

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA  
GREENSBORO DIVISION

COYNE BEAHM, INC., BROWN &  
WILLIAMSON TOBACCO CORPORATION,  
LIGGETT GROUP, INC., LORILLARD  
TOBACCO COMPANY, PHILIP MORRIS,  
INCORPORATED, and R.J. REYNOLDS  
TOBACCO COMPANY,

Plaintiffs,

v.

UNITED STATES FOOD & DRUG  
ADMINISTRATION and DAVID A.  
KESSLER, M.D., Commissioner  
of Food and Drugs,

Defendants.

2:95CV00591

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AMERICAN ADVERTISING FEDERATION,  
AMERICAN ASSOCIATION OF  
ADVERTISING AGENCIES, INC.,  
ASSOCIATION OF NATIONAL  
ADVERTISERS, INC., MAGAZINE  
PUBLISHERS OF AMERICA,  
OUTDOOR ADVERTISING ASSOCIATION  
OF AMERICA, POINT OF PURCHASE  
ADVERTISING INSTITUTE,

Plaintiffs,

v.

DAVID KESSLER, M.D.,  
Commissioner of Food and Drugs,  
and UNITED STATES FOOD & DRUG  
ADMINISTRATION,

Defendants.

2:95CV00593

UNITED STATES TOBACCO COMPANY,  
BROWN & WILLIAMSON TOBACCO  
CORPORATION, CONWOOD COMPANY, L.P.,  
NATIONAL TOBACCO COMPANY, L.P., THE  
PINKERTON TOBACCO COMPANY, SWISHER  
INTERNATIONAL INC., CENTRAL CAROLINA  
GROCERS, INC., J.T. DAVENPORT, INC., N.C.  
TOBACCO DISTRIBUTORS COMMITTEE, INC.,

Plaintiffs,

v.

UNITED STATES FOOD & DRUG  
ADMINISTRATION and DAVID KESSLER, M.D.  
Commissioner of Food and Drugs,

Defendants.

6:95CV00665

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NATIONAL ASSOCIATION OF CONVENIENCE  
STORES, and ACME RETAIL, INC.,

Plaintiffs,

v.

DAVID KESSLER, M.D., Commissioner  
of Food and Drugs, and UNITED  
STATES FOOD & DRUG ADMINISTRATION,

Defendants.

2:95CV00706

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MEMORANDUM AMICI CURIAE OF  
PUBLIC CITIZEN, NATIONAL CENTER FOR TOBACCO-FREE KIDS,  
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  
AFRICAN AMERICANS FOR POSITIVE IMAGERY, NATIONAL ASSOCIATION  
OF ELEMENTARY SCHOOL PRINCIPALS, NATIONAL ASSOCIATION OF  
SECONDARY SCHOOL PRINCIPALS, AND NATIONAL PTA IN  
OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

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## NATURE OF THE MATTER BEFORE THE COURT

This brief is submitted in support of the final rule issued by defendant Food and Drug Administration ("FDA") to restrict the sale and promotion of tobacco products to minors. 61 Fed. Reg. 44396 (1996). Amici are 16 organizations with long-standing interests in public health, especially in the health of children and in protecting children from the harms caused by tobacco products. The groups are more fully described in an appendix to this brief.

## STATEMENT OF MATERIAL FACTS

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 to satisfy nicotine addiction. 61 Fed. Reg. 44915-94.

Amici hereby incorporate by reference the Statement of Material Facts contained in the brief of defendants FDA and Commissioner David Kessler.

## QUESTIONS PRESENTED

1. Has Congress precluded the FDA from regulating tobacco products?
2. Does the Food, Drug, and Cosmetic Act give the FDA jurisdiction over tobacco products?
3. Do any of the FDA's restrictions on the advertising and promotion of tobacco products to minors violate the First Amendment to the United States Constitution?

## SUMMARY OF ARGUMENT

The challenges to the FDA's rule fall into two general categories: those contesting the authority of the FDA to regulate tobacco products at all, and those contesting the validity of specific regulations under the First Amendment. Plaintiffs' jurisdictional challenge raises two separate

claims. In its First Brief, the industry contends that, even if tobacco products meet the definition of drug and drug-delivery systems under the Food, Drug, and Cosmetic Act ("FDCA"), Congress has affirmatively forbidden the FDA from regulating tobacco products. This argument is based on laws in which Congress has assigned certain duties regarding tobacco to other federal agencies, and on instances in which Congress has considered proposals that would have explicitly recognized the FDA's authority over tobacco products. The industry claims that, through such action and inaction, Congress effectively has precluded the FDA from regulating tobacco products, even if the FDCA would otherwise confer jurisdiction over tobacco products on the Agency.

Plaintiffs' argument is fundamentally flawed because it equates congressional inaction with a congressional prohibition enacted into law. Congress can remove or withhold agency power only in the same way that Congress grants it: by passing a law, which it has not done here. Indeed, in various statutes, including one part of the FDCA, Congress has expressly precluded an agency from regulating tobacco. Congress has never done so with regard to the FDA's authority over drugs and medical devices. In fact, even the industry admits 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.

In their Second Brief, plaintiffs question whether the definitions of "drug" and "device" in the FDCA encompass tobacco products, which contain nicotine, a substance that everyone agrees has significant pharmacological effects. The industry principally argues that the statutory definitions cover only products explicitly promoted for therapeutic purposes. This claim overlooks the fact that the applicable definitions are written in the alternative, and the parts of the definitions on which the FDA relies are not tied to health claims. Rather, under the FDCA, a product is a drug or device if it is "intended to affect the structure or any function of the body." Because actors are presumed to intend the foreseeable consequences of their conduct, because the addiction and disease that result from use of tobacco products is well-established, and because voluminous documentation

in the administrative record establishes the industry's knowing exploitation of the effects of nicotine, the nicotine in tobacco products easily falls within the statutory definition of "drug."

Moreover, the FDA has properly determined 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 reveals that the industry purposefully engineers its products to deliver 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.

In their Third Brief, plaintiffs charge that the advertising restrictions adopted by the FDA violate the First Amendment. In making their argument, plaintiffs obscure the most important aspect of these restrictions: They are aimed at reducing the demand for tobacco products by people under the age of 18, who are forbidden by both federal and state law from purchasing such products. Surely, even these plaintiffs would not contend that banning tobacco ads in the Weekly Reader, prohibiting tobacco ads on billboards directly across the street from entrances to schools and playgrounds, or forbidding ads portraying characters such as Big Bird or Barney would run afoul of the First Amendment, yet that is the impact of their argument.

In addition, the Agency 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. As to the restriction on billboard ads, where the agency drew the line at 1000 feet from a school or playground, the industry never mentions that its own voluntary code draws a similar line at 500 feet and never offers any evidence, or even argument, as to why the Constitution requires the FDA to honor the industry's line rather than its own. 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 vital 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. CONGRESS HAS NOT PRECLUDED THE FDA FROM REGULATING TOBACCO PRODUCTS.

The stated question in plaintiffs' First Brief (at 2) is whether Congress "withheld from the FDA the authority to regulate" tobacco products. The brief actually argues, however, that Congress has forbidden the FDA from regulating tobacco products. Plaintiffs point both 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 infra at Part II., but the argument that this case can be decided by discerning the meaning of congressional inaction is without merit. If tobacco products satisfy the FDCA definitions of drug and drug-delivery devices, plaintiffs' argument fails. If they do not, the argument is irrelevant.

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 but two-thirds of each House vote to override. There is no other means by which Congress may constitutionally act. INS v. Chadha, 462 U.S. 919, 951, 103 S.Ct. 2764, 77 L.Ed.2d 317 (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, 128 L.Ed.2d 119 (1994) (cautioning against use of legislative inaction to aid in statutory interpretation). 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, 95 S.Ct. 839, 43 L.Ed.2d 1 (1975) ("Legislative intention, without more, is not legislation.").

Plaintiffs do not cite to any express provision that precludes the FDA from regulating tobacco products as either drugs or medical devices because none exists. This absence is particularly striking since 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."<sup>1</sup> Similar

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<sup>1</sup> 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, the 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

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)). Because Congress has not enacted such an exclusion here, the Court should not do so in its stead.

Moreover, plaintiffs ignore the internal inconsistency of their argument. They admit, in their question presented, that the FDA has at least some jurisdiction over tobacco products. Thus, they do not claim that the FDA acted unlawfully in asserting jurisdiction over cigarettes sold with claims of health benefits. See United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953); United States v. 354 Bulk Cartons, 178 F. Supp. 847 (D.N.J. 1959). Rather, they suggest that Congress "approved" those cases in the same way that it allegedly disapproved the FDA's assertion of jurisdiction here--by doing nothing, First Brief 9 n.10; and they conclude 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 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 there is nothing in the FDCA that makes the FDA's jurisdiction over tobacco products turn on whether the products are "customarily marketed."

Plaintiffs offer a variation on their theme by arguing that Congress has comprehensively regulated tobacco products in a way that leaves no room for the FDA. A number of the statutes they cite--such as those imposing taxes on tobacco or those setting agricultural quotas for tobacco--are so far afield as not to be worthy of a reply. Even the most closely related provision--the Federal Cigarette Labeling and Advertising Act of 1965, as amended ("FCLAA")--does not support the

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those definitions were enacted and, therefore, the exclusion of tobacco products was not redundant at that time. 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.

industry's claim that Congress has affirmatively deprived the FDA of authority to regulate tobacco products.

In essence, plaintiffs argue that the FCLAA regulates tobacco products so comprehensively that it preempts the entire field of tobacco regulation. The industry made a similar argument in opposing state tort law claims for money damages, which the Supreme Court unanimously rejected, see Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), although the Court held that some specific damages claims were preempted by 15 U.S.C. § 1334(b), which applies only to state regulatory requirements. 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. Indeed, 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 it 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, that statute was never a truly comprehensive cigarette regulatory law. Rather, it precludes federal agencies from acting only to the extent stated in 15 U.S.C. § 1334(a). Even with the 1984 addition of statutory warnings for cigarette advertisements, Congress neither expanded the scope of preemption nor included many areas of potential regulation, the most obvious being sales and marketing to minors. Surely, the industry does not contend that state laws banning cigarette sales to minors, which predate the FCLAA, were somehow preempted by Congress in the FCLAA. Nor could industry contend that, if a public elementary school banned cigarette advertisements in its newspaper, or prohibited free samples or Joe Camel posters on its grounds, those measures would be preempted by section 1334(b) of the FCLAA. In fact, the Fourth Circuit 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,

63 F.3d 1318 (4th Cir. 1995). And the Supreme Court vacated and remanded that case solely on a First Amendment issue, although the petition for certiorari also raised a preemption question. See 116 S.Ct. 2574 (1996). Since the FCLAA does not even preempt all regulation of cigarette advertising, it clearly does not preempt the entire field of tobacco regulation.

For similar reasons, 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. 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 Agency does not consider the statement to "relate[]" to smokeless tobacco and health." Rather, the statement identifies the legal classification of the product and who may lawfully purchase it. Accordingly, it is not preempted.

Plaintiffs also claim that the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992, 42 U.S.C. § 300x-26 ("ADAMHA"), eliminated all FDA jurisdiction over tobacco. That claim is without merit. The ADAMHA is a modest effort to reduce underage tobacco use by strengthening state enforcement efforts of laws restricting youth access. The law is not mandatory, as any state may choose not to step up enforcement in return for foregoing federal funding for substance abuse programs. There are no federal sanctions for sales to minors. There are no provisions designed to reduce minors' demand for tobacco products. And, most significantly, there is no preemption provision of any kind. About all that can meaningfully be said about the ADAMHA 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 plaintiffs here was rebuffed by the Supreme

Court not only in Cipollone, but more recently in Medtronic, Inc. v. Lohr, \_\_\_ U.S. \_\_\_, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). Moreover, accepting the logical reach of plaintiffs' 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.

Recognizing that no statute actually forbids the FDA from regulating tobacco, plaintiffs turn to congressional failures to enact positive authorizing legislation as a basis for denying the FDA the power to issue these regulations. However, "[c]ongressional inaction cannot amend a duly enacted statute." Patterson v. McLean Credit Union, 491 U.S. 164, 175 n.1, 109 S.Ct. 2363, 105 L.Ed.2d 132 (1989). Nor should congressional silence be construed as a rejection of the FDA's actions under its existing statutes. 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, 107 S.Ct. 1442, 94 L.Ed.2d 615 (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 explicitly have forbidden the FDA from regulating tobacco products. See 61 Fed. Reg. 45259 (citing bills). Those bills were not enacted. Under plaintiffs' 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 plaintiffs' approach, a court should construe that outcome as acceptance, or at least acquiescence, in the FDA's authority over tobacco products. Moreover, plaintiffs' approach to congressional inaction would

mean that Congress is implicitly ratifying the FDA's final rule, and its jurisdiction, if it fails 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, a task to which we now turn.

## II. 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 frank admissions, plaintiffs argue that tobacco products are neither "drugs" nor "drug-delivery devices" under the FDCA. Their 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. The FDCA definitions of drugs and devices, however, are not nearly so narrow.

Under 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 through which the drug nicotine is delivered 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 the drug or the device authorities.

### A. Nicotine In Tobacco Products Is A "Drug," Within The Meaning Of 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 definition 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, 89 S.Ct. 1410, 22 L.Ed.2d 726 (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.

Under FDA regulations, the phrase "'intended uses' or words of similar import" refers 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). Although plaintiffs contend that the FDA's interpretation of the term "intent" in connection with the regulations is "unprecedented," the regulations defining intent were issued in the 1950s. Id. §§ 210.128, 801.4. See Second Brief 14. Insofar as amici are aware, they have never been challenged. Furthermore, the FDA's interpretation

of "intent" is in keeping with centuries of Anglo-American law. See, e.g., Hadley v. Baxendale, 156 Eng. Rep. 145 (1854).

Consistent with 21 C.F.R. § 201.128 and § 801.4, the phrase "intended to affect" must also mean "objective" intent, that is, whether the effect was a deliberate or foreseeable consequence of the act. See 61 Fed. Reg. 44691 (citing cases and treatise). Here, the administrative record conclusively 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 purposefully engineer their products to exploit and promote those effects, including the effect of addiction. The record, which is based on numerous sources, shows that manufacturers manipulate the amount and delivery of nicotine in tobacco products and that nicotine levels are no longer a by-product of tar levels. The record also establishes that manufacturers consider their products nicotine-delivery systems and that they have done extensive studies of the effects of nicotine, including addictiveness. The record reflects a telling absence of any evidence that the industry perceives the nicotine in its products as having any function other than to create pharmacological effects on the human body.

1. Plaintiffs argue that the intent component of the subsection (C) definition of drugs can be satisfied only by industry statements making express claims regarding health (for example, weight loss, stress reduction, appetite suppression). Second Brief 7. Because manufacturers make no therapeutic claims for their products, plaintiffs argue that the FDA cannot regulate them. However, the statutory definition of drugs requires neither therapeutic uses nor specific therapeutic claims. Again, subsection (B) of the FDCA definition includes as drugs "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," that is, articles intended for therapeutic uses. For instance, if Marlboro cigarettes were marketed to treat nicotine withdrawal, the product would qualify as a "drug" under subsection (B). On the other hand, subsection (C) defines drugs to include "articles (other than food) intended to affect the structure or any function of the body." Both logic and basic rules of statutory construction dictate that subsection (C) must

bring into the definition of drugs items for which no therapeutic use is presented and no therapeutic claims are made. Otherwise subsection (C) would be redundant of subsection (B) and, therefore, surplusage. See National Insulation Transp. Comm. v. ICC, 683 F.2d 533, 537 (D.C. Cir. 1982) (court must, if possible, give effect to every phrase of a statute so that no part is rendered superfluous); Symons v. Chrysler Corp. Loan Guarantee Bd., 670 F.2d 238, 242 (D.C. Cir. 1981) (rejecting interpretation that would render statutory phrase superfluous because statutes should be construed, if possible, to give effect to every word used by Congress).<sup>2</sup>

Accordingly, because under subsection (C) intent is not tied to therapeutic use, 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 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.<sup>3</sup>

2. Of course, the tobacco industry knows that nicotine affects the body and how it does so. The industry has conducted many, if not most, of the studies of nicotine's pharmacological effects.

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<sup>2</sup> Plaintiffs rely 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.

<sup>3</sup> The "combination product" provision of the FDCA was not enacted until 1990.

Even if it feigned ignorance, however, such knowledge would be imputed to it. It is a well-known fact that 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. Applying the intent standard that is integrated into the FDCA's definition of "drugs," 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--carefully controlling the amount, form, and delivery of nicotine in their products--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 would not be credible.<sup>4</sup>

3. Notwithstanding foreseeability, the manufacturers' own documents reveal their actual intent to use their products as nicotine-delivery systems. For example, a Philip Morris report placed tobacco products in the category of "nicotine delivery devices," along with nicotine patches and

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<sup>4</sup> Without explaining why the tobacco industry should not be held accountable for the foreseeable consequences of its acts, plaintiffs argue that foreseeability or consumer use alone does not establish "intent." Second Brief 15-18. In light of the substantial evidence of the industry's control over the nicotine in its products, that argument is irrelevant. See generally FDA's Jurisdiction Determination. In any event, foreseeability and consumer use provide 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 establishes that the foreseeable results in fact come to pass. Id. 44807-46.

nicotine gum. 61 Fed. Reg. 44866. An industry research conference in 1962 candidly discussed the drug effects of nicotine. Id. 44882-83 (Brown & Williamson). Reports of tobacco industry researchers in the 1970s and 1980s confirmed the physiological and psychological effects of nicotine. Id. 44868-73 (RJR), 44886-90 (Brown & Williamson). And industry documents show that tobacco companies, through their manufacturing processes, can and do control the amount, form, and delivery of nicotine in their products, with the pharmacological effects firmly in mind. 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"). Manufacturers have the ability to remove nicotine from tobacco products entirely, as Philip Morris' "Next" brand cigarette demonstrated. See 60 Fed. Reg. 41779-83 (citing patents for methods to extract nicotine from tobacco). Manufacturers also have the ability to increase the amount of nicotine. See, e.g., 61 Fed. Reg. 44952-63. And they have the ability to control the amount and delivery of nicotine in their products. See, e.g., id. 44963-74 (cigarettes); id. 45110-14 (smokeless tobacco).

4. As support for their argument that "intent" can be manifest only by public claims of therapeutic effect, the industry relies on FDA statements made at congressional hearings and on 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. Second Brief 7. Plaintiffs' 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 Goyan to Banzhaf, Nov. 25, 1980, at 8-9 (citing National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974)). The FDA found, however, that the ASH petition lacked sufficient evidence on this point. 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 with no recourse but to disclaim jurisdiction over tobacco products. Thus, even if the FDA agreed with the ASH assertions in 1977, it lacked the evidence on which its 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 enables 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). Tellingly, plaintiffs fail to address the significance of manufacturers' manipulation of nicotine in their products and of the evidence acquired by the FDA in recent years on that topic.

Second, the prior FDA statements on which plaintiffs rely 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, 111 S.Ct. 1759, 114 L.Ed.2d 233 (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 U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837, 862, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)); see 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, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). See United States v. Southwestern Cable Co., 392 U.S. 157, 88 S.Ct. 1994, 20 L.Ed.2d 1001 (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 were advertised without health claims, although its manufacturer knows it will have pharmacological effects and sells 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 claiming that their subjective intent controls, 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 nor sold for that purpose, and are not 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.<sup>5</sup>

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<sup>5</sup> Plaintiffs also argue that the FDA has conceded away any claim to authority over tobacco products. First Brief 17-19. The legal theory behind plaintiffs' historical discussion is unclear. If plaintiffs are suggesting that the FDA is estopped by its prior statements from regulating tobacco products, the argument must fail. Estoppel does not apply to the government on the same terms as it applies to other parties and surely is not applicable here, where the industry could not conceivably show detrimental reliance. Office of Personnel Management v. Richmond, 496 U.S. 414, 422, 110 S.Ct. 2465, 110 L.Ed.2d 387 (1990) (although Supreme Court has declined to rule that no

5. United States Tobacco Co., et al., argues that smokeless tobacco is "merely a processed plant." US Tob. Brief 15. To begin with, 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 is like saying that penicillin is merely processed mold or a biscuit is merely processed wheat. 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, in teabag-like pouches, for example, 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. By the time smokeless tobacco products reach the consumer, they are far from plants. 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.

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estoppel will ever lie against the government, it has "reversed every finding of estoppel" against the government that it has reviewed); Heckler v. Community Health Services, 467 U.S. 51, 60, 61, 104 S.Ct. 2218, 81 L.Ed.2d 42 (1984) (no estoppel where party's detriment is inability to retain money which it should not have received in the first place). In addition, the industry should not be permitted to benefit from the FDA's or Congress's prior conclusions about tobacco products where those conclusions were based in significant part on the industry's misrepresentations to the government and the public.

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

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 devices with the primary purpose of delivering or aiding in the delivery of a drug and which 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.

The delivery of a drug to the body through the means used by cigarettes or smokeless tobacco products is not unique. 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, Asthador 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 354 Bulk Cartons, 178 F. Supp. 847 (cigarette marketed for weight reduction); Fairfax Cigarettes, 113 F. Supp. 336 (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.

Nonetheless, plaintiffs argue 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." Second Brief 27-28; US Tob. Brief 15. 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 any effect on a structure or function of the body." Second Brief 27. 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. 23, 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 plaintiffs would require the FDA to regulate such products as drugs, they offer no cogent reason for imposing this requirement on the FDA. Neither the statute, the regulations, nor FDA precedent requires such a restriction.<sup>6</sup>

Plaintiffs further complain that tobacco products are not combination products because the device components could not be regulated apart from the drug nicotine. Second Brief 29. That argument seeks to impose a requirement beyond that established by the clear language of the statute,

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<sup>6</sup> Of course, plaintiffs also contest regulation of tobacco products as drugs. See generally First Brief.

21 U.S.C. § 353(g), which plainly permits the FDA to regulate products like nebulizers and transdermal patches. See Second Brief 29 (conceding that nicotine patch is regulable as combination product). A nebulizer and a transdermal patch, without their drug components, are basically a canister and a sticker. Like a cigarette or chewing tobacco, the canister and the sticker 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 cigarettes and smokeless tobacco products after their use, when the drug has been extracted, the device becomes worthless.

C. Conclusion

Arguing that the FDA is trying to place "a square peg in a round hole," Second Brief 2, plaintiffs propound a constricted reading of the FDCA and applicable regulations. The FDCA, however, is not the tax code. Rather, 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 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. Therefore, the Court should sustain the FDA's determination that nicotine-containing tobacco products are subject to its regulatory authority.

### III. THE FDA'S REGULATIONS PASS MUSTER UNDER THE FIRST AMENDMENT.

Amici recognize that commercial speech is entitled to substantial protection under the First Amendment.<sup>7</sup> It is by now 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, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977); see also City of Cincinnati v. Discovery Network, Inc., \_\_\_ U.S. \_\_\_, 113 S.Ct. 1505, 1512 & n.17, 123 L.Ed.2d 99 (1993). Our free market system depends on the unimpeded flow of information regarding the price and availability of goods and services to the consuming public. Id.

But there are also dangers in a free-for-all marketplace, 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, 98 S.Ct. 1925, 56 L.Ed.2d 444 (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 to promote dangerous products to impressionable minors. Contrary to the industry's hyperbolic claims, the FDA's regulations do not violate the First Amendment for two interrelated reasons.

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<sup>7</sup> 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, 96 S.Ct. 1817, 48 L.Ed.2d 346 (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, 123 L.Ed.2d 543 (1993), and Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 105 S.Ct. 2265, 85 L.Ed.2d 652 (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., \_\_\_ U.S. \_\_\_, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995); Rubin v. Coors Brewing Co., \_\_\_ U.S. \_\_\_, 115 S.Ct. 1585, 131 L.Ed.2d 532 (1995); Peel v. Attorney Registr'n and Disciplinary Comm'n, 496 U.S. 91, 110 S.Ct. 2281, 110 L.Ed.2d 83 (1990).

First, 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 repeatedly emphasized, protecting children is "an extremely important justification" for imposing restraints on potentially harmful speech. E.g., Denver Area Educ. Telecommunications Consortium v. FCC, \_\_\_ U.S. \_\_\_, 116 S.Ct. 2374, 2392, 135 L.Ed.2d 888 (1996) (plurality opinion); Anheuser-Busch, Inc. v. Schmoke, No. 94-1431, slip op. at 7-8 (4th Cir. Nov. 13, 1996) ("Anheuser-Busch II"). One can search the industry's brief in vain for any discussion of the strength of the interests advanced by the FDA's rules. But the overriding importance of those interests is the industry's Achilles' heel. As even the industry concedes, 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.

Second, the FDA has calibrated its rules as carefully as possible to interdict only selling messages aimed at minors, who may not lawfully purchase tobacco products. Nothing in the FDA's rules deprives the industry of its right to say whatever it wants; all the FDA has regulated are the means by which the industry may convey its selling messages to ensure that they are not directed to children. Only those advertisements certain to be seen by substantial numbers of kids are regulated, leaving ample channels open for industry to communicate with adults. While the industry quibbles with the FDA's line-drawing, it cannot attack the FDA's premise that the industry has no constitutional right to advertise tobacco products directly to minors. Because the FDA has fine-tuned its advertising rules to that end, the rules withstand constitutional challenge.

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

Since 1980, the Supreme Court has employed the four-part Central Hudson test in assessing restraints on commercial speech. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 563-64, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). Accord Florida Bar, 115 S.Ct. at 2376; Rubin, 115 S.Ct. at 1588. The test inquires, in relevant part:

- first, whether the speech concerns an unlawful activity or is misleading;

- second, whether the government's asserted interest in regulating the speech is substantial;
- third, whether the restraint directly advances the government's interest;
- fourth, whether the legislation is no more extensive than necessary to serve the government's interest.

Central Hudson, 447 U.S. at 566. In more recent cases, the Court has explained that "[t]he last two steps of the Central Hudson analysis basically involve a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends." Rubin, 115 S.Ct. at 1591 (citation omitted). The FDA's rules pass muster under each prong of this test.<sup>8</sup>

1. Tobacco Sales To Minors Are Unlawful. The first Central Hudson step is to consider whether the speech concerns lawful activity. Tobacco advertising aimed at minors fails this test. The heart of the FDA's regulation is a nationwide prohibition against the sale of tobacco products to minors that fortifies existing state prohibitions. 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 the wholesale violation of law.<sup>9</sup>

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.

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<sup>8</sup> Despite the industry's heavy reliance on 44 Liquormart v. Rhode Island, \_\_\_ U.S. \_\_\_, 116 S.Ct. 1495, 134 L.Ed.2d 911 (1996), the various opinions for the Court embrace the basic Central Hudson test, except perhaps in those instances where the government has imposed a categorical restraint. See infra pp. 37-38.

<sup>9</sup> 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.

Reg. 41330. The FDA has also assembled copious evidence that 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 industry's promotional 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. In Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 93 S.Ct. 2553, 37 L.Ed.2d 669 (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 the Fourth Circuit's recent ruling in Anheuser-Busch II 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." Slip op. at 7. Just as in Pittsburgh Press and Anheuser-Busch II, 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. But this argument distorts the FDA's rules, which do not simply target ads that "relate" in some amorphous way to an illegal act, but only regulate ads that actually propose an illegal transaction by enticing minors to obtain tobacco products. However much the industry would prefer otherwise, 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." Third Brief 10 n.13. But there is no evidence comparable to that amassed on tobacco that shows that manufacturers of other products have

engaged in broad-scale, sustained campaigns to encourage minors to break the law. Surely the First Amendment would be no impediment to 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, the Fourth Circuit's ruling in Anheuser-Busch II refutes industry's position here, since 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 rules solicits an illegal act, it is entitled to no First Amendment protection.

2. The Governmental Interest Is Substantial. The next Central Hudson inquiry evaluates the governmental interests prompting the restriction. The FDA's rules serve at least two distinct, but interrelated, interests, each of which is compelling. First, the FDA's rules will prevent impressionable minors from being induced into experimentation with tobacco products-- experimentation that often leads to life-long addiction and serious health problems, including premature death. 61 Fed. Reg. 44472; 60 Fed. Reg. 41354. Preventing the addiction of what the FDA estimates to be 250,000 youngsters each year is surely a governmental interest of the highest order. See, e.g., Anheuser-Busch II, slip op. at 7-8 ("[C]hildren deserve special solicitude in the First Amendment balance because they lack the ability to assess and analyze fully the information presented through commercial media").

Second, the FDA seeks to avoid the enormous cost, to both government and the private sector, of providing health care to future generations of smokers. The FDA estimates that the annual benefits of reduced tobacco-related disease mortality range from \$24.6 to \$39.7 billion. 60 Fed. Reg. 41359. Even that estimate understates the benefits of the rule, since it does not take into account "softer," non-quantifiable variables, such as the value to family members of preventing the death or disease of a loved one or a provider, or of avoiding the pain and suffering that smoking-induced illness often inflicts. This Court ought to be reluctant to interfere with a program that confers such dramatic benefits on society.

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 there is a reasonable "fit" between the agency's objectives and the means selected by the agency to achieve them. See, e.g., Rubin, 115 S.Ct. at 1591; Florida Bar, 115 S.Ct. at 2380. The First Amendment demands "a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in 'proportion to the interest served,' In re R.M.J., [455 U.S. 191, 203]. \* \* \* Within those bounds we leave it to the governmental decision makers to judge what manner of regulation may best be employed." Board of Trustees v. Fox, 492 U.S. 469, 475, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989). Accord United States v. Edge Broadcasting Co., \_\_\_ U.S. \_\_\_, 113 S.Ct. 2696, 2707, 125 L.Ed.2d 345 (1993).

In Edenfield v. Fane, the Court explained that the "penultimate prong of the Central Hudson test requires that a regulation impinging upon commercial expression 'directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose.'" 113 S.Ct. at 1800 (quoting Central Hudson, 447 U.S. at 564). The government's burden, the Court has noted, "is not satisfied by mere speculation or conjecture;" rather, the government "must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." Rubin, 115 S.Ct. at 1592 (quoting Edenfield, 113 S.Ct. at 1800). Not surprisingly, the industry has made no serious effort to contest that the "harms" the FDA "recites are real." Indeed, the FDA's findings that tobacco use by minors has reached epidemic proportions and that the inevitable health consequences will exact an appalling toll on society are not disputed.

Similarly, for at least three reasons, the FDA surmounts the hurdle of showing that its proposals will alleviate "to a material degree" the problem of children turning to tobacco products. First, the FDA has compiled substantial evidence showing the direct correlation between colorful,

image-laden ads and underage smoking, 61 Fed. Reg. 44466-68, 44475-88, and studies in the record show that advertising has a profound influence on a minor's decision to experiment with tobacco. Id. 44466-68; 60 Fed. Reg. 41329-24. Additional studies confirm that each of the advertising and promotional techniques addressed by the FDA, such as outdoor advertising and promotional giveaways, has a direct and substantial impact on minors. Id. This evidence--which establishes that the FDA's rules will dramatically lessen tobacco use by minors--surely meets the Edenfield standard. Indeed, Kentucky, North Carolina and Virginia concur in the FDA's assessment. They condemn the FDA rule because it will result in revenue losses occasioned by a decline in tobacco use. KY Brief 2-3; NC Brief 1 n.1; VA Brief 3-4.<sup>10</sup>

Second, the Court has long understood the close connection between advertising and the stimulation of demand, taking it as an article of faith that restraints on advertising will diminish demand. Edge Broadcasting, 113 S.Ct. at 2707; Central Hudson, 447 U.S. at 569. As the Court has often noted, sellers like tobacco companies would not invest enormous sums in advertising unless they expected a pay-off in terms of increased demand. Id.

Third, contrary to the industry's claim, the quantum of evidence required on this point is not high. To be sure, Rubin and Edenfield suggest that the government bears the burden of showing that the advertising restraints "will" alleviate the problem. E.g., Edenfield, 113 S.Ct. at 1800. But the courts, including the Supreme Court, recognize that the showing required is a well-grounded

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<sup>10</sup> The massive record the FDA has amassed here stands in stark contrast to the non-existent record in Edenfield, 113 S.Ct. at 1800, the "absence of evidence" in Ibanez v. Florida Dep't of Bus. & Prof. Regulation, \_\_\_ U.S. \_\_\_, 114 S.Ct. 2084, 2090, 129 L.Ed.2d 48 (1994), the lack "of any convincing evidence" in Rubin, 115 S.Ct. at 1593, and the "absence of proof" in 44 Liquormart, 116 S.Ct. at 1509. Even where the Court has upheld commercial speech restrictions, the evidence was far less compelling than that compiled by the FDA here. For instance, in Florida Bar, the Court sustained a ban on lawyers' direct-mail communication with recent victims of accidents and their families, yet the record consisted of a bare 106-page "summary" of the evidence developed by the Bar which the Court viewed as "sufficient to meet the standard elaborated in Edenfield." 115 S.Ct. at 2378.

predictive judgment--not hard and fast proof, especially since the Court emphasized that it would accept not only "empirical" data, but "anecdotal" and "other evidence" as well. Id. Nor could a court demand more. Obviously, no governmental body can "prove" that a yet-to-be-implemented regulatory restraint "will" alleviate a given problem. All that is required is that the government demonstrate a sound basis for concluding that the proposed regulatory action will be successful. See id.; Edge Broadcasting, 113 S.Ct. at 2707. The fatal flaw in those cases where the Court set aside the restraint was the absence of any evidence showing that the restraint would advance the state's goal, not that the evidence was too paltry. See supra note 10. That is not the case here.<sup>11</sup>

4. The FDA's Rules Are Narrowly Drawn. As discussed above, the Supreme Court has instructed courts to review the final two prongs of Central Hudson by assessing the reasonableness of the "fit" between the government's ends and the means chosen to accomplish those ends. Even based on the final Central Hudson prong alone, however, the FDA's rules are "no more extensive than necessary to serve [the asserted] interests." Ibanez, 114 S.Ct. at 2088. The "narrow tailoring" prong 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.

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,

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<sup>11</sup> The industry wrongly suggests that it is entitled to a trial on the First Amendment issues in the event that the court denies its summary judgment motion. Review in this case is controlled by the Administrative Procedure Act and is limited to the record compiled before the Agency. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 420, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). In accordance with the Administrative Procedure Act, the industry had every opportunity to make its case before the FDA. It would be wholly inappropriate to give the industry a second bite at the apple through additional evidentiary proceedings. Id. Even in the absence of extensive administrative proceedings, the Fourth Circuit in Anheuser-Busch II concluded that, so long as the Court makes an "independent assessment" of the record, a trial is unnecessary. Compare slip op. 3-4 with id. 9-12 (dissent).

the government has sought to curb smoking by minors by taking one measured step at a time. Warnings on packaging, warnings on billboards, public education campaigns, and other measures have been phased in over time. But those measures failed. Tobacco use by minors is an epidemic, and for the government now to take stricter action to reduce minors' use of tobacco products is hardly unreasonable.

The signal defect in the industry's argument is that all of the measures it touts 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 so long as the industry is permitted to continue to stimulate demand.<sup>12</sup>

The FDA recognizes this reality and has reasonably concluded that, to lower teen tobacco use, it is imperative to 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, but only those alternatives that hold real promise of achieving the government's goal of reducing demand, see, e.g.,

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<sup>12</sup> The industry recommends "direct regulations" that it claims would achieve the FDA's goal of reducing underage smoking. Third Brief 19. The record belies this argument. Most of these restrictions--including minimum purchase age, proof of age, false identification, licensing of retailers, clerk training, vending machine location, and so forth--have been in place in many states for years, and have proven ineffectual because demand remains unchecked. See id. 21-22 (detailing state restrictions on youth access to tobacco products). Moreover, this argument is a transparent effort by the industry to shift the regulatory burden to others. Industry's proposals would force states and retailers to expend far more resources policing the sale of tobacco products to minors. Not one of the proposals would require the industry to do anything at all, neither to increase its own enforcement efforts nor to help the states. And all the while, the industry would be free to continue to use its billions of advertising dollars to promote demand for tobacco products by minors.

44 Liquormart, 116 S.Ct. at 1510, not the sort of "let the states bear the enforcement responsibility while we continue to promote our products to minors" approach urged by the industry.<sup>13</sup>

Moreover, a lack of "narrow tailoring" generally manifests itself in a restraint that is either substantially underinclusive or overinclusive. The classic example of an underinclusive restraint was presented in Discovery Network, where Cincinnati's ban on newsracks that distributed commercial flyers, which did not apply to newspaper newsracks, was set aside because "the distinction bears no relationship whatsoever" to the aesthetic interests asserted by the City. 113 S.Ct. at 1514 (emphasis in original). The industry does not accuse the FDA of being underinclusive here. As to overinclusiveness, the Supreme Court has struck down only outright bans or substantially excessive restrictions on that ground. E.g., 44 Liquormart (complete ban on price advertising for alcohol); Virginia Board of Pharmacy (total prohibition on advertising the price of prescription medications); Bates (broad prohibition against advertising by lawyers); Edenfield (categorical ban on in-person, uninvited solicitation by certified public accountants). The FDA's proposal is far narrower and more tailored than the restraints invalidated in those cases.

Nor does 44 Liquormart alter the legal landscape, as the industry claims. In that case, the Court invalidated Rhode Island's ban on price advertising for alcohol products, which was allegedly imposed to promote temperance. Although the Court could not agree on a single rationale, some Justices questioned whether the Central Hudson test ought to be employed where the government imposes an all-out restraint "to keep people in the dark for what the government perceives to be their own good." 116 S.Ct. at 1508 (Stevens, J., concurring); see also id. at 1515 (Scalia, J., concurring); id. at 1520 (Thomas, J., concurring). These Justices were troubled that government could use blanket restraints on price advertising in an effort to decrease demand for alcohol by adults. Despite these concerns, the Court explicitly endorsed the Central Hudson balancing test in cases not

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<sup>13</sup> This reason also dooms the industry's heavy reliance on the ADAMHA, which focuses entirely on the supply side of the equation (minimum age requirements, random inspections of retail outlets, and tougher law enforcement) but does not address demand.

involving a blanket suppression of speech. Id. at 1510 (Stevens, J., concurring); id. at 1521 (O'Connor, J., concurring). Thus, even after 44 Liquormart, the inquiry for this Court is whether the FDA's rule "represents not necessarily the single best disposition but one whose scope is in proportion to the interest served." Id. at 1521 (O'Connor, J., concurring) (citation omitted). Accord Anheuser-Busch II, slip op. at 4.

Several factors confirm the narrow impact of 44 Liquormart. First, as 44 Liquormart stressed, a regulation "is more likely to be considered reasonable" if "alternative channels permit communication of restricted speech." E.g., 116 S.Ct. at 1521 (O'Connor, J., concurring). Here, the FDA has left open numerous channels for the tobacco industry to communicate with adults. Second, in 44 Liquormart the Court was skeptical that the ban served any legitimate interest, and rejected as "without any evidentiary support whatsoever" Rhode Island's argument that the ban would significantly reduce alcohol consumption. 116 S.Ct. at 1509 & n.14 (Stevens, J., concurring). In this case, the FDA is seeking to vindicate an exceptionally compelling state interest and relies on substantial evidence that shows its regulation will advance that interest to a material degree. Finally, the Liquormart Court placed a high value on the information banned: the price and availability of commonly-used products. Nothing in the FDA's rules interferes with the informational content of tobacco advertising, let alone forbids price advertising. Moreover, tobacco ads are rarely used to convey "information" to consumers or to engage in price competition. For these reasons, 44 Liquormart supports, not undercuts, the FDA's position.

B. A Rule-by-Rule Analysis Confirms That The FDA's Rules Pose No First Amendment Problems.

The industry challenges a number of the provisions of the FDA's advertising rule on the ground that they are not "narrowly tailored." The industry does not contend that ads aimed at children are immune from regulation under the First Amendment. Nor does industry claim a right to use cartoon-character illustrations in magazines aimed at children, to advertise on billboards at the entrance of elementary schools, or to give minors T-shirts bearing product logos. Rather, the

industry contends that, in shielding impressionable minors from tobacco advertising, the FDA has gone too far.

The intractable flaw in the industry's position is that it demands a regulatory precision not required by the First Amendment. Narrow tailoring does not "require elimination of all less restrictive alternatives." Fox, 492 U.S. at 478. The 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, the Court added, "we have been loath to second-guess the Government's judgment to that effect." Id. (citations and internal quotations omitted). This 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 rules 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--a factor that exposes the hollowness of its position.<sup>14</sup>

1. Black and White, Text-Only Format Advertisements. The industry challenges this restriction on narrow tailoring grounds because the line the FDA has drawn ensnares too many publications with predominantly adult readership. The industry complains that the "FDA has not found that every use of color or imagery in tobacco advertising 'appeals' to persons under 18 or is

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<sup>14</sup> The industry's complaint that the FDA is engaging in "content-based" regulation is mystifying. By definition, all restraints on commercial speech are "content-based" in that they are imposed precisely because the government is trying to regulate some communicative aspect of a commercial transaction. See, e.g., Boos v. Barry, 485 U.S. 312, 321, 108 S.Ct. 2257, 99 L.Ed.2d 333 (1988) (restraint is content-based if it can be justified "only by reference to the content of the speech.") (emphasis in original). The content-focus of restraints on commercial speech, however, does not require heightened scrutiny, as the long line of cases applying the intermediate, Central Hudson standard make clear.

likely to induce them to use tobacco." Third Brief 32 (emphasis in original). This contention misses the mark.

First, 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 goal--which is unassailable--is to protect minors from being exposed 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 and 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, arguing that magazines such as Popular Science, Cable Guide, and Soap Opera Weekly, should not be subject to the format restrictions.

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 II, slip op. at 4 ("in the regulation of commercial speech there is some latitude in the 'fit' between the regulation and the objective").

Here, of course, it is doubtful that the industry has any argument that the regulation is excessive 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 tobacco advertisements in publications expressly aimed at children, like Sports Illustrated for Kids. Rather than taking that dramatic step, the FDA tried 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 by regulating format, not content.

Line-drawing was essentially the dilemma Congress faced when it enacted the law at issue in Edge Broadcasting, which sought to protect the policies of non-lottery states without unduly interfering with those states that sponsored lotteries. The Court understood that the statutory scheme it upheld was underinclusive, since residents of non-lottery states would be subject to extensive lottery advertising from out-of-state transmitters, and overinclusive, since lottery state residents would be deprived of information about lotteries from broadcasters in adjacent, non-lottery states. Nonetheless, the Court found the scheme constitutional largely because it was evident that Congress had no sensible alternative. 113 S.Ct. at 2705-07.

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, so long as the line is reasonable, the Court may not second-guess the FDA simply because it might have drawn the line somewhat differently. Id.; see also Fox, 492 U.S. at 478. Tellingly, while the industry complains about the 85 percent rule, it has not argued that the FDA has overlooked any obvious alternatives and has not proposed a less-restrictive line that would also achieve the FDA's goals.

The industry's reliance on Zauderer is also misplaced. Zauderer recognizes that images and illustrations can have a powerful communicative impact, and for that reason, even where they are unaccompanied by text, they are entitled to First Amendment protection. But that does not mean that the FDA is disabled from regulating them. Zauderer itself acknowledged that the use of images and illustrations could be restrained or suppressed altogether if they propose an illegality or deceive the viewer. 471 U.S. at 647.

Here, the FDA has made precisely that judgment, concluding on the basis of a substantial record that the use of pictures, cartoons, and colors in tobacco advertising has played a key role in inducing minors to use tobacco products. Study after study demonstrates the special susceptibility

of children and young adults to ads using those techniques, and just how strongly young people respond to these images when used to promote tobacco products. 61 Fed. Reg. 44466-68, 44475-88; see also 60 Fed. Reg. 41329-34. The accuracy of this research is confirmed, in part, by the fact that the vast majority of young people (86%) smoke the three most heavily advertised brands of cigarettes--Marlboro, Newport, and Camel--although those brands are among the expensive premium brands and minors are likely to be the most price-sensitive purchasers of cigarettes. 60 Fed. Reg. 41332, 41336. Based on this and other evidence, the FDA has reasonably concluded that its format restriction will reduce the incidence of minors' illegal tobacco use. That determination should not be disturbed.<sup>15</sup>

2. Ban On Outdoor Advertising Within 1,000 Feet Of Schools And Playgrounds. The industry attacks the FDA's ban on outdoor advertising within 1,000 feet of schools and playgrounds on the theory that this restraint is not narrowly tailored. Once again, the question is one of line-drawing. The industry does not argue that the First Amendment gives it a right to place billboards at the entrances of schools or playgrounds. The only question, then, is whether the FDA has overreached.

The Fourth Circuit's recent rulings in Anheuser-Busch II and Penn Advertising II, No. 94-2414 (4th Cir. Nov. 13, 1996), compel the rejection of industry's argument. In those cases, this Circuit upheld a Baltimore ordinance prohibiting all outdoor tobacco and alcohol advertising in "publicly visible" locations, a much more sweeping prohibition than the FDA's. Although the Court acknowledged that the ordinance might "reduce the opportunities for adults" to receive information, it recognized that there were other means for advertising to adults "that did not subject the children

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<sup>15</sup> The FDA is not alone in concluding that image-laden advertising poses special dangers of overreaching. The Securities and Exchange Commission requires that black and white, text-only "tombstone" advertisements be used to alert investors to forthcoming security issuances, without triggering the requirements that apply to prospectuses or actual security offerings. See 17 C.F.R. §§ 230.134, 230.134a, 230.134b, 203.135 (1995).

to "involuntary and unavoidable solicitation [while] . . . walking to school or playing in their neighborhood." Anheuser-Busch II, slip op. at 4 (quoting Anheuser-Busch, Inc. v. Schmoke, 63 F.3d 1305, 1314 (4th Cir. 1995)). The Court concluded that "no ordinance of this kind could be so perfectly tailored as to all and only those areas to which children are daily exposed" and that Baltimore's ordinance was "not more extensive than is necessary to serve the government interest under consideration." Id.<sup>16</sup>

Moreover, while the industry again whines about the line drawn by the FDA, it has not come close to establishing that the Agency's 1,000 foot mark is unreasonable. The FDA chose 1,000 feet because (a) billboards are plainly visible to minors at that distance, and (b) minors are certain to pass by billboards located that close to parks and schools on a regular basis. The industry has not contended, for instance, that children cannot read the words on signs 1,000 feet away; nor has it argued that minors do not regularly pass by billboards located near schools and parks. Indeed, the industry has not even argued that some lesser limitation (say, 750 feet) would serve the FDA's purpose equally well.

The industry's silence on this score is not surprising, since the FDA's rule largely mirrors the industry's voluntary "Cigarette Advertising and Promotion Code," which proposes a 500-foot tobacco advertising-free zone around schools and parks. In essence, the industry asks this Court to

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<sup>16</sup> The child who confronts a billboard with tobacco advertising when walking to school is no less a "captive" viewer than the bus rider in Lehman v. Shaker Heights, 418 U.S. 298, 94 S.Ct. 2714, 41 L.Ed.2d 770 (1974). Because billboards are part of the topography, viewers exercise "no choice or volition" about observing them, but instead have the billboard's message "thrust upon them." 418 U.S. at 302 (plurality opinion). Because of billboards' intrusiveness, the Court has always granted the government especially broad leeway in regulating billboard advertising. Id. The industry suggests that the imposition of format restrictions on outdoor ads somehow mitigates the ads' effect on children. Third Brief 38. In contrast to advertising in easily disregarded periodicals and magazines, however, a daily barrage of prominent and permanent outdoor ads cannot be overlooked.

find the FDA's regulation unconstitutional based on the Court's judgment about the relative wisdom of 500 versus 1,000 feet. The Court should not undertake such a task. See Fox, 492 U.S. at 478.

Industry complains that the FDA's rule amounts to a de facto ban on outdoor advertising in major urban areas, which, in industry's view, demonstrates its excessiveness. Even if industry is correct about the impact of the FDA's rule, that would not alter the constitutional calculus. The Fourth Circuit upheld Baltimore's ordinance, which imposes a ban even more sweeping than the FDA's. Anheuser-Busch II, slip op. at 3. And in Metromedia, Inc. v. San Diego, 453 U.S. 490, 101 S.Ct. 2882, 69 L.Ed.2d 800 (1981) (plurality opinion), the Court sustained San Diego's complete ban on off-site billboard advertising, even though the ban effectively ended commercial billboard advertising in the city. Thus, the question is not whether the regulation's impact is far-reaching, but whether it goes more than "marginally beyond what would adequately have served the governmental interest." Fox, 492 U.S. at 478. If the FDA's outdoor advertising rule bans billboards in a few major cities because of the wide dispersion of playgrounds and schools, that is a beneficial impact of the rule, not a reason for its invalidation. Anheuser-Busch II, slip op. at 5.

3. Ban On Selling Or Distributing Non-Tobacco Items Bearing Product Brand-Names Or Logos. The industry challenges section 897.34(a), which bans the distribution of promotional items bearing brand names or logos of tobacco products. The industry apparently concedes the validity of the rule as applied to products that are appealing to youngsters, like T-shirts, caps, and sporting goods, but seeks its invalidation because it covers "branded cigarette lighters, ashtrays, and other smoking paraphernalia (which are used by people who are already smoking) as well as office items (such as desk calendars and clocks) that are not likely to be used or seen by persons under 18." Third Brief 41. Once again, the industry's argument misapprehends the requirements of Central Hudson's fourth prong. The agency's task is to adopt a rule that reflects a "reasonable fit" between its goals and the means chosen to achieve them. It has no obligation to review each piece of merchandise that a tobacco company may want to dispense to see if it would be appealing to children.

Focusing on the reasonableness of the fit, the FDA's regulations clearly meet the fourth prong. The FDA has assembled substantial evidence that promotional items have become a pivotal component of the tobacco industry's marketing plans. Tobacco companies spend \$600 million annually to distribute non-tobacco items bearing tobacco product brand names and logos. 61 Fed. Reg. 41336. Many of the promotional campaigns run by tobacco companies involve the exchange of proofs of purchase of tobacco products for items, such as T-shirts, tote bags, caps, and the like. Id. Appallingly, the companies apparently make no effort to exclude minors from these promotional campaigns, and the statistics compiled by the FDA reveal that young people are major targets of these programs. Id. Moreover, the FDA cites evidence, including that compiled by the prestigious Institute of Medicine, that this form of advertising is particularly effective with young people and that a minor's participation in these programs is a solid predictor of susceptibility to future tobacco use. Id.

Firm precedent supports the conclusion that promotional materials of all kinds lay the groundwork for a minor's decision to use tobacco products. Public Citizen v. FTC, 869 F.2d 1541 (D.C. Cir. 1989), involved a challenge by a number of public health organizations to the FTC's failure to require warning statements on promotional items under the Comprehensive Smokeless Tobacco Health Education Act. During the litigation, the Smokeless Tobacco Council argued that organizations representing families with children could not show "injury-in-fact" because there is no correlation between the distribution of promotional items and the likelihood of minors being induced to experiment with snuff or chewing tobacco. Relying on the FTC's record, the court dismissed this claim, finding "that in the case of adolescents, utilitarian items might be among the most effective forms of promotion." 869 F.2d at 1549 n.15 (emphasis in original). The decision was based, in part, on the recognition that utilitarian items are walking billboards for tobacco products.

As the district court observed:

[P]rinted advertising is customarily quickly read (if at all) and discarded (as, of course, are product packages) by typical consumers. "Utilitarian objects," on the other hand . . . are retained, precisely because they continue to have utility. They are also likely to be made of durable substances: fabric, plastic, glass, or metal.

They may be around for years. And each use of them brings a new reminder of the sponsor and his product . . . .

688 F. Supp. 667, 680 (D.D.C. 1988), aff'd, 869 F.2d 1541 (D.C. Cir. 1989). And the industry does not dispute that "there is no way to limit the distribution of these items to adults only." 61 Fed. Reg. at 44525. Thus, the wall clock the industry sends to an office could easily end up on the wall of a home. Equally harmful, utilitarian items are often displayed by minors to minors. The 13-year-old boy who wears a "Skoal Bandit" T-shirt to school is implicitly stating that it is acceptable for minors to use the product, despite the illegality of doing so.

4. Sponsorship Of Musical, Athletic, Social, And Other Events. Over the past decade, tobacco companies have shifted a substantial portion of their advertising budgets to the sponsorship of sporting, musical, artistic, and other events. They do so to heighten their product's visibility, mold consumer attitudes, link their product with a particular lifestyle, and thereby increase sales. 60 Fed. Reg. 41336-37. Because of the impact these events have on the attitudes of young people toward tobacco products, the FDA has restricted the industry's sponsorship of these events. The FDA's rule (section 897.34(c)) prohibits a sponsored event from being identified with a cigarette or smokeless tobacco brand name or any other identifying characteristic. While events may be sponsored in the name of the tobacco company (for those corporations in existence on January 1, 1995), the sponsor may not use brand names, logos, selling messages, or any other indicia of product identification. This rule also easily passes the "reasonable fit" test.

To begin with, industry does not dispute that these events have a direct and powerful impact on young adults. The events are fun, exciting, and glamorous. Tennis tournaments, sports car, motorcycle and powerboat racing, and rodeos all are aimed at sports enthusiasts--many of whom are children or teenagers. Rock concerts and country music festivals are also magnets for adolescents. When minors view these events, either in-person or on television, they are inundated with images of the brand-name or product logo (on uniforms, vehicles, signs, and virtually every surface

imaginable), creating a direct and compelling association between the product and an enjoyable experience.<sup>17</sup>

This association is fortified by the connection between the event and the "image" the company is trying to project. Virginia Slims sponsors tennis tournaments because it wants young women to believe that smoking cigarettes (especially Virginia Slims) is entirely compatible with the lifestyle of young, athletic, sophisticated female tennis professionals. Marlboro sponsors racing events to reinforce the rugged, individualistic, and stoic image of a Marlboro smoker. 60 Fed. Reg. 41337. Indeed, were that not the case, the industry would not spend enormous sums to sponsor these events. As the Chairman and CEO of R.J. Reynolds bluntly admitted, from the first time the company sponsored such events, "we were in the business of selling cigarettes, not the racing business." Id.

Although the FDA considered the option of an outright ban on sponsorship of such events, it did not impose such a drastic prohibition. Rather, the FDA chose the approach that best effectuates its goal of reducing tobacco consumption by minors, without needlessly restricting the industry's ability to sponsor events and garner the good will that flows from such sponsorship. The industry remains free to sponsor whatever events it wants; it just can no longer link the event with the name of one of its products.<sup>18</sup>

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<sup>17</sup> Sponsorship of events is routinely used by the industry to evade the prohibition against tobacco advertising on television. In the televising of the Indianapolis 500 alone, Marlboro received almost 3½ hours of television exposure and 146 mentions of its brand name. 60 Fed. Reg. 41337. Eliminating this evasion is another powerful government interest.

<sup>18</sup> The industry complaint that the FDA's ban will interfere with its ability to sponsor events that would be attractive only to seniors, such as "classical music concerts, theater events, and seniors golf tournaments" (Third Brief 39) is a diversion. The record suggests that sponsorship of these events, if not simply the invention of industry counsel, is the exception rather than the rule, and that sporting events and concerts appealing to young people dominate the industry's efforts. In any event, industry's theory that the FDA was required to pass judgment on any conceivable event that it might want to sponsor is

Accordingly, the industry's half-hearted attack on this provision should be summarily rejected. The FDA has drawn an eminently reasonable line that allows tobacco companies to continue to sponsor events and therefore to reap the corporate good will that flows from sponsorship, while compelling the companies to jettison the hard-sell message to impressionable young people that now accompanies these events.

#### CONCLUSION

For the foregoing reasons, each of plaintiffs' summary judgment motions should be denied.

Dated: November 27, 1996

Respectfully submitted,

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George M. Cleland  
One Salem Tower  
119 Brookstown Avenue  
Winston-Salem, NC 27101  
(910) 725-0234

Of counsel:  
Allison M. Zieve  
David C. Vladeck  
Alan B. Morrison  
PUBLIC CITIZEN LITIGATION GROUP  
1600 20th Street, NW  
Washington, DC 20009  
(202) 588-1000

Matthew L. Myers  
NATIONAL CENTER FOR TOBACCO-FREE  
KIDS  
1701 L Street, NW Suite 800  
Washington, DC 20036  
(202) 296-5469

Counsel for Amici  
Public Citizen, et al.

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unsupported by Central Hudson and its progeny.

## APPENDIX

The foregoing memorandum is submitted on behalf of the following 16 amici:

PUBLIC CITIZEN is a consumer advocacy organization founded by Ralph Nader in 1971, and has approximately 100,000 members and supporters nationwide. Public Citizen's members are ordinary consumers who are gravely concerned that their children and grandchildren will be enticed into experimenting with tobacco products by the promotional efforts of the tobacco industry and that they may become addicted to tobacco products as a result. Public Citizen has substantial experience working on tobacco-related issues before courts, regulatory agencies, and Congress. In addition, Public Citizen has long been active before Congress, regulatory agencies, and the courts in matters relating to public health in general and drug and medical device regulation in particular. And Public Citizen's lawyers have been in the vanguard in pressing for extending reasonable constitutional protection for truthful commercial speech. In addition, Public Citizen submitted comments to the Food and Drug Administration (FDA) on the agency's proposed tobacco regulations.

THE NATIONAL CENTER FOR TOBACCO-FREE KIDS works to protect minors from tobacco by raising awareness that tobacco is a pediatric disease, changing public policies to limit the marketing and sales of tobacco to children, and altering the environment in which tobacco use and policy decisions are made. The National Center has over 100 member organizations, including health, civic, corporate, youth, and religious groups dedicated to reducing children's use of tobacco products. In addition, as the Campaign for Tobacco-Free Kids, the Center submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN ACADEMY OF PEDIATRICS (AAP) is a non-profit corporation with 66 chapters in the United States, its territories, and Canada. AAP and its approximately 50,000 member pediatricians dedicate their efforts and resources to the health, safety, and well-being of infants, children, adolescents, and young adults. AAP engages in advocacy, research, and public education, among other things, on issues related to tobacco and the health of minors. In addition, AAP submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN CANCER SOCIETY is the world's largest voluntary health organization with a membership of 2.2 million, including over 50,000 physicians, nearly all of the leading oncologists in the United States, and many victims of tobacco-caused cancer and their family members. The Society has representation in every state and 3400 units located throughout the United States. The Society is dedicated to eliminating cancer as a major health problem by preventing it, to saving lives, and to diminishing suffering from cancer through research, education, advocacy, and service. The American Cancer Society has been a leader in research on the relationship between tobacco and cancer; and it devotes substantial resources to research, public education, and direct service to those suffering from cancer caused by tobacco. In addition, the Society submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN COLLEGE OF PREVENTIVE MEDICINE (ACPM) is the national professional society for physicians committed to disease prevention and health promotion. ACPM's 2,100 members are engaged in preventive medicine practice, teaching, and research. The organization is a major national resource of expertise in prevention, including the prevention of disease caused by tobacco use. ACPM supports the FDA's regulations on tobacco and minors because it believes the regulations are essential to assisting its members in reducing the use of tobacco and the incidence of tobacco-caused disease.

THE AMERICAN HEART ASSOCIATION is the nation's second largest voluntary health organization, with 52 affiliates, over 2,000 local divisions across the country, and more than 4.5

million volunteers. The mission of the American Heart Association is to reduce death and disability from cardiovascular disease and stroke, the nation's first and third leading causes of death. The Association has devoted substantial resources to research, education, and other efforts to reduce the use of tobacco because of its addictive nature and because cigarette smoking is a major risk factor in cardiovascular disease, sudden cardiac death, and peripheral vascular disease. As part of the Coalition on Smoking OR Health, the Association has long been active before Congress and regulatory agencies on tobacco and health-related matters and has petitioned the FDA on several occasions to have cigarettes and other tobacco products regulated under the Food, Drug, and Cosmetic Act. In addition, the Association submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN LUNG ASSOCIATION is the nation's oldest voluntary health organization, with volunteers and affiliates in all 50 states, the District of Columbia, Puerto Rico and the Virgin Islands. The Lung Association includes more than 150,000 volunteers and more than 10,000 medical professionals, including most of the nation's leading pulmonary physicians, who belong to its medical section, the American Thoracic Society. Cigarette smoking is a major cause of chronic obstructive lung disease. Therefore, the Association has long been active in research, education and public policy advocacy on the adverse health effects of tobacco products. In addition, the Society submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN MEDICAL ASSOCIATION (AMA), with a membership of more than 280,000 physicians, is the largest private nonprofit organization of physicians in the United States. The AMA's mission is to promote the science and art of medicine and the betterment of the public health. The AMA has long opposed tobacco use, based on the massive body of scientific evidence that tobacco is addictive and kills smokers. The consequences of tobacco use to the public health have been staggering, and the importance of bringing tobacco use under control is correspondingly great. In addition, the AMA submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN MEDICAL WOMEN'S ASSOCIATION (AMWA) is a national association of over 11,000 women physicians and medical students. Founded in 1915, AMWA has worked on women's health issues, including tobacco control and prevention, through legislative and media advocacy, public education, and physician training. Recognizing the terrible toll tobacco takes on women, AMWA's members have long counseled their patients on the health effects of tobacco use, and AMWA has long supported progressive policy measures to reduce tobacco use, especially measures that reduce the tobacco industry's ability to sell and promote its products to youth. In addition, AMWA submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN PUBLIC HEALTH ASSOCIATION (APHA) is the oldest and largest public health society in the world, with combined national and affiliate membership of 50,000 health professionals, including physicians, dentists, nurses, social workers, academics and researchers specializing in public health issues. During its 125 years, APHA's members have dealt with tobacco use directly at the community level. APHA has worked to influence public health policies and priorities and has been in the forefront of efforts to prevent disease and promote health relating to the health hazards of tobacco products. In addition, APHA submitted comments to the FDA on the agency's proposed tobacco regulations.

THE AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM) is an association of 3,000 physicians dedicated to improving the treatment of alcoholism and other addictions (including addiction to nicotine), educating physicians and medical students, promoting research and prevention, and informing the medical community and the public about addictions, their treatment,

and prevention. ASAM believes that nicotine addiction is the most serious addiction problem in the nation because of the vast numbers of people affected and the enormous suffering it causes. In addition, ASAM submitted comments to the FDA on the agency's proposed tobacco regulations.

THE HMO GROUP is an alliance of 30 mostly not-for-profit group-model based health maintenance organizations that operate in half of the states and enroll approximately seven million members. As providers of comprehensive, population-based health care services, the organizations of The HMO Group confront the impact of tobacco in their work everyday. The HMO Group's plans have implemented and coordinated significant clinical and behavioral interventions to reduce tobacco use. Many of these efforts are specifically targeted at children. The HMO Group and its member plans have worked at the federal, state, and local levels to educate the public about the public health crisis posed by tobacco use. It is working on a public and private effort to stop children's use of tobacco by determining what interventions are currently in use and using effective interventions to effect positive, clinical, behavioral, and community changes. In addition, The HMO Group submitted comments to the FDA on the agency's proposed tobacco regulations.

THE NATIONAL ASSOCIATION OF AFRICAN AMERICANS FOR POSITIVE IMAGERY (NAAAPI) is a non-profit organization formed in 1991 to help end the excessive marketing of alcohol, tobacco, and other harmful products in communities of color. NAAAPI works to mobilize black communities around the nation, to support media and advertising images that are positive and healthy, and to oppose images that are harmful. Through its affiliates and supporters, NAAAPI has engaged in grassroots organizing to strengthen communities and protect those who are most at risk--children and elders.

THE NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS serves 27,000 elementary and middle school principals and maintains a close relationship with 51 state and local affiliates and other national, international, private, and non-profit organizations. As Elementary School principals, the organization's members are directly involved with and concerned about tobacco use among the nation's children. The Association is an advocate for the profession with local, state, and federal governments and the news media.

THE NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS (NASSP) is the nation's largest administrator organization, representing 44,000 middle, junior, and senior high school principals and assistance principals. NASSP also administers the National Association of Student Activity Advisers, which represents 57,000 members, as well as the National Association of Student Councils, the National Honor Society, the American Technology Honor Society, and the National Alliance of High Schools. Because of the physical consequences of tobacco use, NASSP is concerned about the rising use of tobacco products by youth. Consistent with NASSP's commitment to the intellectual growth, academic achievement and leadership development, and physical well-being of youth, NASSP supports the Food and Drug Administration's regulation of the sale and advertising of tobacco products to minors.

THE NATIONAL PTA is a nonprofit educational and charitable organization with over 6.8 million members. Among other things, the National PTA supports and speaks on behalf of children and youth in schools, the community, and before governmental bodies and other organizations that make decisions affecting children. For many years, the organization has worked in support of efforts to reduce the use of tobacco by youth and the advertising and promotion of tobacco products to youth.