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.*,
Respondents.

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

BRIEF *AMICUS CURIAE* OF PUBLIC CITIZEN, INC., AND 33 OTHER PUBLIC HEALTH, CONSUMER, PARENT, EDUCATOR, AND HEALTH PROFESSIONAL ORGANIZATIONS IN SUPPORT OF PETITIONERS FOOD AND DRUG ADMINISTRATION, *ET AL.*

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This brief is submitted in support of the Food and Drug Administration ("FDA") rule restricting the sale and promotion of tobacco products to minors. 61 Fed. Reg. 44396 (1996). *Amici* seek reversal of the Fourth Circuit's ruling that the Food, Drug, and Cosmetic Act ("FDCA") does not authorize the FDA to regulate the sale and promotion of tobacco products.[1]

INTEREST OF *AMICI*

Through this brief, 34 *amici* offer the voices of parents, educators, public health advocates, consumers, and physicians and other health professionals. These *amici* have an interest in the reduction of children's access to tobacco products and in shielding children from advertising and promotional efforts aimed at enticing them to use tobacco. *Amici* are more fully described in the attached Appendix.

STATEMENT OF THE CASE

The FDA's petition described the decisions below and the regulatory background. Our statement of the case, therefore, will briefly address only a few important areas of the factual background.

Tobacco use is the single most preventable cause of premature death and disease in the United States. Millions of

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[1] In this brief, Petitioners are referred to as the "FDA" or the "Agency." Respondents are referred to collectively as "the industry."

Letters of consent to the filing of this brief have been lodged with the Clerk. Pursuant to Rule 37.6 of this Court, *amici* state that no party had any role in writing this brief and that no one other than *amici* or their counsel made a monetary contribution to its preparation or submission.

Americans are addicted to tobacco products; more than 400,000 people die each year of diseases attributable to tobacco use; nearly one in five eighth graders and one in three twelfth graders smoke cigarettes; and tobacco use that results from addiction to the nicotine in cigarettes causes more Americans' deaths each year than AIDS, alcohol, car accidents, murders, suicides, and fires combined. 60 Fed. Reg. 41314, 41314-15 (1995). Each year, an estimated one million adolescents start smoking, and one-third of those adolescents will die prematurely as a result. 61 Fed. Reg. 44568. Manufacturers carefully engineer their tobacco products to deliver doses of nicotine to consumers, to create and satisfy nicotine addiction. *Id.* 44915-94.

With these facts before it, the FDA determined that the nicotine in tobacco products is "intended to affect the structure or any function of the body," thus bringing it within the FDCA definition of "drugs." 21 U.S.C. § 321(g)(1). That same evidence established that tobacco products are nicotine-delivery systems—a type of "combination product" consisting of drug and device components. 21 U.S.C. § 353(g). Based on these findings, the FDA asserted jurisdiction over tobacco products.

Having concluded that nicotine-containing tobacco products fell within its statutory authority, the FDA promulgated regulations consistent with the public health goals of the FDCA. 61 Fed. Reg. 44398. Two factors were central to the FDA's approach. First, the FDA considered and rejected a ban on tobacco products. *Id.* 44412. The Agency reasoned that determining whether there is a "reasonable assurance" of safety requires consideration of both the risks of using the product and the dangers of withdrawal of the product from the market. *Id.* at 44412-13. Weighing these considerations, the FDA concluded that public health was best served by not banning tobacco products. *Id.*

Second, the FDA concluded that the best way to address the death and disease caused by tobacco products was to eliminate or reduce addiction. And because the overwhelming majority of tobacco users begin to use tobacco products as minors, the FDA determined that the best way to address addiction was to direct its initial regulation at use by young people. *Id.* 44398-99. To effectuate that goal, the FDA issued a number of specific regulations to ensure that tobacco products are not sold or otherwise provided to minors. Among those regulations are requirements that:

- retailers and their employees verify by means of photographic identification that purchasers of tobacco products are 18 years or older (21 C.F.R. § 897.14(b));
- tobacco products be sold in-person, rather than through vending machines or similar devices (§ 897.14(c));
- retailers not open a package of cigarettes or smokeless tobacco to sell a quantity smaller than the quantity in an unopened package (*id.* § 897.14(d)), and that cigarettes not be sold in packages containing fewer than 20 cigarettes (*id.* § 897.16(b)); and
- free samples of cigarettes and smokeless tobacco products not be given to minors (*id.* § 897.16(d)).

In addition, based on evidence that advertising "plays a material role in the decision of children" to use tobacco products, 61 Fed. Reg. 44489, the FDA rule imposes a number of restraints to ensure that the industry's advertising and promotional practices are not directed at minors. These restraints include regulations prohibiting tobacco manufacturers and retailers from:

- using any outdoor advertising, including billboards, within 1,000 feet of any playground or elementary or secondary school (21 C.F.R. § 897.30 (b));

• selling or otherwise distributing promotional items bearing the name, selling message, or logo of a tobacco product (*id.* § 897.34(a)); and

• sponsoring any athletic, musical, artistic or other event that involves a brand name, selling message, logo, or other indicia of product identification (*id.* § 897.34(c)).

The FDA rule represents the first comprehensive federal effort at reducing both the supply of and the demand for tobacco products by our nation's children and adolescents.

In November 1998, 46 state attorneys general and the major domestic tobacco companies reached a settlement of lawsuits brought against the companies by the states. That settlement does not diminish the importance of the FDA rule. The settlement does not grant the states regulatory authority over the manufacture of tobacco products. It does nothing meaningful to warn the public about the health effects of tobacco products, does virtually nothing to restrict the sale of tobacco products to minors, and contains only a fraction of the FDA's restrictions on marketing to children. In addition, the settlement does not require tobacco companies to disclose or alter their products' ingredients and additives, whereas the FDA could promulgate regulations on those topics. Perhaps most importantly, the settlement is an inflexible contract, whereas the FDA's assertion of jurisdiction enables the Agency to continue to revise and refine its regulations based on new science, new studies, or new industry marketing tactics.

The FDCA provides the FDA with broad authority to regulate products that meet the Act's definitions of "drugs" and "devices." With the benefit of research and documents that the industry kept hidden for years, the FDA found that tobacco products fall within those definitions. No one disputes that the

FDA has the power to regulate other nicotine-delivery systems, such as nicotine patches and nicotine gum. No one disputes that the FDA properly intervened when a tobacco company marketed its cigarettes for weight reduction. The only dispute here is whether Congress intended to preclude the FDA from using its authority to protect our children from nicotine addiction and the resulting diseases associated with tobacco use.

SUMMARY OF ARGUMENT

Tobacco is the leading preventable cause of death among Americans, and more than 80 percent of smokers start smoking before they turn 18. Confronted with this public health problem of epidemic proportions, the FDA examined an enormous quantity of material regarding tobacco products. Those documents, which included a wealth of information kept secret by the industry for decades, revealed that tobacco companies had long known more than the public or the government about the health hazards of tobacco products, that the industry purposely marketed its products to children and adolescents, and that it recognized and exploited the addictive nature of nicotine by carefully calibrating nicotine levels in tobacco products.

Based on the evidence it had compiled, the FDA concluded that tobacco products fell within its jurisdiction, as defined under the FDCA. The first step in the Agency's determination was its finding that nicotine in tobacco products is a drug within the meaning of the FDCA because it is "intended to affect the structure or any function of the body." Next, the FDA found that cigarettes and smokeless tobacco products are "pre-filled drug-delivery systems"—combination products consisting of (1) a drug component (nicotine) and (2) device components (filter, ventilation system, processed tobacco) used to deliver the drug to the body. The voluminous

administrative record established that manufacturers knowingly exploit the pharmacological effects of nicotine in tobacco products. Together with the principle that actors are presumed to intend the foreseeable consequences of their conduct, and the fact that the addiction and disease that result from use of tobacco products is well-established, these findings provide a firm basis for the FDA's position. Indeed, many of the industry's own documents confirm that the priamry purpose of tobacco products is to deliver nicotine to the body.

In response to the overwhelming body of evidence supportive of the FDA's jurisdictional finding, the industry argues that, even if tobacco products fall within the jurisdictional provisions of the FDCA, those provisions do not provide a basis for the FDA's assertion of authority because Congress has never explicitly said that it intended to allow the FDA to regulate tobacco products. This argument, however, ignores the structure of the Act and the broad authority granted the FDA under it. It also ignores the industry's own conduct in hiding from Congress and the FDA its knowledge about the addictive effect of nicotine and its manipulation of nicotine to exploit that effect. Further, the industry undercuts its own argument by conceding that the FDA may regulate tobacco products marketed with claims of pharmacological effect, such as to help with weight loss. Yet if the industry's theory were correct, the FDA would be precluded from regulating in those instances as well.

Moreover, to the extent that the industry bases its argument on the presence of other statutes that address tobacco products, its plea for repeal by implication falls short. Those other statutes are modest attempts to deal with discrete aspects of the hazards posed by use of tobacco products. The FDA's rule does not conflict with those other statutes, none of which

provides the type of regulation proposed by the FDA or attempts anything near the FDA's comprehensive strategy.

The FDA is the only governmental agency with the authority and expertise to provide comprehensive regulation of the sale, use, and manufacturing of tobacco products. Research shows that the FDA's rule would significantly reduce youth smoking, both by making it more difficult for kids to obtain tobacco products and by eliminating various marketing practices that entice kids to use them. The industry's arguments cannot change the plain language of the FDCA. Combined with the powerful administrative record, that language demonstrates that the FDA's assertion of jurisdiction over tobacco products is well-founded.

ARGUMENT

I. THE FDCA AUTHORIZES THE FDA TO REGULATE TOBACCO PRODUCTS.

In 1972, an R.J. Reynolds researcher wrote, "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry." 61 Fed. Reg. 44867. That same year, a Philip Morris scientist wrote, "Think of the cigarette as a dispenser for a dose unit of nicotine." *Id.* 44856. In 1981, Brown & Williamson's parent corporation, BATCO, wrote, "In a nutshell, our approach has been to regard nicotine as a drug." *Id.* 44888.

Notwithstanding this record, the industry argues that tobacco products are neither "drugs" nor "drug-delivery devices" under the FDCA. This argument is based on the mistaken claim that only a company's *public* representations about a product's *therapeutic* effects can bring the product

within the statutory definitions of drugs or devices. According to the industry, as long as manufacturers are careful about what they say, the FDA cannot act, no matter how addictive a product or how much evidence the Agency possesses about manufacturers' intent. As the district court recognized, however (Pet. App. 109a, 115a), and the majority below never disputed, the FDCA definitions of drugs and devices are not nearly so narrow.

Applying the FDCA definitions, the nicotine in tobacco products is a drug because it is intended to have a pharmacological effect, and cigarettes and smokeless tobacco products are devices used to deliver the drug nicotine to the body. Together, the drug and the device form a "drug-delivery system," a type of "combination product" that (1) contains a drug, as that term is defined by the FDCA, and (2) has the primary purpose of delivering or aiding in the delivery of the drug. The FDA may appropriately regulate such products under either its drug or device authorities.

A. Nicotine In Tobacco Products Is A "Drug" As Defined In The FDCA.

The FDCA defines the term "drugs" as, among other things, "(B) articles intended for 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." 21 U.S.C. § 321(g)(1). Thus, a product that has pharmacological effects on the body—bringing it within the lay understanding of "drug"—falls within the statutory definition if it is intended *either* (1) to be used to treat or prevent disease *or* (2) to otherwise affect the body. *See also United States v. An Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 793 (1969) (FDCA

definition of "drug" is term of art that encompasses far more than strict medical definition).

The fact that nicotine has pharmacological effects on the human body is undisputed. Indeed, the FDA regulates other nicotine products, such as nicotine patches and nicotine chewing gum; and the tobacco industry has not challenged the FDA's assertion of jurisdiction over those products. In this case, the FDA's authority is based on its determination that nicotine in tobacco products is a drug within the meaning of subsection (C) because it is "intended to affect the structure or any function of the body." 61 Fed. Reg. 44403.

1. The FDA based its finding of "intent" on evidence of foreseeability, consumer use, and internal industry documents. The FDCA does not define "intend." Thus, the Court should construe the term according to "its ordinary meaning." *Asgrow Seed Co. v. Winerboer*, 513 U.S. 179, 187 (1995). The dictionary cited by the district court defined "intend" as "[t]o have in mind; plan . . . . [t]o design for a specific purpose. . . . [t]o have in mind for a particular use." Pet. App. 105a (quoting *The American Heritage Dictionary* 668 (2d ed. 1991)). As the district court further noted, the legal usage of the word "includes the principle that one intends the readily foreseeable consequences of his actions." Pet. App. 105a (citing *Agnew v. United States*, 165 U.S. 36, 53 (1897)). Given these definitions, nothing in the plain meaning of the FDCA indicates that Congress intended to limit the FDA to evidence based on manufacturers' marketing claims.[2]

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[2] As the district court found, the legislative history of the FDCA and court decisions construing the Act support this conclusion. *See* Pet. (continued...)

The FDA's regulations regarding the meaning of "intended uses" also support the Agency's assertion of jurisdiction here. Those regulations state that "'intended uses' or words of similar import" refer to the "objective intent of the persons legally responsible for the labeling of drugs." 21 C.F.R. § 201.128; *see id.* § 801.4 (devices).

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, . . . be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. . . .

Id. § 201.128 (drugs); *id.* § 801.4 (devices). This definition plainly allows the Agency to rely on evidence other than manufacturer representations to establish intended use.[3]

Foreseeability: Nicotine affects the structure or function of the body. "Nicotine's effects on the brain are the biological basis of nicotine addiction—an addiction that has been proven by a wealth of laboratory and epidemiological evidence and

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[2](...continued)
App. 107-08.

[3] The industry claimed below that the FDA's interpretation of the term "intent" in connection with the regulations was "unprecedented." In fact, the regulations defining intent, 21 C.F.R. §§ 201.128, 801.4, were issued in the 1950s and are in keeping with centuries of Anglo-American law. *See Hadley v. Baxendale*, 156 Eng. Rep. 145 (1854).

recognized by every major independent medical organization that has studied the question." 61 Fed. Reg. 44701; *id.* 44702-06. Of course, having conducted numerous studies on nicotine's pharmacological effects, the industry knows this fact. Even if the manufacturers feigned ignorance, however, they have no legal right to disregard facts that have become common knowledge.

Applying an "objective" standard for "intent," the manufacturers are charged as a matter of law with having foreseen the reasonable consequences of their actions. *See Lee v. Lee County Bd. of Educ.*, 639 F.2d 1243, 1267 (5th Cir. 1981) (objective intent "presumes that a person intends the natural and foreseeable consequences of his voluntary actions"). And the reasonable consequence of the manufacturers' actions—marketing products containing a pharmacologically active dose of nicotine—was and is to affect the structure and function of the bodies of users of tobacco products. Because the effect is so great—as many as 92 percent of smokers are addicted to nicotine, 61 Fed. Reg. 44730—any claim that such consequences are not foreseeable is not credible.

Consumer use: Evidence of actual consumer use is also germane to intent. *See* H.R. Rep. No. 94-853 at 14 (1976) (FDA may consider "actual use of a product in determining whether or not it is a device."); Pet App. 111a-112a (district court opinion) (citing cases in which courts have recognized that intended use may be determined by looking to actual use). Here, consumer use confirms that the manufacturers' purposeful manipulation of the form and content of nicotine in their products is intended to create and satisfy consumer addiction. Manufacturers' own documents reaffirm that the industry "foresees" the connection between its manipulation of nicotine delivery and the public's use of tobacco products for

pharmacological effects. 61 Fed. Reg. 44854-5097. Data regarding consumer use establish that the foreseeable results in fact come to pass. *Id.* 44807-46.

Industry documents: Industry documents show that tobacco manufacturers are keenly aware that consumers buy tobacco products mainly to satisfy addiction. *See* 21 C.F.R. § 201.128. For example, a Philip Morris report cited nicotine as "the primary reason" why people smoke and placed tobacco products in the category of "nicotine delivery devices," along with nicotine patches and nicotine gum. 61 Fed. Reg. 44854, 44866. An R.J. Reynolds memorandum, referring to "the confirmed user of tobacco products," acknowledged that "[h]is choice of product and pattern of usage are primarily determined by his individual nicotine dosage requirements. . . ." *Id.* 44868. And Brown & Williamson and its parent BATCO have referred to nicotine as the reason "why people inhale smoke." *Id.* 44880. These and numerous similar statements found in company documents are not stray comments of low-level employees. Rather, they are admissions rightly imputed to the companies and accepted by the FDA to show that the industry intends its products to have pharmacological effects.

In addition to establishing the industry's knowledge that its products are used as nicotine-delivery devices, documents before the FDA reveal that manufacturers research and design their products specifically for this purpose. The documents show that tobacco companies, through their manufacturing processes, can and do control the amount, form, and delivery of nicotine in their products, all in a deliberate effort to exploit the pharmacological effects. *Id.* 44917-46 (cigarettes); *id.* 45108-24 (smokeless tobacco companies use product-design features to control nicotine delivery and to promote tolerance and addiction to nicotine); *e.g.*, *id.* 44942 (addition of ammonia to

increase delivery of nicotine); *id.* 44868 (memo from cigarette manufacturer referring to cigarette as "nicotine delivery system"). Such documents offer unambiguous evidence that tobacco products are "design[ed] for a specific purpose" and that manufacturers have their products "in mind for a particular use"—that is, to deliver nicotine to the body. *See* Pet. App. 105a (district court) (quoting definition of "intent" in *The American Heritage Dictionary*).

Thus, the administrative record demonstrates not only that manufacturers of tobacco product reasonably foresee that their products will be used for the pharmacological effects of nicotine, and that their products are actually used for this purpose, but also that they engineer their products to exploit and promote those effects, in particular the effect of addiction. The voluminous record establishes that manufacturers consider their products nicotine-delivery systems and that they have done extensive studies of the effects of nicotine, including addictiveness, to enable them to better design their products to maintain addiction.

Manufacturer claims: The industry has further argued that the intent component of the subsection (C) definition of drugs, *see supra* p. 8, can be satisfied *only* by industry statements making express health claims (for example, weight loss, stress reduction, appetite suppression). Because manufacturers make no therapeutic claims for their products, the industry contends, the FDA cannot regulate them.

Neither the statutory language nor the legislative history requires therapeutic uses or specific therapeutic claims for a product to qualify as a drug or device. Rather, under subsection (C), the FDA may regulate products marketed without such representations as long as the products are *intended* to be used

for their pharmacological effects. *See United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992) ("All of the circumstances surrounding the promotion and sale of the product constitute the 'intent.' It is not enough for the manufacturer to merely *say* that he or she did not 'intend' to sell a particular product as a device."). Thus, for example, in 1987, the FDA determined that Advanced Tobacco Products' new product FAVOR, a cigarette-like device consisting of a plug impregnated with a nicotine solution inserted with a tube, corresponding in appearance to a conventional cigarette, was a new drug intended as an alternative nicotine-delivery system for cigarette smokers, to satisfy nicotine dependence and to create nicotine effects.[4]

As support for the argument that "intent" can be manifested only by public claims of therapeutic effect, the industry has relied on FDA statements made at congressional hearings and on the FDA's denial of a 1977 petition to the FDA filed by Action on Smoking and Health ("ASH"), which urged the FDA to assert jurisdiction over cigarettes sold without therapeutic claims. The industry's reliance on the Agency's past statements is misplaced.

First, the FDA's response to the ASH petition explicitly recognized that the determination of intent was not dependent on manufacturers' public claims and that objective evidence, including evidence of consumer use, could outweigh the manufacturers' statements. Letter from FDA Commissioner to John Banzhaf, Nov. 25, 1980, at 8-9 (citing *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir.

[4] The "combination product" provision of the FDCA was not enacted until 1990.

1974)) (Exh. 2 to Plaintiffs' Second Brief in Support of Summary Judgment). The FDA found, however, that the ASH petition lacked sufficient evidence on this point. *Id.* Accordingly, until the FDA obtained additional evidence (for example, that as many as 92 percent of smokers are addicted and that manufacturers deliberately control the level and form of nicotine in their products to addict users, to keep users hooked, and to provide the physical effects of nicotine), the Agency's consideration of intent was controlled by the industry's promotional statements. The tobacco industry's avoidance of express health claims and its lies to Congress and the public about its knowledge of nicotine's addictiveness left the FDA in 1977 with no recourse but to disclaim jurisdiction over tobacco products. Even if the FDA agreed with the ASH assertions in 1977, it lacked the *evidence* on which its 1996 final rule is based. Only now does the FDA have proof of manufacturers' extensive research into the pharmacological effects of nicotine and their manipulation of the amount and delivery of nicotine entitles the Agency to regulate tobacco products as drugs. *See generally* 61 Fed. Reg. 44915-49; *see also Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) ("Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch" regarding its jurisdiction over tobacco products).

Second, the prior FDA statements on which the industry relies do not bear on whether the FDCA grants the FDA authority over tobacco products. Even if the Agency had previously interpreted the FDCA to assess intent solely by whether a manufacturer made express therapeutic claims, the Agency would be free to reject a prior interpretation of its organic statute. *Rust v. Sullivan*, 500 U.S. 173, 186 (1991) (even where agency's interpretation of statute represents "break

with prior interpretations," courts will grant it substantial deference) (citing *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 862 (1984)); *id.* at 184. An agency must "provide a reasoned explanation for its" change in position, *Action on Smoking and Health*, 655 F.2d at 242 n.10, but it is not required to "establish rules of conduct to last forever." *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 42 (1983). *See United States v. Southwestern Cable Co.*, 392 U.S. 157 (1968). And if the statutory language is ambiguous, an agency's regulations will be upheld as long as they are "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 842-43.

Here, the FDA's present interpretation is the most straightforward because nothing in the statutory language defining "drug" or the regulatory language defining "intent" limits determinations of intent to public statements. If it did, Prozac could be sold as an unregulated product as long as it was advertised without health claims, although its manufacturer knew it would have pharmacological effects and controlled its contents to produce those effects.

The FDA's interpretation also serves the important policy goal of preventing drug manufacturers from side-stepping the regulatory process by misrepresenting their true objectives or by carefully phrasing public statements in the face of known pharmacological effects produced by ordinary use of the product. At the same time, the FDA's interpretation protects against FDA regulation of products, for example, model airplane glue, that can be used to affect the structure or function of the body but are neither engineered, sold, nor used by most consumers for that purpose. Accordingly, the FDA's action is based on "a plausible construction of the plain language of the

statute and does not otherwise conflict with Congress' expressed intent." *Rust v. Sullivan*, 500 U.S. at 184.

B. Cigarettes And Smokeless Tobacco Products Are Nicotine-Delivery Systems.

The FDA properly decided to regulate tobacco products as drug-delivery systems. Because nicotine is a drug within the meaning of the FDCA, and because tobacco products are intended to deliver that drug to the user, cigarettes and smokeless tobacco products precisely fit the definition of "combination products," 21 U.S.C. § 353(g). The designation and treatment of combination products is not an *ad hoc* artifice created by the FDA for the purpose of regulating tobacco. Rather, the FDA's action is based on the FDCA and an agreement between the FDA's Center for Drug Evaluation and Research ("CDER") and its Center for Devices and Radiological Health ("CDRH"), entered into in October 1991, well before tobacco was on the FDA's agenda. Pursuant to that agreement, the FDA treats products that are distributed containing a drug and that have the primary purpose of delivering or aiding in the delivery of the drug (a "pre-filled drug-delivery system," such as a pre-filled syringe) as combination products, which may be regulated under either the drug or the device regulations. 61 Fed. Reg. 44402-03.

Cigarettes deliver the drug nicotine to the body through inhalation into the lungs, much like other combination products, such as nebulizers. In addition, certain cigarettes have been specifically marketed for drug delivery. For example, in the 1970s, Asthmador cigarettes were sold as an asthma treatment in the United States. As recently as a few years ago, in France, Cigarettes Schulze Bengalias used the cigarette form to treat respiratory systems disorders by delivering to the body drugs

such as those in stramonium leaf and digitalis leaf. *See also United States v. 354 Bulk Cartons*, 178 F. Supp. 847 (D.N.J. 1959) (cigarette marketed for weight reduction); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (cigarette marketed to prevent respiratory and other disease).

Smokeless tobacco products deliver nicotine to the body through absorption into the buccal pouch, the inner lining of the cheek. This means of delivery is particularly effective because it allows the drug to enter the bloodstream directly from the buccal pouch, in contrast to the slower passage of a pill through the stomach. Other products that deliver drugs to the body through the membranes lining the mouth, without being swallowed, include various nitrates used to treat chest pain, such as angina; Fentanyl Oralet, a lollipop that delivers an anesthetic by initial rapid absorption through the mouth, as well as by slower delivery through the gastrointestinal tract; asper-gum, and nicotine gum.

The industry argued below that the FDA may not regulate tobacco products under the device regulations because the products achieve their effect through "chemical action," and the definition of devices excludes items that "achieve [their] primary intended purposes through chemical action." *See* 21 U.S.C. § 321(h). Under the FDCA, however, combination products necessarily have both drug components, which affect the body through chemical action, and device components, which do not. 21 U.S.C. § 353(g). Frequently, the device components of the combination product do not in themselves have an effect on the structure or function of the body. A syringe, for example, does not affect the body; only the drug injected through that device does so.

Moreover, although the statute specifies that for combination products that act primarily as drugs (such as tobacco products), "the persons charged with premarket review of drugs shall have primary jurisdiction," the FDCA says nothing about which regulations the FDA must apply to those products. 21 U.S.C. § 353(g). That issue is addressed only by the agreement between CDER and CDRH, *supra* p. 17, which allows the FDA to regulate a pre-filled drug-delivery system under either the drug or the device regulations, no matter what the product's primary mode of action. 61 Fed. Reg. 44400-01. Although the industry seeks to force the FDA to regulate such products as drugs, it has offered no cogent reason for imposing such a requirement on the FDA. Neither the statute, its legislative history, the regulations, nor FDA precedent requires such a restriction. Thus, the district court properly deferred to the FDA's decision to regulate tobacco products as devices.

The industry further contended below that tobacco products are not combination products because the device components could not be regulated apart from the drug nicotine. That argument seeks to impose a requirement beyond that established by the clear language of the statute, 21 U.S.C. § 353(g), which plainly permits the FDA to regulate products like nebulizers and transdermal patches as combination products. (In fact, the industry has conceded that nicotine patches are regulable as combination products. *See* Industry D. Ct. "Second Brief" at 28, 29.) Nebulizers and transdermal patches, without their drug components, are basically canisters and stickers. Like cigarettes or chewing tobacco, those canisters and stickers are intended to deliver a drug to the product's user. Thus, for regulatory purposes under the FDCA, each is a drug-delivery system. *See also* 61 Fed. Reg. 44866 (Philip Morris report places cigarettes and smokeless tobacco in same category of "nicotine delivery devices" as nicotine patches and gum). And,

like used cigarettes and used smokeless tobacco products, when the drug has been extracted from the canisters or stickers, the devices are worthless.

C. The Fourth Circuit's Approach Is Contrary To The Structure Of The FDCA.

Although the definition provisions of the FDCA establish the scope of the FDA's jurisdiction, the Fourth Circuit found that the FDA had no jurisdiction over tobacco products based on a lack of specific indicia that Congress intended to give the Agency such authority. By framing the jurisdictional question in that way, the court below transformed the relevant question from whether Congress *withheld* authority over tobacco products from the FDA to whether Congress *delegated* such authority to the FDA. Pet. App. 15a.

The Fourth Circuit's approach is contrary to the structure of the FDCA. The FDCA's definitions do not name any specific products. The statute works as a general grant of authority over the categories of products set forth in the definition provisions. Thus, if a product fits the definition of "drugs" or "devices" and is not expressly excluded from the scope of the definition, the FDA is empowered to assert jurisdiction.

In essence, the Fourth Circuit was concerned that the FDA was trying to fit a square peg into a round hole. Purporting to discern congressional intent by considering the jurisdictional provisions in the context of the statute as a whole, the court claimed to have found that regulation of tobacco products did not fit comfortably into other specific FDCA provisions. In this regard, the court erred for several reasons.

First, the applicability of the definition provisions is apparent on their face. *See supra* at I.A. Indeed, the Fourth Circuit's opinion suggests that the FDA's reading of the definition provisions is entirely plausible. Pet. App. 19a. Yet not only did the court give the Agency no deference as to the scope of those provisions, the court rushed past those provisions with minimal discussion and no analysis. *Id.*

Second, although consideration of other provisions often aids statutory interpretation, the court below nonetheless erred in giving other provisions more weight than the jurisdictional provisions actually at issue. That is, the Fourth Circuit's approach robbed the definition provisions of their function—to outline the scope of FDA jurisdiction—on the theory that those definitions do not apply to a product unless regulation of that product fits as neatly into all of the other provisions as it does into those jurisdictional provisions. In this way, the Fourth Circuit improperly substituted its judgment on how to regulate tobacco products for the judgment of the expert agency charged by Congress with implementing the statute. The answer to the question of how to regulate, however, is one uniquely within the Agency's expertise. Accordingly, as to that question, the Agency's view deserves deference if it reflects a plausible construction of the statute. *Rust v. Sullivan*, 500 U.S. at 184; *Chevron*, 467 U.S. at 843. Thus, even if the FDA's regulatory scheme were imperfect, as the Fourth Circuit thought, that imperfection would not constitute grounds for stripping the FDA of statutory authority founded on the FDCA's jurisdictional provisions.

Furthermore, the Fourth Circuit's approach suggests that the FDA must decide all issues about how to regulate a product at the point at which it first asserts jurisdiction and that the assertion of jurisdiction requires the Agency to apply all relevant

statutory provisions in a timely manner. Thus, for example, the Fourth Circuit said that the FDA's failure yet to classify tobacco products as class I, II, or III devices is evidence that tobacco products do not fall within the Agency's jurisdiction because the FDCA requires the FDA to classify all medical devices. Pet. App. 27a. The Fourth Circuit's approach, however, does not reflect the way in which FDA regulates medical devices. In practice, the FDA often delays regulatory action with respect to specific products. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 n.3 & 479 (1996) (noting slow pace of FDA's initiation of premarket approval process for devices already on market). For example, the FDA did not classify numerous medical devices until years after enactment of the medical device laws in 1976. *See, e.g.*, 21 C.F.R. §§870.3600, 870.3610, 870.3620, 870.3680, 870.3700 (numerous pacemaker components classified in 1980); *id.* § 876.3350 (penile implants classified in 1983); *id.* § 870.3375 (cardiovascular intravascular filters classified in 1980); *id.* § 868.5610 (membrane lungs for long-term pulmonary support classified in 1982). Thus, the FDA's failure to classify tobacco products in 1996 is not an indication that the Agency cannot regulate in accordance with the statute. Rather, it reflects the usual pace of Agency action in this area.

The Fourth Circuit took its argument about classification one step further by suggesting that the FDA did not classify tobacco products because all three device categories require that the products within that category have a reasonable assurance of safety and effectiveness. Because the FDA does not believe that tobacco products are safe, the Fourth Circuit continued, classifying tobacco product would require the Agency to ban them. Pet App. 27a-28a. First, the FDA disagrees that asserting jurisdiction requires it to ban tobacco products. *See*

supra p. 3.[5] Second, the lower court's argument does not constitute a reason to find that the FDCA does not confer authority on the Agency where such authority is found in the jurisdictional provisions of the statute. Speculation about what the Agency could, would, or should do if it has jurisdiction is a separate question from whether the Agency has jurisdiction at all. And at this stage of the proceedings, the question of how the Agency should regulate—as opposed to whether it can regulate at all—is not even before the Court.

* * * * *

In crafting the broad definitions that form the basis of the FDA's authority, Congress left to the FDA's expertise decisions about which specific products are covered by the Act. Exercising its expertise, the FDA regulates numerous products that fall within the FDCA's definitions but might not comport with a lay understanding of a drug or a medical device. *See, e.g.*, 21 C.F.R. § 878.4635 (tanning booth), § 880.6050 (ice bag), § 880.6265 (examination gown), § 886.5842 (eyeglass frames), § 886.5850 (non-prescription sunglasses). Nonetheless, unless expressly excluded from the FDCA's definitions of drugs or devices, any product that meets one of those definitions falls within the FDA's jurisdiction. Nicotine in tobacco products meets the FDCA definition of a drug. Therefore, the Court should uphold the district court's ruling

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[5] The FDA has stated that it has no intention of banning tobacco products. 61 Fed. Reg. 44419. In reaching this decision, the FDA looked to the public health impact and the economic impact of banning tobacco products and concluded that the public health would best be served by taking steps to reduce the number of children who start smoking. *Id.* 44412-13.

that nicotine-containing tobacco products are subject to the FDA's regulatory authority.

II. CONGRESS HAS NOT PRECLUDED THE FDA FROM REGULATING TOBACCO PRODUCTS.

Because tobacco products fit the FDCA definition of combination drug-device products, the FDA has jurisdiction to regulate them unless Congress has otherwise withheld jurisdiction. Attempting to uncover such congressional intent, the industry has pointed to statutes specifically authorizing other agencies to regulate some aspect of the tobacco business and to the fact that Congress has not enacted laws that explicitly tell the FDA to regulate tobacco. Yet Congress nowhere indicated that the statutes on which the industry relies were intended to affect the scope of the FDA's jurisdiction under the FDCA. And the argument that this case can be decided by divining the meaning of congressional silence is without merit.

1. Under our Constitution, Congress may make laws that affect the conduct of others only in one manner: "by a bill that passes both Houses and is either signed by the President or repassed by a supremajority after his veto." *United States v. Estate of Romani*, 118 S. Ct. 1478, 1488-89 (1998) (Scalia, J., concurring) (citing U.S. Const., Art. I, § 7). There is no other means by which Congress may constitutionally act. *INS v. Chadha*, 462 U.S. 919, 951 (1983) ("[T]he legislative power of the Federal Government [must] be exercised in accord with a single, finely wrought and exhaustively considered, procedure"). *Accord Central Bank v. First Interstate Bank*, 511 U.S. 164, 186 (1994). Since, as *Chadha* held, Congress may not, even in a statute, delegate the power to make law in any other way, congressional inaction here cannot deny to the FDA the power to regulate tobacco products if the FDA otherwise has such

power. *Cf. Train v. City of New York*, 420 U.S. 35, 45 (1975) ("Legislative intention, without more, is not legislation.").

The industry has never claimed that any express provision precludes the FDA from regulating tobacco products as drug-delivery systems because no such provision exists. This absence is striking because when Congress wants to preclude an agency from exercising authority over tobacco products, it does so explicitly. For example, as part of the Dietary Supplement Amendments of 1994, Congress defined "dietary supplement" to exclude "tobacco" products. 21 U.S.C. § 321(ff). That definition is in the same statute, the FDCA, as the definitions of drug and device on which the FDA relies. *See* 21 U.S.C. §§ 321(g)(1) & (h). Thus, Congress could have precluded FDA jurisdiction here had it intended to do so. Also in Title 21, Congress defined "controlled substance" by expressly excluding "tobacco." 21 U.S.C. § 802(6). And elsewhere, Congress expressly prohibited other agencies from regulating tobacco products under other broad regulatory regimes: "chemical substance" under the Toxic Substances Control Act excludes "tobacco or any tobacco product," 15 U.S.C. § 2602 (2)(B)(iii); "hazardous substance" under the Federal Hazardous Substances Act, 15 U.S.C. § 1261(f)(2), excludes "tobacco or tobacco products." Similar exclusions are also contained in the Consumer Product Safety Act (15 U.S.C. § 2052(a)(1)(B)) and the Fair Packaging and Labeling Act (15 U.S.C. § 1459(a)(1)). Congress has not enacted such an exclusion here, and the Court should not do so in its stead.

The industry admits that the FDA has jurisdiction over *some* tobacco products—those sold with claims of health benefits. *See Fairfax Cigarettes*, 113 F. Supp. 336; *354 Bulk Cartons*, 178 F. Supp. 847. Attempting to make its position seem consistent, the industry suggests that Congress "approved"

those cases in the same way that it allegedly disapproved the FDA's assertion of jurisdiction here—by doing nothing. To distinguish cases in which FDA jurisdiction is appropriate from cases in which it is not, the industry says that Congress has "withheld" FDA authority only over tobacco products "as customarily marketed." That phrase, however, appears nowhere in the statute or its history, although Congress has written that type of restriction into other statutes. *See* 15 U.S.C. § 1459(a) ("consumer commodity" is product "customarily produced or distributed for sale through retail sales agencies"). Yet if Congress actually forbade the FDA from regulating tobacco products, such a ban would include cases where health claims are asserted because nothing in the FDCA makes the FDA's jurisdiction over tobacco products turn on how the products are "customarily marketed." Even the industry concedes that such a result would not square with the FDCA.

2. In a related argument, the industry has asserted that Congress has comprehensively regulated tobacco products in a way that leaves no room for the FDA. The Fourth Circuit restated this theory as an argument that tobacco-specific statutes show that Congress did not intend to allow the FDA to regulate tobacco products under the general authority provided it in the FDCA. As the district court found, however, the statutes at issue do not support the arguments built upon them.

FCLAA: The industry has argued that the Federal Cigarette Labeling and Advertising Act of 1965, as amended, ("FCLAA") regulates tobacco products so comprehensively that it preempts the entire field of tobacco regulation. The FCLAA's federal preemption provision, 15 U.S.C. § 1334(a), restricts federal agencies only from mandating additional statements relating to smoking and health "on any cigarette package," which the FDA's rules do not do. Furthermore, prior to the

1969 amendments to the statute, when a broader preemption provision applied to federal agencies, the D.C. Circuit in *Banzhaf v. FCC*, 405 F.2d 1082, 1088, 1090 (1968), narrowly construed the preemption provision to cover only requirements for affirmative statements related to smoking and health.

Although the declaration of policy contained in section 1 of the original 1965 FCLAA stated that Congress intended to enact a "comprehensive" program regarding the labeling and advertising of cigarettes, the statute plainly is not a comprehensive cigarette regulatory law. Rather, the statute precludes federal agencies from acting only to the extent stated in 15 U.S.C. § 1334(a). Surely, the industry does not contend that state laws banning cigarette sales to minors are somehow preempted by the FCLAA. And no one could seriously suggest that a public school's ban on cigarette advertisements in the school newspaper or a prohibition on distributing free samples on school grounds would be preempted. In fact, the Fourth Court has rejected a preemption challenge to a Baltimore ordinance that contains an even broader ban on billboard tobacco advertising than the FDA rule. *Penn Advertising v. Mayor & City Council of Baltimore*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 117 S. Ct. 1569 (1997). Since the FCLAA does not even preempt all regulation of cigarette advertising, it certainly does not preempt the entire field of tobacco regulation.

Smokeless Tobacco Act: For similar reasons, the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4406(a), does not preempt the field of smokeless tobacco regulation. The preemption provision in that Act bans federal and state laws requiring additional statements on packages and in advertisements beyond those mandated by Congress (but excludes billboards from its reach). It does not preempt any other federal, state, or local regulation.

ADAMHA: The industry has also claimed that the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, 42 U.S.C. § 300x-26 ("ADAMHA"), eliminates all FDA jurisdiction over tobacco. In fact, the ADAMHA is a modest effort to reduce underage tobacco use by strengthening state efforts to enforce laws restricting youth access. The ADAMHA does not impose mandatory requirements, as any state may choose to forego federal funding for substance abuse programs rather than to increase enforcement. The statute imposes no federal sanctions for sales to minors. It contains no provisions designed to reduce minors' demand for tobacco products. And, most significantly, it has no preemption provision of any kind. About all that can meaningfully be said about the ADAMHA in the context of this case is that it confirms the FDA's view that underage tobacco use is a serious problem and shows that Congress was willing to use federal tax dollars to enlist the states in the fight.

Moreover, the broad preemption by implication theory espoused by the industry here was rebuffed by the Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and more recently in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Indeed, accepting the logical reach of the ADAMHA argument would result in revocation of the FDA's long-standing jurisdiction over tobacco products for which health claims are made. The Court should reject this attempt to transform a narrow law designed to protect minors into a law that shields the tobacco industry.

3. Because no statute actually forbids the FDA from regulating tobacco, the industry has tried to convert congressional failures to enact positive authorizing legislation into a basis for denying the FDA the power to regulate tobacco products. However, "[c]ongressional inaction cannot amend a

duly enacted statute." *Patterson v. McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989). As Justice Scalia has admonished:

> [O]ne must ignore rudimentary principles of political science to draw any conclusions regarding [congressional] intent from the failure to enact legislation. The "complicated check on legislation," The Federalist No. 62, p. 378 (C. Rossiter ed. 1961), erected by our Constitution creates an inertia that makes it impossible to assert with any degree of assurance that congressional failure to act represents (1) approval of the status quo, as opposed to (2) inability to agree upon how to alter the status quo, (3) unawareness of the status quo, (4) indifference to the status quo, or even (5) political cowardice.

Johnson v. Transportation Agency, 480 U.S. 616, 671-72 (1987) (Scalia, J., joined by Rehnquist, C.J., dissenting). *See Estate of Romani*, 118 S. Ct. at 1488-89 (Scalia, J., concurring).

An example forcefully illustrates why it is inappropriate to rely on congressional inaction to establish the meaning of duly enacted laws. After the FDA published its proposed rule, several Members of Congress from North Carolina and Kentucky introduced bills that would have explicitly forbidden the FDA from regulating tobacco products. *See* 61 Fed. Reg. 45259 (citing bills). Those bills were not enacted. Under the industry's theory, such inaction would constitute a decision by Congress to allow the FDA to proceed. Or suppose that such a bill were passed by both Houses, but that the President vetoed it, and an override vote fell one vote short in one House. Under the industry's approach, a court should construe that outcome

as acquiescence in the FDA's authority over tobacco products. Indeed, the industry's approach to congressional inaction would mean that Congress implicitly ratified the FDA's final rule, by failing to overrule the rule pursuant to the 1996 amendments to the Administrative Procedure Act, under which the effective date of all major rules is delayed to allow Congress time to enact a joint resolution of disapproval. 5 U.S.C. §§ 800 *et seq.*

All of these attempts to use legislative silence are inappropriate. The only way to interpret what Congress meant in a statute is by examining that statute, with all of the proper tools of legislative interpretation. As discussed above, such examination demonstrates that the FDCA authorizes the FDA to regulate tobacco products.

CONCLUSION

For the foregoing reasons, the decision of the Fourth Circuit should be reversed.

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