

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1604
(CA 95-591-2)

and consolidated cases
No. 97-1605 (CA 95-665-6) and
No. 97-1606 (CA 95-591-2)

BROWN & WILLIAMSON TOBACCO CORP., et al.

Plaintiffs/Appellants/Cross-Appellees,

v.

UNITED STATES FOOD & DRUG ADMINISTRATION, et al.

Defendants/Appellees/Cross-Appellants.

BRIEF AMICI CURIAE OF PUBLIC CITIZEN, AMERICAN
ACADEMY OF PEDIATRICS, AMERICAN CANCER SOCIETY,
AMERICAN COLLEGE OF PREVENTIVE MEDICINE,
AMERICAN HEART ASSOCIATION, AMERICAN LUNG
ASSOCIATION, AMERICAN MEDICAL ASSOCIATION,
AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN
PUBLIC HEALTH ASSOCIATION, AMERICAN SOCIETY
OF ADDICTION MEDICINE, THE HMO GROUP, NATIONAL
ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS,
NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS,
AND NATIONAL CENTER FOR TOBACCO-FREE KIDS
IN SUPPORT OF DEFENDANTS/APPELLEES/CROSS-APPELLANTS
THE FOOD AND DRUG ADMINISTRATION, ET AL.

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This brief is submitted by 14 public health, consumer, and educational organizations, which appeared below 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 affirmance of the district court's ruling insofar as it holds that the FDA may exercise jurisdiction over tobacco products. Amici seek reversal of the district court's ruling insofar as it finds that section 520(e) of the Food, Drug, and Cosmetic Act ("FDCA") does not authorize the FDA to impose restrictions on the advertising and promotion of tobacco products. Finally, although the industry may argue that the district court's ruling on the advertising and promotion restrictions could be affirmed on First Amendment grounds, the FDA's regulations do not violate the First Amendment.¹

STATEMENT OF THE ISSUES

1. Does the FDA have jurisdiction under the FDCA over tobacco products?
2. Does 21 U.S.C. § 360j(e) authorize the FDA to regulate the promotion and advertising of "restricted devices"?
3. Do the FDA's promotion and advertising regulations violate the First Amendment?

INTEREST OF AMICI

Amici are 14 organizations with long-standing interests in public health, especially in the health of children and in

¹ Throughout this brief, defendants below are referred to as the "FDA" or the "Agency." Plaintiffs below are referred to collectively as "the industry."

protecting children from the harms caused by tobacco products. The groups are more fully described in the accompanying Motion of Public Citizen, et al. for Leave to File Brief Amici Curiae.

STATEMENT OF THE CASE

Tobacco use is the single most preventable cause of premature death and disease in the United States. Millions of 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). Tobacco product manufacturers carefully engineer their products to deliver doses of nicotine to consumers, to create and satisfy nicotine addiction. 61 Fed. Reg. 44915-94.

SUMMARY OF ARGUMENT

I. The district court held that the FDCA authorizes the FDA to regulate tobacco products. In so ruling, the court correctly rejected the industry's two related jurisdictional arguments.

First, the industry argues that the definitions of "drug" and "device" in the FDCA do not encompass tobacco products, which contain nicotine, a substance that indisputably has significant pharmacological effects. The industry principally argues that the statutory definitions cover only products promoted for therapeutic purposes. Under the FDCA, however, a product is a

drug or device if it is "intended to affect the structure or any function of the body." Because voluminous documentation in the administrative record establishes manufacturers' knowing exploitation of the effects of nicotine in tobacco products, because actors are presumed to intend the foreseeable consequences of their conduct, and because the addiction and disease that result from use of tobacco products is well-established, the district court's finding that nicotine in tobacco products falls within the statutory definition of "drug" is correct and should be affirmed.

The court below also properly upheld the FDA's determination that cigarettes and smokeless tobacco products are "pre-filled drug-delivery systems," a combination product consisting of (1) a drug and (2) a device used to deliver the drug to the body. The administrative record confirms that the industry purposefully engineers its products to deliver carefully calibrated doses of the drug nicotine to the body. Indeed, numerous industry documents openly state that their products' purpose is to deliver nicotine. And because the FDA's existing procedure allows the FDA to regulate such combination products as either drugs or devices, the Agency acted properly in deciding to apply the device authorities to tobacco products.

Second, the industry contends that, even if tobacco products meet the definition of drug and drug-delivery systems under the FDCA, Congress has affirmatively forbidden the FDA from regulating tobacco products. This argument is based on laws

assigning certain duties regarding tobacco to federal agencies other than the FDA, and on instances in which Congress has considered--but not enacted--proposals that would have explicitly recognized the FDA's authority over tobacco products. The industry claims that, through such action and inaction, Congress has precluded the FDA from regulating tobacco products, even if the FDCA otherwise confers jurisdiction over tobacco products on the Agency.

The industry's argument is fundamentally flawed because it equates congressional inaction with a congressional prohibition enacted into law. Congress can forbid an agency from acting within its delegated sphere of authority only by passing a law. Congress never did so, however, with regard to the FDA's authority over drugs and medical devices. In fact, even the industry effectively concedes that no such prohibition exists, for it acknowledges that the FDA may regulate tobacco products that are marketed with claims of pharmacological effect, such as to help with weight loss. Yet, if the industry's argument were correct, the FDA would be precluded from regulating in those instances as well.

II. The district court erred in ruling that section 520(e) of the FDCA, 21 U.S.C. § 360j(e), does not authorize the FDA to regulate the promotion and advertising of restricted devices. Section 520(e) authorizes the FDA to impose whatever "conditions" on "sale, distribution, or use" it deems necessary and

appropriate to assure the "safety and effectiveness" of "restricted" medical devices.

The district court did not question the FDA's decision to designate tobacco products as "restricted" devices. In enacting section 520(e), Congress delegated sweeping power to the FDA to impose strict controls on certain medical devices that the FDA decides ought to be available, despite the serious risks they pose. The language of section 520(e) underscores the breadth of the FDA's powers over this narrow class of devices: it imposes no limitation on the FDA's power to regulate sale, distribution, or use under this provision. The FDA's interpretation of "conditions" on "sale" as authorizing restrictions on advertising and promotion--both of which are activities designed to sell products that pose serious risks--is a reasonable one, entitled to deference. Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 842-43 (1984).

As an alternate basis for affirming the district court's decision on advertising and promotion restrictions, the industry may argue that these restrictions violate the First Amendment. That argument, however, ignores the fundamental purpose of the restrictions: They are aimed at reducing the demand for tobacco products by minors, who are forbidden by both federal and state law from purchasing such products. Surely, even the industry would not contend that banning tobacco ads in the Weekly Reader or prohibiting tobacco ads on billboards directly across the

street from entrances to schools and playgrounds would run afoul of the First Amendment, yet that is the impact of its argument.

The FDA has carefully tailored its restrictions to apply only where tobacco advertisements would be seen by substantial numbers of minors and only to the types of ads that have the greatest impact on children. Such regulations inevitably require line drawing. Here, where the Agency has cited substantial evidence in support of its rule and has provided all interested parties an opportunity to comment and provide additional evidence, the FDA is entitled to reasonable latitude, particularly where no blanket ban is involved and the industry is left numerous alternative means of communication. Thus, for example, limiting advertisements that young people are likely to see to a black and white, text-only format required the FDA to draw a bright line, and it drew that line at publications with 15 percent minor readership or 2,000,000 minor readers. The industry did not suggest any alternative lines that would serve the FDA's goals in a less intrusive way.

Given the nature of the harm that can befall children who become addicted to tobacco products, the evidence relied on by the Agency, and the paramount need to cut down on demand for those products among minors, the FDA was well within the boundaries set by the First Amendment in restricting advertising and promotion with the greatest impact on minors, while continuing to permit the industry to use any approach it chooses when its efforts are directed at adults.

ARGUMENT

I. THE FDA HAS THE AUTHORITY TO REGULATE TOBACCO PRODUCTS.

A. The District Court Correctly Found That 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 these admissions, 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. As the district court recognized, however, 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. As the district court held, the FDA may appropriately regulate such products under either the drug or the device authorities.

1. 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 the 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.

a. The FDA based its finding of "intent" on evidence of foreseeability, consumer use, and internal industry documents. In upholding the FDA's finding, the district court properly held that the first two types of evidence were proper indicia of intent. The court erred, however, in ruling that internal industry documents could not be used to prove intent.

Noting that the FDCA does not define "intend," the court first construed the term according to "its ordinary meaning." Slip Op. 30 (to be reported at 958 F. Supp. 1060). Thus, the court looked to the dictionary, which 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." Id. at 31 (citing The American Heritage Dictionary 668 (2d ed. 1991)). The court also noted the FDA's citation to the legal usage of the word, "which includes the principle that one intends the readily foreseeable consequences of his actions." Id. Based on these definitions, the district held that the plain meaning of the FDCA did not indicate that intent must be proven by any particular type of evidence. The court further found that the legislative history of the FDCA and court decisions construing the Act supported this conclusion. Id. at 32-34.

Finally, the court considered the FDA's regulations regarding the meaning of "intended uses." 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). The district court found that this definition also allowed "reliance on evidence other than manufacturer representations to establish intended use." Slip Op. 35.²

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 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, the district court correctly held that such common knowledge should be imputed to them. Slip Op. 36, 40.

² Although the industry claimed in the district court that the FDA's interpretation of the term "intent" in connection with the regulations was "unprecedented," the regulations defining intent were issued in the 1950s and are in keeping with centuries of Anglo-American law. Compare 21 C.F.R. §§ 201.128, 801.4, with Hadley v. Baxendale, 156 Eng. Rep. 145 (1854).

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 consumers 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.³

Industry documents: Although the district court affirmed the FDA's finding that the industry "intends" its tobacco products to affect the structure or function of the body, the court rejected the Agency's reliance on manufacturers' statements and conduct as proof of intent. The court, without discussion, agreed with the industry that such evidence shows "subjective" intent and that the FDA regulation (but not the FDCA) requires

³ The court also correctly found that evidence of actual consumer use can be used to establish intent. Slip Op. 37. Evidence of consumer use provides confirmatory evidence 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 use of its 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.

evidence of "objective" intent. Because the court suggested that it was applying the FDA's regulation, Slip Op. 31, 35, the court erred in failing to give the Agency deference in construing its own regulations. Thomas Jefferson University Hospital v. Shalala, ___ U.S. ___, 114 S. Ct. 2381, 2386-87 (1994).

In any event, industry documents easily satisfy the FDA's regulatory requirement for a showing of "intent," for they show conclusively that tobacco products are, "with the knowledge of [the manufacturers] offered and used for a purpose for which [they are] neither labeled nor advertised." 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, and the statements are rightly imputed to the companies.

In addition to establishing the industry's knowledge that its products are used as nicotine-delivery devices, many of the documents before the FDA reveal that manufacturers research and

design their products for this use. 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 of objective intent. The documents show that tobacco products are "design[ed] for a specific purpose" and that manufacturers have their products "in mind for a particular use," Slip Op. 31 (quoting definition of "intent" in The American Heritage Dictionary 668), that is, to deliver nicotine to the body.

Thus, the administrative record demonstrates not only that tobacco product manufacturers could reasonably foresee that their products would be used for the pharmacological effects of nicotine, but also that they engineer their products to exploit and promote those effects, including 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. And the record reflects a telling absence of evidence that the industry perceives the nicotine in its products

as having any function other than to create pharmacological effects on the human body. The district court erred in holding that such concrete evidence of the industry's "plan," Slip Op. at 31, to exploit the pharmacological effects of nicotine did not constitute the showing of "intent" required under the FDCA.

Manufacturer claims: The industry argued below that the intent component of the subsection (C) definition of drugs, see supra p. 8, can be satisfied only by industry statements making express claims regarding health (for example, weight loss, stress reduction, appetite suppression). Because manufacturers make no therapeutic claims for their products, the industry contended that the FDA cannot regulate them. As the district court recognized, however, neither the statutory language nor the legislative history requires therapeutic uses or specific therapeutic claims. Slip Op. 40.⁴ Rather, under subsection (C), the FDA may regulate products marketed without such representations if 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

⁴ In the district court, the industry relied on United States v. Articles of Drug for Veterinary Use, 50 F.3d 497 (8th Cir. 1995), to argue that only promotional materials may evidence intended use. Although that case focused on whether the material at issue was promotional, it does not hold that only promotional material can evidence intent. In fact, the opinion states that "[t]he vendor's intended application for a product may be derived from any relevant source" Id. at 500.

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.⁵

As support for the argument that "intent" can be manifest only by public claims of therapeutic effect, the industry has relied on FDA statements made at congressional hearings and to the FDA's response to 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 Banzhaf, Nov. 25, 1980, at 8-9 (citing National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974)) (Exh. 2 to

⁵ The "combination product" provision of the FDCA was not enacted until 1990.

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. Now, the evidence before the FDA 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 is free to reject prior interpretations of its organic statute. Chisholm v. FCC, 538 F.2d 349, 364 (D.C. Cir.) ("[A]n administrative agency is permitted to change its interpretation of a statute, especially where the prior interpretation is based on error, no matter how longstanding."), cert. denied, 429 U.S. 890 (1976); see also Rust v. Sullivan, 500 U.S. 173, 186 (1991) (where an agency's interpretation of the statute represents a "break with prior interpretations," the courts will nonetheless grant it substantial deference) (citing Chevron, 467 U.S. at 862); id. at 184. The 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); accord Chisholm v. FCC, 538 F.2d at 364. 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 will have pharmacological effects and sold it for that reason, and although it would still be a "drug" when promoted as an anti-depressant.

The FDA's interpretation prevents drug manufacturers from side-stepping the regulatory process by misrepresenting their true objectives or by carefully phrasing public statements, even 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 the majority of 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.

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

The district court also correctly held that the FDA could properly regulate tobacco products as drug-delivery systems. Slip Op. 45. Because nicotine is a drug within the meaning of the FDCA and 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. Pursuant to that agreement, the FDA treats products with the primary purpose of delivering or aiding in the delivery of a drug and that are distributed containing a 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, Asthmador cigarettes were sold as an asthma treatment in the United States as recently as the 1970s. In France, Cigarettes Schulze Bengalias today uses 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 a drug can directly enter the bloodstream 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 which delivers an anesthetic by initial rapid absorption through the mouth, as well as slower delivery through the gastrointestinal tract; asper-gum, and nicotine gum.

a. 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. 19, 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 would require the FDA to regulate such products as drugs, it has offered no cogent reason for imposing this requirement on the FDA. Neither the statute, its legislative history, see Slip Op. 50-52, 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.

b. The industry further complained 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 concedes that a nicotine patch is regulable as a combination product.) Nebulizers and transdermal patches, without their drug components, are basically canisters and

stickers. Like cigarettes or chewing tobacco, the 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 tobacco products in same category of "nicotine delivery devices" as patches). And, like used cigarettes and used smokeless tobacco products, when the drug has been extracted from the canisters or stickers, the devices become worthless.

c. In the district court, United States Tobacco Co., et al., argued separately that smokeless tobacco is not a drug-delivery system but "merely a processed plant." The fact of being a plant is not sufficient ground for evading FDA jurisdiction. For example, a prosthetic device called gutta percha is basically coagulated tree sap extracted from certain tropical trees and used to fill root canal. 21 C.F.R. § 872.3850.

In any event, to say that smokeless tobacco products are "merely" processed plants is like saying that penicillin is merely processed mold or blue cheese is merely processed milk. In processing the tobacco plant, ingredients and flavorings are added in carefully calibrated proportions. In addition, to facilitate the absorption of nicotine by the user, manufacturers control alkalinity through fermentation or the addition of buffering agents, such as sodium carbonate or ammonium carbonate. 61 Fed. Reg. 45110-15. The processed tobacco is then packaged in different ways, for example in teabag-like pouches, to further

control the delivery of nicotine to the body. Id. 45115. The final product is no more a "mere" plant than the cancer drug Taxol, which is processed from tree bark.

The FDA's assertion of jurisdiction over tobacco products is based in part on the industry's extensive research and processing in order to control precisely the quantity and delivery of the pharmacologically-active nicotine. Given the manufacturers' well-documented control over the amount and form of nicotine in the processed product, the FDA has rightly determined that nicotine is intended by manufacturers "to affect the structure or any function" of the body. Accordingly, nicotine in smokeless tobacco products satisfies the FDCA definition of a drug.

3. Conclusion

In crafting the broad definitions which form the basis of the FDA's authority, Congress left to the FDA's expertise the 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 definitions of drugs or devices, any product that meets one of those definitions falls within the FDA's jurisdiction. Nicotine in tobacco products meet the FDCA definition of "drug." Therefore, the Court should uphold the

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

B. The District Court Correctly Found That Congress Has Not Precluded The FDA From Regulating Tobacco Products.

The district court held that, because tobacco products fit the FDCA definition of combination drug-device products, the FDA could regulate them unless Congress had expressed a clear intent to withhold jurisdiction from the FDA. Slip Op. 7. Attempting to uncover such congressional intent, the industry 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. That history arguably bears on the proper interpretation of the statute relied on by the FDA that Congress did enact into law, discussed supra at I.A. But, as the district court found, the argument that this case can be decided by discerning the meaning of congressional inaction is without merit.

1. Under our Constitution, Congress may make laws that affect the conduct of others only in one manner: by the passage of a bill approved by both Houses, which the President signs or which he vetoes, in which case a two-thirds vote of each House is needed to override. 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, ___ U.S. ___, 114 S. Ct. 1439, 1453 (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 cannot cite to any express provision precluding the FDA from regulating tobacco products as drug-delivery systems because none 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) & (h). Thus, Congress could have precluded FDA jurisdiction here if it had wanted 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 Hazardous Substances

Act, 15 U.S.C. § 1261(f)(2), excludes "tobacco or tobacco products."⁶ 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's argument also fails because 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. In an attempt 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; and it concludes that FDA authority has been "withheld" only over tobacco products "as customarily marketed"--a phrase that 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

⁶ The fact that the former provision also excludes any "drug, cosmetic or device" under the FDCA, and the latter also excludes "foods, drugs, and cosmetics" does not detract from the basic point that Congress has failed to create any such exclusion of tobacco products from either drugs or medical devices. Arguably, if tobacco products are drugs and/or devices, an exclusion for tobacco in those statutes would be redundant. That argument, however, is inapplicable here since neither Congress nor the FDA treated tobacco products as drugs or devices when those definitions were enacted. Therefore, a specific exclusion of tobacco products, at the time that those statutes were written, would not have been redundant. Moreover, the issue of whether the FDA has authority to issue these rules is determined by what the definitions mean, not whether Congress was aware that the definitions might encompass tobacco products.

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 whether 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 asserted that Congress has comprehensively regulated tobacco products in a way that leaves no room for the FDA. As the district court found, the statutes on which the industry relied do not support the claim that Congress has deprived the FDA of authority to regulate tobacco products.

FCLAA: The industry argues that the Federal Cigarette Labelling 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 require. See Slip Op. at 21. Furthermore, prior to the 1969 amendments to the statute, when a broader state preemptive 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 extend only to

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 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 one could not seriously suggest that a public school's ban on cigarette advertisements in the school newspaper or prohibition on distributing free samples on school grounds would be preempted. In fact, this Court recently 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. Thus, the FDA's tobacco regulations "do not conflict with the text of the FCLAA, and the general structure and purpose of the FCLAA do not evidence Congress' clear intent to withhold jurisdiction from FDA to regulate tobacco products." Slip Op. 23.

Smokeless Tobacco Act: For similar reasons, the district court found that the preemption provision of the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4406(a), does not preempt the field of smokeless tobacco regulation. Slip Op. 24. That provision 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.

In regard to the few areas in the FDA's rule involving labeling on packages, the FDA correctly concluded that the Smokeless Tobacco Act does not preempt any of the regulations at issue. 61 Fed. Reg. 44396, 44544-45. With respect to the requirement that smokeless ads include the words "A Nicotine-Delivery Device for Persons 18 or Older" (21 C.F.R. § 897.32(c)), the statement does not "relate[] to smokeless tobacco and health." Rather, the statement identifies the legal classification of the product and who may lawfully purchase it. Such a statement is not a "cautionary statement" of the type preempted by the Smokeless Tobacco Act. Slip Op. 23, 24.

ADAMHA: The district court also correctly rejected the industry's claim 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. 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 not to step up enforcement in return for foregoing federal funding for substance abuse programs. 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 the ADAMHA 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 Supreme Court in Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), and more recently in Medtronic, Inc. v. Lohr, ___ U.S. ___, 116 S. Ct. 2240 (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 convert a narrow law designed to protect minors into one that would shield 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 the courts:

[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).

An example forcefully illustrates the inappropriateness of relying 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 was 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. Moreover, the industry's approach to congressional inaction would mean that Congress implicitly ratified the FDA's final rule, and its

jurisdiction, 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 to overrule the agency's rulemaking. 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, supra I.A., such examination demonstrates that the FDCA authorizes the FDA to regulate tobacco products.

II. THE FDCA AUTHORIZES THE FDA TO REGULATE PROMOTION AND ADVERTISING OF "RESTRICTED DEVICES."

The FDA relied on section 520(e) of the FDCA as the basis for its restrictions on tobacco advertising and promotion.

Section 520(e), entitled "Restricted Devices," states:

The Secretary may by regulation require that a device be restricted to sale, distribution, or use--(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or (B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of the potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360j(e). The decision to regulate a device under section 520(e) falls within the FDA's discretion. The evidence in the administrative record adequately demonstrates the "potentiality for harmful effect" from use of cigarettes and smokeless tobacco products. Given the current state of knowledge about the effects of tobacco products on the body, this

potentiality cannot be questioned. Thus, the district court did not suggest that the FDA cannot regulate tobacco products as "restricted devices." The court did find, however, that section 520(e) does not authorize the FDA to regulate advertising and promotion. As explained below, the broad language of section 520(e) reveals the Court's error.

A. The FDA Has Reasonably Interpreted Section 520(e) To Authorize Regulation Of Advertising And Promotion Of Restricted Devices.

Section 520(e) authorizes restrictions as to "sale, distribution, or use," without placing any limitations on those three terms. The restrictions may consist of such "conditions" as the FDA prescribes, and the provision places no limitations on the type of conditions. It is hard to imagine Congress crafting a broader delegation of power to the FDA than that conferred by section 520(e). Thus, although the FDA has not previously invoked section 520(e) as authorization for a regulatory program as comprehensive as the program at issue here, the breadth of the statutory language gives the FDA substantial discretion. State Farm Mutual Insurance Co., 463 U.S. at 42-43.

Sound reasons underlie Congress' decision to give the FDA far-reaching power in regulating devices as to which there are questions regarding safety and effectiveness. Implicit in the FDCA is the understanding that drugs and devices all carry with them potential risks, as well as potential benefits. Generally, the FDA permits marketing only of those drugs and devices for which potential benefits exceed likely risks. But section 520(e)

deals with a special breed of devices--those for which the FDA finds that, without special measures, the risks could outweigh the benefits. For that reason, Congress delegated to the FDA the power to allow such devices to be marketed if special measures were taken to limit the devices' "potentiality for harmful effect." Given that Congress understood that in such cases the FDA would be regulating at the margins of safety, Congress coupled that authorization with sweeping power to take the measures the FDA deemed appropriate to minimize risk.

Moreover, courts historically have given broad constructions to delegations of agency power where the delegation is written in the expansive language that marks section 520(e). For instance, the Federal Trade Commission Act, 15 U.S.C. §§ 41, et seq. ("FTC Act"), gives the FTC broad authority to restrict unfair trade practices. Specifically, under the FTC Act, the FTC is "empowered and directed to prevent" a wide range of "persons, partnerships, and corporations" from "using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices affecting commerce." Id. § 45(a)(2). Because the scope of the actions the FTC is authorized to take is not defined by the statute, the FTC has taken a wide range of actions to prevent unfair competition pursuant to § 45(a)(2). See, e.g., Sears, Roebuck & Co. v. FTC, 676 F.2d 385, 391 (9th Cir. 1982) (even where violation found as to only one product, FTC may issue order applicable to range of products); Fedders Corp. v. FTC, 529 F.2d 1398, 1401, 1403 (2d Cir.) (FTC order covering ads regarding

"performance characteristics" upheld, although violation involved "uniqueness" claims, for FTC can enjoin acts "like and related" to act condemned and its findings must be given great weight), cert. denied, 429 U.S. 818 (1976). The breadth of the statutory language in the FTC Act vests the FTC with wide discretion in its choice of remedies, and the courts defer to that choice where it is reasonably related to the unlawful practices found. Adolph Coors Co. v. FTC, 497 F.2d 1178, 1189 (10th Cir. 1974), cert. denied, 419 U.S. 1105 (1975).

Likewise, the language of section 520(e) vests the FDA with wide discretion in its choice of the conditions placed on a restricted device. Because the FDA's tobacco restrictions are reasonably related to the sale, distribution, or use of a device with a potentially harmful effect, the Court should defer to the Agency's choice. Here, in the language of section 520(e), each of the FDA's choices is designed to reduce minors' "use" of tobacco products either by preventing the "sale" or "distribution" of tobacco products to them or by placing "conditions" on labeling and advertising to reduce the attractiveness of the products to minors so that they do not seek to evade the "sale" or "use" restrictions.

Thus, although the court was correct that "other conditions" is properly construed within the context of section 520(e) as a whole and other relevant sections of the FDCA, Slip Op. 56, the context strongly supports the FDA's interpretation. As the FDA stated in issuing the rule, "The plain language of the enacted

provision contains no limitation on the types of restrictions that can be imposed and certainly is not limited by its terms to restriction to prescription use." 61 Fed. Reg. 44407. In fact, while the district court accepted the industry's assertion that section 520(e) is the device counterpart to the prescription drug provision of the FDCA, "the legislative history specifically states that the agency's authority under section 520(e) is broader than its authority under the prescription drug provisions. (H. Rept. 94-853, 94th Cong., 2d sess., 24-25, 1976)." Id.⁷

The district court's narrow construction of section 520(e) was based in part on a distinction between "sale" and "offer for sale." The court did not dispute that advertising is part of an "offer for sale" but disagreed that an "offer for sale" is part of the "sale" of a product and that advertising can be regulated as a restriction on "sale." Because section 520(e) uses the word "sale," while "offer for sale" appears elsewhere in the FDCA, the Court found that the FDA could not rely on section 520(e) as authority for regulating advertising and promotion. The court's construction of "sale," however, was unsupported by the dictionary definition cited by the court. According to that definition, "sale" means, among other things, "the act of selling," and "[a]ctivities involved in the selling of goods or services." Slip Op. 55 n.23. Surely, advertising and promotion

⁷ Furthermore, the FDA has long regulated aspects of prescription drug advertising. See 21 C.F.R. § 202.1(e)(4).

are "activities involved in . . . selling." Indeed, what are advertising and promotion if not efforts to sell products?

Moreover, the court's view of the distinction between "sale" and "offer for sale" cannot defeat the deference owed to a reasonable FDA interpretation of the statute the FDA is charged with implementing. Chevron, 467 U.S. at 843 (where statute is silent or ambiguous as to issue, courts will defer to reasonable interpretation of agency charged with implementing statute). "Offer for sale" is a sub-part of "sale." Thus, in general, the FDCA uses "sale" in a general way, to refer to all the activities surrounding the seller's activities, while it uses "offer for sale" when limiting the context to the seller's presentation of the product. See, e.g., 21 U.S.C. § 352(q) & (r). For example, section 502(q), 21 U.S.C. § 352 (q), deems misbranded "any restricted devices distributed or offered for sale in any State, if . . . it is sold, distributed, or used in violation of regulations prescribed under section 520(e)" (emphasis added). Under the district court's interpretation, "sold" could only refer to a completed transaction. In the context of section 502(q), however, "sold" is reasonably interpreted to refer also to the act of being available for purchase--that is, the offering as well as the purchase.

Or, applying the district court's constricted construction of the word "sale," the clause, "the sale of papayaa in Virginia is unusual," could only convey that people rarely purchase papayas in Virginia. In fact, however, the clause may also

convey the idea that papayas are not usually "offered for sale" in Virginia. Thus, as the dictionary definition confirms, common usage is not nearly as narrow as the court found it to be. Common usage supports the FDA's interpretation of "sale" as including "offer for sale," and the Court should defer to this reasonable interpretation of the broad language of section 520(e). Chevron, 467 U.S. at 842-43 (if statutory language is ambiguous, agency's regulations upheld as long as they are "based on a permissible construction of the statute.").

B. The FDA's Advertising And Promotion Regulations Comply With The First Amendment.

Although the district court did not decide the industry's First Amendment challenge to the advertising and promotion regulations, the industry may present a First Amendment argument as an alternative basis for affirming the court's rejection of those regulations. Because the issue was fully briefed below, amici offer only a few points that might not stand out in the FDA's more comprehensive brief as appellee.

Amici recognize that commercial speech is entitled to substantial protection under the First Amendment.⁸ It is by now

⁸ Amici's counsel, Public Citizen Litigation Group, has been in the forefront in challenging restrictions on commercial speech. Public Citizen's lawyers handled Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 763 (1976), the first Supreme Court case holding that commercial speech merits protection under the First Amendment, as well as Edenfield v. Fane, ___ U.S. ___, 113 S. Ct. 1792 (1993), and Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985). They also represented amici curiae in many other key commercial speech cases, urging the Court to strike down the challenged restriction. See, e.g., Florida Bar v. Went for It, Inc., ___

(continued...)

a truism that for the average American the "concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue." Bates v. State Bar of Arizona, 433 U.S. 350, 364 (1977); see also City of Cincinnati v. Discovery Network, Inc., ___ U.S. ___, 113 S. Ct. 1505, 1512 & n.17 (1993). Nonetheless, a free-for-all marketplace poses dangers; and, at times, vigilant government action is needed to protect vulnerable segments of the public from false, deceptive, or overbearing sales campaigns. See, e.g., Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447 (1978). The stream of commercial speech must flow "cleanly as well as freely." Edenfield v. Fane, 113 S. Ct. at 1799. This concern takes on special force where, as here, a powerful seller--the tobacco industry--has used its resources to saturate the marketplace with promotions of dangerous products to impressionable minors.

Since 1980, the Supreme Court has employed the four-part Central Hudson test to assess restraints on commercial speech. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 563-64 (1980). Accord Florida Bar, 115 S. Ct. at 2376; Rubin, 115 S. Ct. at 1588. Under Central Hudson, the first inquiry is whether the speech concerns an unlawful activity or is misleading. Central Hudson, 447 U.S. at 566. The second inquiry is whether the governmental interest is substantial. Id. The

⁸(...continued)
U.S. ___, 115 S. Ct. 2371 (1995); Rubin v. Coors Brewing Co., ___ U.S. ___, 115 S. Ct. 1585 (1995); Peel v. Attorney Registr'n and Disciplinary Comm'n, 496 U.S. 91 (1990).

third and fourth prongs ask whether the restriction on commercial speech directly advances the governmental interest and whether the restriction is no more extensive than necessary to serve that interest. The FDA's advertising and promotion regulations pass this First Amendment test.

1. The First Amendment Does Not Bar
The FDA From Regulating Tobacco
Advertising Directed At Minors.

The heart of the FDA's regulation is a nationwide prohibition against the sale of tobacco products to minors. Thus, the FDA's advertising rules regulate speech that, to a large degree, concerns an unlawful activity--promoting tobacco products to minors. Indeed, when the tobacco industry targets teenagers in its ads, it is, at the very least, encouraging violation of law.⁹

For example, many of the industry's advertising campaigns--such as the "Joe Camel" campaign--were initiated to seduce kids into trying cigarettes. See 61 Fed. Reg. 44479-81; 60 Fed. Reg. 41330. The FDA has assembled copious evidence that the industry's advertising campaigns are tailored to induce minors to experiment with tobacco products. 60 Fed. Reg. 41330-31. And the FDA's evidence shows that the industry's promotional

⁹ The activities of tobacco companies to stimulate demand by minors may not constitute aiding and abetting within the meaning of the criminal law since the companies do not have a single, identifiable "principal" in mind. See 18 U.S.C. § 2(a); see also LaFave & Scott, Jr., Criminal Law § 63 (1972). Nonetheless, the companies' knowing and deliberate promotion of their products to minors surely is a first cousin to aiding and abetting.

campaigns have failed adequately to distinguish between minors and adults, frequently resulting in, for example, samples being given to teenagers. Id. 41337-38.

The Supreme Court has emphatically sustained efforts to forbid advertising that promotes unlawful activities. For example, in Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376 (1973), the Court upheld a ban on advertising employment opportunities in sex-designated columns. For the Court, the dispositive fact was that discrimination based on sex in employment "is illegal activity." Id. at 388 (emphasis in original). And this Court's recent ruling in Anheuser-Busch, Inc. v. Schmoke emphasized that Baltimore's restrictions on outdoor advertising of tobacco and alcohol products were justified because the consumption of those products by minors "has already [been] banned directly and forthrightly through legislation." 101 F.3d 325, 329 (4th Cir. 1996), cert. denied, 117 S. Ct. 1569 (1997). Just as in Pittsburgh Press and Anheuser-Busch, the only advertising regulated by the FDA relates to an illegal transaction: the sale of tobacco products to minors.

The industry does not challenge the principle that speech proposing an illegality may be restrained. Instead, it argues that the FDA overreaches by restricting ads that "relate to" illegal conduct. This argument, however, distorts the FDA's rule, which does not target ads that simply "relate" in some amorphous way to an illegal act, but rather regulates ads that

actually propose an illegal transaction by enticing minors to obtain tobacco products. Ads need not say "Children: Please Smoke Camels" to propose an illegal transaction.

The industry's own illustration exposes the hollowness of its position. The industry argues that many legal products, such as automobiles, firearms, and alcohol, are subject to unlawful use by minors and that the "fact that some 14-year-olds attempt to drive would mean that car advertisements are `related to' unlawful activity." Plaintiffs' Third Brief in Support of Summary Judgment ("Third Industry Br.") 10 n.13. No evidence comparable to that amassed on tobacco, however, shows that car manufacturers, for example, have engaged in broad-scale, sustained campaigns to encourage minors to break the driving laws. Surely the First Amendment would be no impediment to the government prohibiting ads that enticed minors to "borrow" their parents' cars or ads that used Joe Camel-like cartoon figures to coax kids into using hunting rifles or drinking vodka. Indeed, this Court's ruling in Anheuser-Busch refutes the industry's position here, since there the Court upheld restraints on tobacco and alcohol ads precisely because they encouraged children to obtain products forbidden to them by law. Accordingly, because the "speech" restrained by the FDA's rule solicits an illegal act, it is entitled to no First Amendment protection.

2. The Government Interest Is Substantial.

It is impossible to imagine a more compelling governmental interest than protecting children from being enticed into

experimenting with addictive and often deadly tobacco products. As the Supreme Court has emphasized, protecting children is "an extremely important justification" for imposing restraints on potentially harmful speech. See, e.g., Denver Area Educ. Telecommunications Consortium v. FCC, ___ U.S. ___, 116 S. Ct. 2374, 2392 (1996) (plurality opinion); see also Anheuser-Busch, 101 F.3d at 327. One can search the industry's district court briefs in vain for any discussion of the strength of the interests advanced by the FDA's rule. But the overriding importance of those interests is the industry's Achilles' heel. The First Amendment demands a balancing test in commercial speech cases, and the governmental interests here overshadow the minimal intrusion on the industry's First Amendment rights.

3. The FDA's Regulations Are Well-Tailored To The Agency's Stated Objectives.

The final two prongs of the Central Hudson test--whether the restriction on commercial speech directly advances the governmental interest and whether the restriction is no more extensive than necessary to serve that interest--are analyzed together by asking whether the "fit" between the agency's objectives and the means selected by the agency to achieve them is reasonable. See, e.g., Rubin, 115 S. Ct. at 1591; Florida Bar, 115 S. Ct. at 2380. This "narrow tailoring" requirement is met so long as there are no "obvious less burdensome alternatives to the restriction on commercial speech." Discovery Network, 113

S. Ct. at 1510 n.13; see also Florida Bar, 115 S. Ct. at 2380; Rubin, 115 S. Ct. at 1593.

The industry's claim that the FDA has disregarded non-speech regulatory alternatives is implausible. To begin with, the FDA's rules are hardly a bolt out of the blue. For the past 30 years, the government has taken one measured step at a time to curb smoking by minors. Warnings on packaging, warnings on billboards, public education campaigns, and other measures have been phased in. Unfortunately, those measures failed. Tobacco use by minors remains an epidemic, and for the government now to take stricter action to reduce minors' use of tobacco products is entirely reasonable.

The industry recommends "direct regulations" that it claims would achieve the FDA's goal of reducing underage smoking, such as requirements relating to minimum purchase age, proof of age, licensing of retailers, clerk training, and vending machine location. Third Industry Br. 19. The signal defect in the industry's argument is that all of the measures it touts as alternatives to speech restrictions relate to the supply side of the equation and place the burden on others to police the sale of tobacco products. None of the measures goes to reducing demand by minors. Even the toughest measures to interdict supply cannot stem the flood of tobacco products to minors as long as the industry is permitted to continue to stimulate demand.¹⁰

¹⁰ Most of the restrictions listed by the industry, Third Industry Br. 21-22, have been in place in many states for years
(continued...)

The FDA recognizes this reality and has reasonably concluded that, to lower teen tobacco use, it must address demand as well as supply. Nothing in First Amendment jurisprudence requires an agency to continue to travel down a road to nowhere. To be sure, under cases like Rubin, the FDA was required to consider non-speech alternatives that held real promise of achieving the government's goal of reducing demand. See, e.g., 44 Liquormart v. Rhode Island, __ U.S. __, 116 S. Ct. 1495, 1510 (1996). The FDA was not required, however, to consider the sort of "let the states bear the enforcement responsibility while we continue to promote our products to minors" approach urged by the industry.¹¹

The industry does not contend that ads aimed at children are immune from regulation under the First Amendment. Nor does the industry claim a right to use cartoon characters in magazines aimed at children, to advertise on billboards at entrances to elementary schools, or to give minors t-shirts bearing product logos. Rather, the industry contends that, in shielding

¹⁰ (...continued)
but have proven ineffective because demand remains unchecked. Moreover, this argument is a transparent effort by the industry to shift the regulatory burden to others. The industry's proposals would force states and retailers to expend far more resources policing the sale of tobacco products to minors. None of the proposals would require the industry to do anything, neither to increase its own enforcement efforts nor to help the states. Meanwhile, the industry would be free to continue to use its billions of advertising dollars to promote demand for tobacco products by minors.

¹¹ For this reason, the industry's heavy reliance on the ADAMHA is misplaced, as that statute focuses entirely on the supply side of the equation (minimum age requirements, random inspections of retail outlets, and tougher law enforcement).

impressionable minors from tobacco advertising, the FDA has gone too far. In this way, the industry demands a regulatory precision not required by the First Amendment. Narrow tailoring does not "require elimination of all less restrictive alternatives." Board of Trustees v. Fox, 492 U.S. 492 U.S. 469, 478 (1989). The Supreme Court has "not insisted that there be no conceivable alternative, but only that the regulation not burden substantially more speech than is necessary to further the government's legitimate interests." Id. And Court the "ha[s] been loath to second-guess the Government's judgment to that effect." Id. (citations and internal quotations omitted).

Thus, the test is far less exacting than the one the industry advocates, which, in effect, asks this Court to review de novo the lines the FDA has drawn. Not only should this Court be "loath" to embark on that exercise, but the industry has failed to show that any of the FDA restrictions burdens "substantially" more speech than is necessary. Indeed, in most cases, the industry does not even say where it believes the line should have been drawn--an indication of the hollowness of its position.¹²

¹² The industry has complained that the FDA is engaging in "content-based" regulation requiring strict scrutiny. By definition, however, all restraints on commercial speech are "content-based" in that the government imposes them to regulate a communication only because the subject is some form of commercial transaction. The content focus of restraints on commercial speech does not require heightened scrutiny, as the long line of cases applying the intermediate, Central Hudson standard make clear.

Although the Court will have to consider each of the regulations challenged by the industry, one example should suffice to illustrate the flaw in the industry's overbreadth analysis. The industry challenges on narrow tailoring grounds the requirement that text-only, black-and-white format advertisements be used in periodicals widely circulated to minors. The industry complains that the line that the FDA has drawn ensnares too many publications with predominantly adult readership and that the "FDA has not found that every use of color or imagery in tobacco advertising 'appeals' to persons under 18 or is likely to induce them to use tobacco." Third Industry Br. 32 (emphasis in original). This contention misses the mark.

As noted above, the industry substantially overstates the FDA's burden. The "reasonable fit" inquiry looks only at whether the government has adopted means that are appropriate to achieve its objectives, not whether it has examined each and every advertisement to measure its impact on children. Applying the correct standard--reasonableness of fit--the FDA's format rule plainly withstands review.

The FDA's unassailable goal is to protect minors from exposure to color and image-laden advertising. To achieve that goal, the FDA has said that periodicals with significant underage readership may not carry such ads, designating periodicals with 85 percent or more adult readership or fewer than 2,000,000 underage readers as "adult" publications. The industry's quarrel

is not with principle, but with the FDA's line-drawing. Under settled commercial speech jurisprudence, however, some degree of overinclusiveness is not only tolerated but expected because of the inherent difficulties in fine-tuning any regulation on expressive commercial activities. As the Supreme Court stated in Fox, if a regulation extends only "marginally beyond what would adequately have served the government interest," it will not be invalidated. Only when a regulation is "substantially excessive, disregarding far less restrictive and more precise means" will it be set aside. 492 U.S. at 479. See also Anheuser-Busch, 101 F.3d at 327 ("in the regulation of commercial speech there is some latitude in the 'fit' between the regulation and the objective").

Here, the industry has no argument that the regulation is overly broad since it permits the industry to say whatever it wants in any magazine and regulates only the colors and imagery that accompany the text. No one disputes that the FDA could constitutionally ban all tobacco advertisements in publications expressly aimed at children, such as Sports Illustrated for Kids. Rather than imposing a ban, the FDA has regulated format, not content, to try to ensure that advertising likely to be seen both by significant numbers of young people and by adults does not entice minors into using tobacco products.

Line-drawing was essentially the dilemma Congress faced when it enacted the law at issue in United States v. Edge Broadcasting Co., ___ U.S. ___, 113 S. Ct. 2696 (1993), which sought to protect

the policies of non-lottery states without unduly interfering with those states that sponsored lotteries. Reviewing the statute, the Supreme Court understood that the line was imperfect; but it sustained the statute because it was evident that Congress had no sensible alternative. 113 S. Ct. at 2705-07. Likewise, in the political speech context, the Supreme court does not require "fine-tuning," but rather reasonable line-drawing given the complexities of the problem at issue. Buckley v. Valeo, 424 U.S. 1, 30 (1975) ("court has no scalpel to probe"... "distinctions in degree").

The same is true here. The FDA's rule draws a sensible line between advertising in magazines and periodicals that significant numbers of minors are likely to see and advertising that they are unlikely to see. Under Edge Broadcasting, as long as the line is reasonable, this Court may not second-guess the FDA simply because it might have drawn the line somewhat differently. Id.; see Fox, 492 U.S. at 478; see also Buckley, 424 U.S. at 30. Tellingly, although the industry complains about the 85 percent rule, it has not argued that the FDA has overlooked any obvious alternatives; and it has not proposed a less restrictive line that would achieve the FDA's goal.

The same flaw pervades the industry's attack on the other FDA regulations governing advertising and promotion. Because it is clear that the FDA's rules are a "reasonable fit" and achieve the FDA's manifestly permissible goal without seriously impairing the tobacco industry's channels of communications to adults as

opposed to minors, the FDA's rule passes First Amendment muster and should be upheld.

CONCLUSION

For the foregoing reasons, the decision of the district court should be affirmed insofar as it found that the FDCA confers authority on the FDA to regulate tobacco products as drug-delivery systems. The decision of the district court should be reversed insofar as it found that 21 U.S.C. § 520(e) does not authorize the FDA to restrict the promotion and advertising of restricted devices.

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CERTIFICATE OF SERVICE

I hereby certify that two copies of the Brief Amici Curiae of Public Citizen, et al. in Support of Defendants/Appellees/Cross-Appellants the Food and Drug Administration, et al. were served by first-class mail, postage prepaid, this 10th day of June 1997, on each of the parties listed below.

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