended to serve—as a mechanism for protecting the public health through comprehensive nationwide regulation of tobacco products. (For the terms of the agreement, see National Association of Attorneys General, *Master Settlement Agreement* (visited Jan. 19, 1998) http://www.naag. org/tob2.htm).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General
FRANK W. HUNGER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
IRVING L. GORNSTEIN
Assistant to the Solicitor General
EUGENE THIROLF
DOUGLAS LETTER
GERALD C. KELL
CHRISTINE N. KOHL
Attorneys

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

JANUARY 1999