NLWJC - Kagan
DPC - Box 047 - Folder-004

Tobacco-Litigation [4]

Tobacco - Litigation

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

COYNE BEAHM, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	2:95CV00591
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,	)	
	)	
Defendants.	)	

* * * * * * * * * *

AMERICAN ADVERTISING FEDERATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	2:95CV00593
	)	
DAVID A. KESSLER, M.D., et al.,	)	
	)	
Defendants.	)	

* * * * * * * * * *

UNITED STATES TOBACCO COMPANY, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	6:95CV00665
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,	)	
	)	
Defendants.	)	

* * * * * * * * * *

NATIONAL ASSOCIATION OF CONVENIENCE STORES, et al.,	)	
Plaintiffs,	)	
v.	)	2:95CV00706
DAVID A. KESSLER, M.D., et al.,	)	
Defendants.	)	

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

FRANK W. HUNGER
Assistant Attorney General
Civil Division

WALTER C. HOLTON, JR.
United States Attorney

GEORGE J. PHILLIPS
Counselor to the
Assistant Attorney General
Civil Division

EUGENE M. THIROLF
Director
Office of Consumer Litigation

GERALD C. KELL
N.C. State Bar No. 5698
DEBORAH M. AUTOR
GREGORY T. EVERTS
DOUGLAS N. LETTER
SCOTT R. McINTOSH
Department of Justice
Washington, D.C. 20530
(202) 514-1586

OF COUNSEL:

MARGARET JANE PORTER
Chief Counsel

KAREN E. SCHIFTER
PATRICIA J. KAEDING
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

TABLE OF CONTENTS

PAGE

PAGE

TABLE OF AUTHORITIES

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

CASES (Continued) **PAGE(S)**

STATUTES AND REGULATIONS

STATUTES AND REGULATIONS (Continued) **PAGE(S)**

STATUTES AND REGULATIONS (Continued) **PAGE(S)**

FEDERAL REGISTER **PAGE(S)**

HOUSE AND SENATE REPORTS

HOUSE AND SENATE REPORTS (Continued) **PAGE(S)**

MISCELLANEOUS

MISCELLANEOUS (Continued) **PAGE(S)**

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

STATEMENT OF THE MATTER BEFORE THE COURT

On August 28, 1996, the United States Food and Drug Administration ("FDA") published in the Federal Register "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (the "Rule"). 61 Fed. Reg. 44396 (1996). Annexed to the Rule was FDA's "Jurisdictional Determination" that "Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act." 61 Fed. Reg. 44619 (1996).

Plaintiffs now seek summary judgment claiming that, as a matter of law: (1) Congress has withheld from FDA the authority to regulate cigarettes and smokeless tobacco as marketed by plaintiffs; (2) the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") does not authorize FDA to regulate cigarettes and smokeless tobacco as "drugs" or "devices"; and (3) the restrictions that the Rule places on advertising and promotion of cigarettes and smokeless tobacco violate the First Amendment to the United States Constitution. Coyne Beahm Motion for Summary Judgment at 2-3 (Oct. 15, 1996). All of the plaintiffs, with the exception of the advertisers, have joined in three briefs ("First Brief," "Second Brief," and "Third Brief"), separately addressing each of the foregoing claims.[1/] Additionally, plaintiffs United States Tobacco Company and National Association of

---

[1/] The advertisers have joined in the Third Brief attacking on First Amendment grounds FDA's regulation of advertising and promotion of cigarettes and smokeless tobacco.

Convenience Stores have each filed supplemental briefs ("UST Brief" and "Convenience Stores Brief," respectively), that address these claims from their perspectives.

In moving for summary judgment, plaintiffs have accepted as true the facts found by FDA in its jurisdictional determination and the preamble to the Rule. Second Brief at 2 n.1; UST Brief at 2 n.2. Even if plaintiffs had not made this concession, "[a]s with any motion for summary judgment, [the court] must view the evidence in the light most favorable to the nonmovant." Pittman v. Nelms, 87 F.3d 116, 119 (4th Cir. 1996). Further, "the court must draw any permissible inference from the underlying facts as established in the record in the light most favorable to the nonmoving party." Austin v. Clark Equipment Co., 48 F.3d 833, 835 (4th Cir. 1995) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986)); Pulliam Inv. Co. v. Cameo Prop., 810 F.2d 1282, 1286 (4th Cir. 1987).

In this brief, the government will demonstrate, based upon the facts found by FDA, the reasonable inferences to be drawn from them, and the applicable law, that:

(1) By enacting the FDCA, Congress provided FDA with the authority to regulate any product meeting the definition of drug or device, including cigarettes and smokeless tobacco, and nothing that Congress has done in the past, either by affirmatively enacting other legislation or by inaction, has deprived FDA of that authority;

(2) FDA's finding that cigarettes and smokeless tobacco meet the Act's drug and device definitions because they are intended to affect the structure or function of the body, and its regulation of cigarettes and smokeless tobacco under the Act's device provisions, are appropriate exercises of its authority under the FDCA; and

(3) The restrictions adopted by FDA on advertising and other promotional activities for cigarettes and smokeless tobacco are consistent with the First Amendment.

Because each of plaintiffs' claims is invalid as a matter of law, their motions for summary judgment must be denied. Moreover, the Court has the power to, and should, enter summary judgment in defendants' favor on each of these claims. See, e.g., Roberts v. Fuquay-Varina Tobacco Bd. of Trade, Inc., 223 F. Supp. 212, 215 (E.D.N.C. 1963), aff'd in relevant part and remanded with directions, 332 F.2d 521 (4th Cir. 1964); 6 James W. Moore et al., Moore's Federal Practice ¶ 56.12 at 56-162 n.5 (2d ed. 1985) (collecting cases).

STATEMENT OF MATERIAL FACTS

FDA's decision to regulate cigarettes and smokeless tobacco to reduce the use of those products by persons under 18 was based on the most comprehensive rulemaking in the agency's history. To develop its proposed rule and jurisdictional analysis, the agency assembled and considered a record containing over 200,000 pages of factual and analytical materials. 61 Fed. Reg. 44557. After publishing the proposed rule and jurisdictional analysis on August 11, 1995, 60 Fed. Reg. 41314, 41453 (1995), FDA received over 700,000 comments from the public. 61 Fed. Reg. 44557. Each of the plaintiffs in these cases submitted extensive comments to the administrative record, including the cigarette companies' joint submission of 2,000 pages of comments and 45,000 pages of exhibits. The agency carefully considered all of these comments and, in response, made certain changes in the final Rule.

Critical to the Rule and jurisdictional determination, FDA made well-founded factual findings regarding: (1) the health effects of cigarettes and smokeless tobacco; (2) the bases

for the assertion of jurisdiction; and (3) the basis for the Rule. A summary of these findings and of the Rule are set out below.

I. The Health Effects of Cigarettes and Smokeless Tobacco

Tobacco use is the largest cause of preventable death in the United States, accounting for approximately 20% of all deaths. More than 400,000 people die each year from tobacco-related illnesses such as cancer, respiratory illnesses, and heart disease. Tobacco alone kills more Americans each year than AIDS, alcohol, car accidents, homicides and suicides, illegal drugs, and fires combined. The average tobacco victim loses 15 years of life. 61 Fed. Reg. 44398, 44571.

Although death from tobacco use occurs among adults, FDA found that tobacco use is a "pediatric disease" because most adult smokers become addicted to nicotine in tobacco during childhood. 61 Fed. Reg. 44421. Over 80% of the adult smokers in the U.S. started to smoke as children or adolescents. Most of the children and adolescents who now smoke already regret their decision to start and say they want to quit, but cannot. 61 Fed. Reg. 44398.

Approximately three million American children and adolescents currently smoke and an additional one million adolescent males use smokeless tobacco. Every year, approximately one million children and adolescents begin to smoke--nearly 3,000 per day. FDA found that one out of every three of them will die from a tobacco-related disease. 61 Fed. Reg. 44398, 44568.

As alarming as those statistics are, the problem of youth tobacco use is getting worse. FDA found that the percentage of eighth and tenth graders who smoke has risen for four

consecutive years. Currently, 19% of eighth graders, 28% of tenth graders, and 33% of high school seniors smoke. These prevalence rates are 20% to 30% higher than in 1991. 61 Fed. Reg. 44399. Based on these facts, FDA concluded that cutting in half the number of children and adolescents who start to use cigarettes and smokeless tobacco--the goal of the FDA Rule--will have profound beneficial effects on public health. 61 Fed. Reg. 44568-69.

II. The Basis for the Assertion of Jurisdiction

As the principal public health regulatory agency in the United States, FDA has both the duty and the authority to address the serious public health problems found to be caused by cigarettes and smokeless tobacco if they are "drugs" or "devices" under the Act. The relevant statutory definitions provide that drugs and devices are products that are either (1) "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or (2) "intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1), (h). In determining to regulate cigarettes and smokeless tobacco, FDA focused on whether these products meet the "structure or function" test.

Historically, FDA has asserted jurisdiction over tobacco products when there was sufficient evidence to establish that the products were "intended" to affect the structure or function of the body. Over thirty years ago, for instance, FDA asserted jurisdiction over cigarettes intended to reduce body weight. United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959). Conversely, when the evidence failed to support a finding of intent, FDA has determined that it lacked jurisdiction to regulate tobacco products. 61 Fed. Reg. 45222-23.

Prior to the initiation of this rulemaking, the agency last considered whether it had jurisdiction over cigarettes (for which no express therapeutic claims were made) in the late 1970s, when it rejected petitions by the organization Action on Smoking and Health ("ASH") urging FDA to regulate cigarettes as drugs or devices.[2/] FDA concluded that the evidence then available was insufficient to establish that cigarettes, as a class of products, were intended to affect the structure or function of the body. In a challenge to that determination, the D.C. Circuit deferred to FDA's judgment but expressly left open the possibility that, in the future, FDA could have sufficient factual support to exercise jurisdiction generally over cigarettes and smokeless tobacco. ASH v. Harris, 655 F.2d 236, 239-41, 242 n.10 (D.C. Cir. 1980).

In April 1988, the American Heart Association and other public health organizations petitioned FDA and urged the agency to regulate low-tar cigarettes as drugs. Petition of the American Heart Association, No. 88P-0156 (Apr. 25, 1988) (AR: Vol. 504, Ref. 8934). After initiating an investigation, FDA announced its intention to reconsider its jurisdiction over cigarettes and smokeless tobacco, citing an accumulation of new evidence. Letter from David A. Kessler, Commissioner of Food and Drugs (Feb. 25, 1994) (AR: Vol. 53, Ref. 604). The jurisdictional determination published on August 28, 1996, reflects the agency's decision. As summarized below, FDA has now found that (A) cigarettes and smokeless

---

[2/] Letter from FDA Commissioner Kennedy to ASH Executive Director Banzhaf (Dec. 5, 1977) (AR: Vol. 28, Ref. 240); Letter from FDA Commissioner Goyan to Banzhaf (Nov. 25, 1980), at 8-9 (AR: Vol. 28, Ref. 238). (References in this brief to "AR" are to the Administrative Record amassed by FDA in the course of its tobacco investigation and rulemaking proceeding. Although the record is far too voluminous to reproduce and file with the Court in its entirety, the government is prepared to provide to the Court any excerpts which either the Court or any party requests.)

tobacco "affect the structure or any function of the body" and (B) these effects are "intended" by the manufacturers.

A. The Evidence That Nicotine in Cigarettes and Smokeless Tobacco "Affect[s] the Structure or Any Function of the Body"

The agency's determination that nicotine in cigarettes and smokeless tobacco affects the "structure or any function of the body" is based on three central findings:

(1) Nicotine in cigarettes and smokeless tobacco causes and sustains addiction;

(2) Nicotine in cigarettes and smokeless tobacco causes other psychoactive (mood-altering) effects, including tranquilization and stimulation; and

(3) Nicotine in cigarettes and smokeless tobacco controls weight.

61 Fed. Reg. 44630, 44665-66.

Nicotine in cigarettes and smokeless tobacco achieves its addictive effects by exerting psychoactive, or mood-altering, effects on the brain and by producing chemical reactions in the brain that motivate repeated, compulsive use and create dependence in the user. 61 Fed. Reg. 44666. In addition, nicotine in cigarettes and smokeless tobacco, under some circumstances, can have a sedating or tranquilizing effect on mood and brain activity. Under other circumstances, nicotine in cigarettes and smokeless tobacco can have a stimulant or arousal-increasing effect on the body. Id. Further, clinical and animal studies indicate that nicotine causes weight loss and that cessation of nicotine administration results in weight gain. Id.

The agency found that these effects on the structure and function of the body are significant and quintessentially drug-like. They are effects of drugs that FDA has traditionally regulated, including stimulants, tranquilizers, appetite suppressants, and narcotic

drugs (e.g., methadone) that are used in the treatment of addiction. For these reasons, FDA found that nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" within the meaning of the Act. 61 Fed. Reg. 44632, 44666-70.

B. The Evidence That the Pharmacological Effects of Nicotine in Cigarettes and Smokeless Tobacco Are "Intended"

In considering whether the pharmacological effects of nicotine in cigarettes and smokeless tobacco are "intended" by the manufacturers, the agency found that "three important categories of evidence . . . have emerged since FDA last declined to exercise jurisdiction over tobacco products." 61 Fed. Reg. 45227. The agency concluded that "[t]he evidence . . . is now sufficient to establish that cigarettes and smokeless tobacco are in fact intended to affect the structure and function of the body." 61 Fed. Reg. 44653 (emphasis added).

1. New Evidence of Foreseeability

The first category of new evidence was "the development of a scientific consensus, on the basis of overwhelming scientific evidence, that nicotine in cigarettes and smokeless tobacco is highly addictive and produces significant effects on the structure and function of the body." 61 Fed. Reg. 45227. Before 1980, no major public health organization had determined that nicotine was an addictive drug. By 1995, however, all major public health organizations in the United States and abroad with expertise in tobacco or drug addiction, including the American Psychiatric Association (1980), the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994), had concluded that nicotine is

addictive. 61 Fed. Reg. 44634, 45228-33. In addition, substantial evidence since 1980 has established that nicotine has other significant pharmacological effects, such as changes in mood and alertness. 61 Fed. Reg. 45229-32.

With this scientific consensus, a reasonable manufacturer must foresee that cigarettes and smokeless tobacco cause consumers to become addicted to nicotine and will be used by consumers for pharmacological purposes, including satisfying their addiction. 61 Fed. Reg. 44634, 44701-39. Applying the legal principle that "every man intends the legitimate consequence of his own acts," Agnew v. United States, 165 U.S. 36, 53, 17 S. Ct. 235, 242, 41 L. Ed. 2d 624 (1897), the agency concluded that the manufacturers intend cigarettes and smokeless tobacco to result in addiction and thereby affect the structure and function of the body. 61 Fed. Reg. 44633-35, 44690-91.

2. New Evidence of Consumer Use

The second category of new evidence was "scientific data establishing that the vast majority of consumers who use cigarettes and smokeless tobacco are addicted to them and use these products nearly exclusively to obtain the pharmacological effects of nicotine." 61 Fed. Reg. 45227. Scientific evidence accumulated since 1980 showed that over 75% of smokers and as many as 75% of young regular smokeless tobacco users are addicted to nicotine and use cigarettes and smokeless tobacco to satisfy their addiction. 61 Fed. Reg. 45233. The agency further found that a large proportion of smokers and consumers of smokeless tobacco also use cigarettes and smokeless tobacco for their mood-altering effects. Id. The fact that consumers are using cigarettes and smokeless tobacco predominantly for pharmacological purposes provided another independent basis for establishing the

manufacturers' intent to affect the structure or function of the body. 61 Fed. Reg. 44635-36, 44807-08.

3. New Evidence of Manufacturers' Intent

The third category of new evidence was "newly disclosed evidence showing that tobacco companies have in mind that their products will be used by consumers for pharmacological purposes and have designed their products to affect the structure and function of the body." 61 Fed. Reg. 45227. Although this evidence included three decades of tobacco industry statements, research, and actions, virtually none of it was known by anyone other than the manufacturers or disclosed to FDA until it was recently revealed through the agency's investigation, congressional hearings, and disclosures by tobacco company officials and employees. 61 Fed. Reg. 45235-36.

This evidence led to two central findings regarding the manufacturers' intent. First, FDA found that "[m]anufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine . . . , and that consumers use their products primarily to obtain the pharmacological effects of nicotine." 61 Fed. Reg. 44630 (emphasis added).

This finding was based in part on evidence that senior officials and researchers for the tobacco manufacturers for decades had consistently--but secretly--characterized nicotine in cigarettes and smokeless tobacco as a pharmacologically active drug. For instance, industry officials and researchers called nicotine:

"'a very remarkable beneficent drug,'" 61 Fed. Reg. 44882 (quoting C. Ellis, science advisor to BATCO board (1962)) (emphasis added);[3/]

"'addictive,'" 61 Fed. Reg. 44884 (quoting A.Y. Yeaman, general counsel of Brown & Williamson (1963)) (emphasis added);

"'a potent drug with a variety of physiological effects . . . [and] a habit-forming alkaloid,'" 61 Fed. Reg. 44867 (quoting C.E. Teague, assistant director of research for R.J. Reynolds (1972)) (emphasis added);

"'a narcotic, tranquilizer, or sedative,'" 61 Fed. Reg. 44857 (quoting A. Udow, Philip Morris researcher (1976)) (emphasis added);

"'pharmacologically active in the brain,'" 61 Fed. Reg. 44887 (quoting BATCO researchers (1976)) (emphasis added);

"'the physiologically active component of smoke having the greatest consequence to the consumer,'" 61 Fed. Reg. 44857 (quoting Philip Morris, "Research and Development Five-Year Plan" (1978)) (emphasis added);

"'a powerful pharmacological agent with multiple sites of action,'" 61 Fed. Reg. 44857 (quoting J.L. Charles, Philip Morris researcher (1980)) (emphasis added);

"'an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses,'" 61 Fed. Reg. 44888 (quoting BATCO researchers (1980)) (emphasis added);

"'a drug,'" 61 Fed. Reg. 44888 (quoting the Tobacco Advisory Council, a trade association representing U.K. tobacco manufacturers (1981)) (emphasis added); and

"'a physiologically active . . . substance . . . [that] alters the state of the smoker by becoming a neurotransmitter and a stimulant,'" 61 Fed. Reg. 44866 (quoting Philip Morris, "Project Table" (approx. 1992)) (emphasis added).

The agency's finding was also supported by "evidence show[ing] that the manufacturers have known for decades . . . that consumers use cigarettes primarily to obtain the pharmacological effects of nicotine, including satisfaction of their addiction." 61 Fed.

[3/] BAT Industries PLC, formerly the British-American Tobacco Company (BATCO), is the corporate parent of Brown & Williamson Tobacco Corp., the third largest domestic cigarette manufacturer.

Reg. 44849. For example, researchers for R.J. Reynolds recognized in the 1970s that "'[t]he confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine,'" 61 Fed. Reg. 44868 (emphasis added), and that "'[w]ithout any question, the desire to smoke is based upon the effect of nicotine on the body,'" 61 Fed. Reg. 44871 (emphasis added). The knowledge of the researchers was communicated to the highest levels of the tobacco companies. As early as 1969, Philip Morris's vice president for research and development notified the board of directors that "'the ultimate explanation for the perpetuated cigaret[te] habit resides in the pharmacological effect of smoke upon the body of the smoker.'" 61 Fed. Reg. 44856 (quoting H. Wakeham (1969)) (emphasis added).

Second, FDA found that "[m]anufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine." 61 Fed. Reg. 44630 (emphasis added). In the case of cigarettes, FDA found:

> Manufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers. The principal techniques that are used to control and manipulate nicotine deliveries include: (1) the use of nicotine-rich tobacco blends in low-tar cigarettes; (2) the use of filtration and ventilation technologies that selectively remove more tar [than nicotine] from smoke; and (3) the use of chemical additives that increase the percentage of "free" nicotine in cigarette smoke.

61 Fed. Reg. 44951 (emphasis added). In the case of smokeless tobacco, FDA found that:

> [S]mokeless tobacco manufacturers manipulate the nicotine delivery of their products to produce graduated deliveries of nicotine that promote tolerance and addiction. Specifically, the evidence shows that the nicotine deliveries of smokeless tobacco are manipulated so that products intended for new users deliver low amounts of nicotine, while products intended for experienced users deliver far higher amounts of nicotine.

61 Fed. Reg. 45108 (emphasis added).

Indeed, the tobacco company documents revealed that senior officials and researchers for the tobacco manufacturers expressly conceived of cigarettes and smokeless tobacco as:

> "'a dispenser for a dose unit of nicotine,'" 61 Fed. Reg. 44856 (quoting W.L. Dunn, Philip Morris researcher (1972)) (emphasis added);
>
> "'[n]icotine delivery devices,'" 61 Fed. Reg. 44866 (quoting Philip Morris, "Project Table" (approx. 1992)) (emphasis added);
>
> "'a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form,'" 61 Fed. Reg. 44868 (quoting C.E. Teague, assistant director of research for R.J. Reynolds (1972)) (emphasis added); and
>
> "'the means of providing nicotine dose in a metered fashion,'" 61 Fed. Reg. 44890 (quoting BATCO researchers (1984)) (emphasis added).

Under the Act, these findings of the manufacturers' knowledge and product design provided another basis for FDA's finding that the manufacturers intend their products to affect the structure and function of the body. 61 Fed. Reg. 44636-45, 44847-50, 45098-99.

C. The Evidence That Cigarettes and Smokeless Tobacco Are "Combination Products"

Under the Act, products such as cigarettes and smokeless tobacco that are intended to affect the structure and function of the body can be a "drug," 21 U.S.C. § 321(g)(1)(C), or a "device," 21 U.S.C. § 321(h)(3). The critical distinction between a drug and a device is that a device "does not achieve its primary intended purposes through chemical action within or on the body . . . and . . . is not dependent upon being metabolized" to achieve its primary intended purposes. 21 U.S.C. § 321(h). With the enactment of the Safe Medical Devices Act of 1990, a product that has the attributes of both a drug and a device can now be regulated as a "combination product." 21 U.S.C. § 353(g). Combination products include drug delivery systems (i.e., products that combine a drug component and a device component

as a single entity, see 21 C.F.R. § 3.2(e)), such as preloaded inhalers or syringes, or transdermal adhesive patches preloaded with nicotine to help relieve tobacco-related withdrawal symptoms. 61 Fed. Reg. 45210-11.

Based on the agency's findings regarding the pharmacological effects and intended uses of nicotine, FDA concluded that the nicotine in cigarettes and smokeless tobacco, is a "drug." 61 Fed. Reg. 45207. FDA further found that cigarettes and smokeless tobacco are not simply packaged nicotine. Instead, FDA found that cigarettes are "a highly engineered product" with device components that "have been carefully designed to deliver controlled, pharmacologically active doses of nicotine to the smoker." 61 Fed. Reg. 45209. Similarly, FDA found that processed tobacco in smokeless tobacco functions "to deliver the nicotine to the cheek and gum tissue for absorption into the body." 61 Fed. Reg. 45213-14. FDA determined that these components of cigarettes and smokeless tobacco (e.g., tobacco blend, filter, and the ventilation system) meet the statutory definition of a "device." Thus, FDA determined that cigarettes and smokeless tobacco, which contain both a drug component and device components, are "combination products." 61 Fed. Reg. 45208-16.

III. The Rule

A. Cigarettes and Smokeless Tobacco as Combination Products

Once FDA found that cigarettes and smokeless tobacco are "combination products" under the Act, the agency had to choose whether it would regulate these products as drugs, devices, or both. 61 Fed. Reg. 44400-03. Had the agency applied the Act's drug authorities, however, the result could have been the removal of cigarettes and smokeless tobacco from the market. See 60 Fed. Reg. 41345. The agency elected to use the Act's

device authorities because they offered the agency "additional flexibility" to develop "careful, tailored solutions" to the unique safety problems presented by tobacco products. 61 Fed. Reg. 44404.

B. The Regulatory Goal

Considering the large number of Americans who are currently addicted to nicotine, FDA determined that a ban on cigarettes and smokeless tobacco would unlikely be effective in protecting consumers from the serious risks of these products. Black markets and smuggling could develop, offering products that likely "would be even more dangerous than those currently marketed." 61 Fed. Reg. 44413; see also 61 Fed. Reg. 44398, 44405. Furthermore, a ban could result in adverse health consequences for the millions of people who are dependent on nicotine; the nation's health care system might not be able to provide sufficient support for such a precipitous withdrawal; and it was viewed as unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Id.

FDA concluded that to effectively address the death and disease caused by cigarettes and smokeless tobacco, addiction to these products must be eliminated or substantially reduced. 61 Fed. Reg. 44398, 44413. The agency found that this goal can be achieved best by preventing children and adolescents from beginning to use cigarettes and smokeless tobacco. This was based on the fact that "[m]ost people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin their use before they reach the age of 18, an age when they are not prepared for, or equipped to, make a decision that, for many, will have lifelong consequences." 61 Fed. Reg. 44398. The agency found that young

people do not fully understand or appreciate the serious health risks of these products, and "are very vulnerable to the sophisticated marketing techniques employed by the tobacco industry." Id. Once addicted to these products, "these youths lose their freedom to choose whether or not to use the products as adults." 61 Fed. Reg. 44398-99.

The agency found that "limiting the use of these products to the adult population would substantially reduce the principal source of new users." 61 Fed. Reg. 44399. For these reasons, FDA determined that "restrictions to reduce the use of cigarettes and smokeless tobacco by individuals under the age of 18 while leaving these products on the market for adults . . . is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed. Reg. 44398.

Because the evidence before the agency demonstrated that the most effective way to achieve such a reduction was by limiting the access to, and attractiveness of, cigarettes and smokeless tobacco to young people, FDA developed a regulatory scheme using its "restricted device" authority, 21 U.S.C. § 360j(e), which authorizes the agency to impose conditions on the "sale, distribution, or use" of a device if "there cannot otherwise be reasonable assurance of its safety and effectiveness." Pursuant to section 360j(e), FDA developed restrictions designed: (1) "to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco"; and (2) "to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions." 61 Fed. Reg. 44406.

C. The Youth Access Restrictions

To develop effective measures to keep cigarettes and smokeless tobacco away from children and adolescents, FDA reviewed the available evidence regarding youth access. This

evidence revealed that despite state laws outlawing sales of tobacco products to minors, adolescents have little difficulty purchasing tobacco products. A review of 13 studies of over-the-counter sales by the Surgeon General in 1994, for instance, showed that 67% of minors are able to purchase tobacco products illegally. A higher percentage (88%) is able to illegally purchase tobacco products from vending machines. 60 Fed. Reg. 41322. The evidence also showed that children and adolescents frequently obtain access to tobacco products through free samples, 60 Fed. Reg. 41326, and shop-lifting from self-service displays, 60 Fed. Reg. 41325.

In response to this evidence, FDA proposed to reduce such easy access to cigarettes and smokeless tobacco by minors, while permitting continued availability to adults. These measures included prohibiting the sale of cigarettes and tobacco products to persons under age 18, requiring retailers to check for photographic identification, banning distribution of free samples, requiring retailers to remove self-service displays of tobacco products, and prohibiting the use of vending machines for selling cigarettes or smokeless tobacco. 60 Fed. Reg. 41315. FDA received extensive comments from the public on its proposed access restrictions. After reviewing the comments, FDA found that "an effective, mandatory program under the act to restrict young people's access to cigarettes and smokeless tobacco" is essential. 61 Fed. Reg. 44429-30. The agency did, however, modify the proposed restrictions in response to public comment in order to better tailor them to the goal of reducing youth access. For example, the agency determined that it would be appropriate to permit vending machines, 61 Fed. Reg. 44450, and self-service displays, 61 Fed. Reg. 44457, in adult-only locations. The agency also determined that mail-order sales should be

permitted after the comments demonstrated that minors do not purchase these products through the mail. 61 Fed. Reg. 44459.

D. The Advertising and Promotion Restrictions

FDA also investigated the effect of tobacco advertising on children and adolescents. FDA found that cigarettes and smokeless tobacco are "among the most heavily advertised and widely promoted products in America." 61 Fed. Reg. 44475. In 1993 alone, the cigarette and smokeless tobacco industries spent over $6.1 billion to market and promote their products in diverse media, including "magazines, newspapers, outdoor advertising, point of purchase, direct mail, in-store, dissemination of nontobacco items with brand identification [such as t-shirts and hats], and sponsorship of cultural and sporting events." Id.

Two recent and comprehensive analyses by the National Academy of Science's Institute of Medicine ("IOM") and the U.S. Surgeon General found that tobacco advertising plays a significant role in the decisions of young people to use cigarettes and smokeless tobacco. 60 Fed. Reg. 41332; 61 Fed. Reg. 44487-88. The IOM report recommended that tobacco advertising be banned entirely or restricted to text-only. 60 Fed. Reg. 41329.

In evaluating the effect of advertising on youth cigarette and smokeless tobacco use, FDA considered evidence that included the conclusions of the nation's largest psychological association that "color and imagery in advertisements are important components for young people" because "they generally have less information-processing ability than adults and are less able or less willing to pay attention to the factual information in the advertisements," 61 Fed. Reg. 44468, and that tobacco advertising "plays directly to the factors" that are most appealing to youth. 61 Fed. Reg. 44488; see also 61 Fed. Reg. 44485-86.

Numerous studies and surveys also showed that "children are exposed to substantial and unavoidable advertising, that exposure to tobacco advertising leads to favorable beliefs about tobacco use, that advertising plays a role in leading young people to overestimate the prevalence of tobacco use, and that these factors are related to young people's tobacco initiation and use." 61 Fed. Reg. 44488; see also 61 Fed. Reg. 44475-76. A study conducted by the Centers for Disease Control and Prevention showed that more than twice as many children and adolescents (86%) than adults are likely to buy the three most heavily advertised brands--Marlboro, Camel, and Newport. 60 Fed. Reg. 41332. This study demonstrated that children's choices of cigarettes and smokeless tobacco are "directly related to the amount and kind of advertising." Id.

The record also shows that advertising campaigns employing appealing imagery "have been particularly effective with children." 61 Fed. Reg. 44476; see also 60 Fed. Reg. 41333. For instance, the "Joe Camel" campaign, featuring a fanciful cartoon figure, had a dramatic effect on Camel's share of the youth market, increasing it from less than 3% in 1988, when "Joe Camel" was introduced, to over 13% by 1992. During the same period, the campaign had no effect on Camel's share of the adult market, which remained flat at 4%. Moreover, 30% of three-year-olds and more than 90% of six-year-olds were able identify "Joe Camel" as a symbol for smoking. 61 Fed. Reg. 44476-78; 60 Fed. Reg. 41333.

Further, internal tobacco company documents provided "convincing evidence" of "the company's intention to attract young smokers and so-called presmokers." 61 Fed. Reg. 44480. For example, one document from R.J. Reynolds stated that "if our Company is to survive and prosper, over the long-term we must get our share of the youth market." Id.

(quoting C.E. Teague, assistant director of research for R.J. Reynolds (1972)) (emphasis added). Another document recited that "[e]vidence now available . . . indicate[s] that the 14 to 18 year old group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained." 61 Fed. Reg. 44481 (quoting R.J. Reynolds, "Planning Assumptions and Forecast for the Period 19**-1986" (1976)) (emphasis added).

Further, the agency found that empirical evidence from the experiences of other countries showed that increases in advertising expenditures lead to increases in smoking. 61 Fed. Reg. 44487-93. These international studies provided "empirical evidence that restrictions on tobacco advertising, when given appropriate scope and when fully implemented, will reduce cigarette and smokeless tobacco use among children and adolescents." 61 Fed. Reg. 44493 (emphasis added).

The evidence led FDA to find that "young people . . . are also very impressionable and vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence," 61 Fed. Reg. 44398; that "cigarette and smokeless tobacco advertising has a powerful appeal to children and adolescents," 61 Fed. Reg. 44471; and that "the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products," 61 Fed. Reg. 44571. Thus, the agency concluded, "the evidence in this proceeding demonstrates that cigarette and smokeless

tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use." 61 Fed. Reg. 44489 (emphasis added).

Based on the record, the agency concluded that advertising restrictions are necessary to "ensur[e] that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people." 61 Fed. Reg. 44465. FDA further determined that "[t]o be effective, these restrictions must be comprehensive." 61 Fed. Reg. 44489-90.

For these reasons, FDA developed restrictions on tobacco advertising that "retain the informational function of advertising by permitting text-only advertising while removing color and imagery from those advertisements to which young people are unavoidably exposed." 61 Fed. Reg. 44469. The restrictions include: the use of a black-and-white, text-only advertising format, except in adult publications and adult-only facilities; a ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and public playgrounds; a prohibition on the sale or distribution (by tobacco companies and distributors) of non-tobacco products, such as hats and t-shirts, bearing a tobacco product brand name or logo; and a prohibition on sponsoring athletic, cultural or other events in the tobacco brand name. See 61 Fed. Reg. 44617-18.

QUESTIONS PRESENTED

1. Whether Congress has precluded FDA from regulating cigarettes and smokeless tobacco under the FDCA.

2. Whether cigarettes and smokeless tobacco are subject to jurisdiction under the FDCA because they are "intended to affect the structure or any function of the body."

3. Whether the restrictions imposed by FDA on advertising and other promotion of cigarettes and smokeless tobacco are consistent with the First Amendment to the United States Constitution.

ARGUMENT

CONGRESS HAS NOT PRECLUDED FDA FROM REGULATING CIGARETTES AND SMOKELESS TOBACCO UNDER THE FDCA

Plaintiffs argue that "Congress has withheld from FDA the authority to regulate tobacco products as customarily marketed." First Brief at 6. This argument presents two distinct issues: (1) whether "customarily marketed" cigarettes and smokeless tobacco are exempt from the FDCA when such products are "drugs" or "devices" under the Act;[4/] and (2) if the FDCA does not exempt cigarettes and smokeless tobacco from FDA jurisdiction, whether any other federal statute forecloses FDA from exercising that jurisdiction. The answer to both questions is no.

I. "Customarily Marketed" Cigarettes and Smokeless Tobacco Are Not Exempt from Regulation under the FDCA

A. Standard of Review: *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*

Judicial review of an agency's construction of the statute it administers must follow the two-step analysis set forth in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.:

[4/] The question of whether cigarettes and smokeless tobacco are intended to affect the structure or function of the body, and thus are "drugs" and/or "devices," is the logical starting point of the statutory construction analysis. However, plaintiffs have chosen to defer this issue until their Second Brief. For the convenience of the Court, the government will address the issues in the same order as plaintiffs and make cross-references where necessary.

> When a court reviews an agency's construction of the statute it administers, it is confronted with two questions: First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781-82, 81 L. Ed. 2d 694 (1984); accord Young v. Community Nutrition Inst., 476 U.S. 974, 980, 106 S. Ct. 2360, 2364, 90 L. Ed. 2d 959 (1986); Kofa v. INS, 60 F.3d 1084, 1087-88 (4th Cir. 1995).

Here, "the precise question at issue" is whether "customarily marketed" cigarettes and smokeless tobacco are exempt from regulation under the FDCA. See First Brief at 6. As shown below, the language, history and purpose of the FDCA demonstrate Congress' clear intent to regulate any product meeting the FDCA's definition of "drug" or "device," with no exception--explicit or implicit--for cigarettes and smokeless tobacco. Thus, this Court need not proceed past step one of the Chevron analysis. However, if the Court finds it necessary to undertake step two of the Chevron analysis, it should defer to FDA's determination that cigarettes and smokeless tobacco are drugs and devices under the Act because that determination is predicated on "a permissible construction of the statute."

B. *Chevron*, Step One

1. The FDCA Applies Broadly to Any Product Meeting the "Drug" or "Device" Definition

The Court's inquiry into whether Congress intended the FDCA to exempt cigarettes and smokeless tobacco begins with the text of the Act. Mead Corp. v. B.E. Tilley, 490 U.S.

714, 722, 109 S. Ct. 2156, 2162, 104 L. Ed. 2d 796 (1989); Kofa v. INS, 60 F.3d at 1088; see also Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54, 112 S. Ct. 1146, 1149, 117 L. Ed. 2d 391 (1992) ("in interpreting a statute a court should always turn first to one, cardinal canon before all others. We . . . must presume that a legislature says in a statute what it means and means in a statute what it says there"); Consumer Product Safety Comm'n v. GTE Sylvania, 447 U.S. 102, 108, 100 S. Ct. 2051, 2056, 64 L. Ed. 2d 766 (1980) ("the starting point for interpreting a statute is the language of the statute itself").[5/]

A product is subject to the FDCA if it meets one or more of the definitions in the Act. See 21 U.S.C. § 321. These definitions, which include "foods," "drugs," "devices," and "cosmetics," are stated as broad categories, rather than specific types of products (e.g., vegetable, stimulant, intravenous infusion pump, and skin moisturizer). Because no such comprehensive list is practicable and, as shown below, Congress intended the FDCA to have broad coverage, the fact that Congress has not expressly identified tobacco as being within the scope of the FDCA is completely consistent with the structure of the Act.

FDA's Rule is predicated on the agency's conclusion that cigarettes and smokeless tobacco are combination products consisting of the "drug" nicotine and "devices" intended to deliver nicotine to the body. "Drugs" and "devices" are specifically defined in the FDCA. 21 U.S.C. §§ 321(g), (h). These definitions do not exclude cigarettes or smokeless tobacco.

[5/] Despite this time-honored rule, plaintiffs focus almost exclusively on other laws to find Congress' intent in the FDCA. See, e.g., First Brief at 4 (Court must look to the "text, structure, context, and history of all relevant statutes") (emphasis added). As already noted, the question of whether the FDCA exempts tobacco from regulation is distinct from the question (addressed in Part II, infra) of whether any of the other statutes that plaintiffs cite forecloses FDA regulation of tobacco.

To the contrary, their "literal language" fully encompasses tobacco products intended to affect a structure or function of the body, and thus they are not limited by an implied exemption as plaintiffs assert. United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798, 89 S. Ct. 1410, 1418, 22 L. Ed. 2d 726 (1969).

The legislative history of the FDCA also fails to provide any support for an exemption for cigarettes and smokeless tobacco.[6/] This history demonstrates a clear Congressional intent that the FDCA's definitions of "drugs" and "devices" be applied broadly, without implied exemptions.

The Pure Food and Drugs Act of 1906 defined "drug" more narrowly than the 1938 FDCA, the current law, by focusing primarily on articles intended for therapeutic or medical use.[7/] In 1938, Congress expanded the definition of "drug" to include articles "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C). This expansion was intended to "amplif[y] and strengthen[]" the FDCA by extending its reach to "certain drugs that now escape regulation," including "[d]rugs intended for diagnosing illness or for remedying underweight or overweight or for otherwise affecting bodily structure or function . . . ." H.R. Rep. No. 75-2139, at 2 (1938), reprinted in 6 A Legislative History of the

---

[6/] Whether legislative history should be part of the Chevron step one analysis has not been conclusively resolved. See I Kenneth Culp Davis, Administrative Law Treatise, § 3.6 (3d ed. 1994). To whatever extent it is relevant, however, it does not support plaintiffs here.

[7/] See Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768, 769 (1906) (defining "drug" to include "all medicines and preparations recognized in the United States Pharmacopeia or National Formulary for internal or external use, and any substances or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals").

Federal Food, Drug, and Cosmetic Act and Its Amendments, at 301 (emphasis added) [hereinafter "Legislative History"]; see also id. at 302 ("These expansions [of the "drug" definition] are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law"); Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 336 (7th Cir. 1983) (expansion of drug definition necessary to cover products that are not alleged to be treatments for disease conditions); American Health Products Co. v. Hayes, 574 F. Supp. 1498, 1506 (S.D.N.Y. 1983) (structure-function provision enacted to "reach those products . . . which evaded regulation altogether because they were neither foods nor therapeutic agents"), aff'd, 744 F.2d 912 (2d Cir. 1984).

In 1938, Congress also created an entirely new category called "device[s]," to encompass "instrument[s], apparatus, . . . contrivance[s], . . . including any component, part, or accessory . . . intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(3). Congress determined that "[t]he expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." S. Rep. No. 74-646, at 1 (1935), reprinted in 4 Legislative History, at 93.

These definitional expansions are evidence of Congress' intent to make the FDCA broadly applicable. As the Supreme Court has stated:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates--and equally clearly, broader than any strict medical definition might otherwise allow. . . . [R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.

Bacto-Unidisk, 394 U.S. at 798, 89 S. Ct. at 1418 (emphasis added).

Thus, the language, legislative history, and remedial purpose of the FDCA all argue against reading into the Act an implied exemption for cigarettes and smokeless tobacco. Congress' intent was to subject to regulation under the FDCA any product, whatever its composition and including cigarettes and smokeless tobacco, whose intended use brings it within the terms of the FDCA's definitions of "drug" or "device."

2. Plaintiffs Fail To Demonstrate Any Congressional Intent To Exclude Cigarettes and Smokeless Tobacco from the FDCA

Plaintiffs make essentially three arguments for why the FDCA should be construed not to cover tobacco:

(a) Congress never intended to subject cigarettes and smokeless tobacco to regulation under the FDCA.

(b) FDA has repeatedly disclaimed jurisdiction over tobacco products except where such products are sold with medical claims.

(c) Congress has somehow "ratified" FDA's alleged disclaimer of jurisdiction over tobacco.

As shown below, these arguments, when assessed under the proper legal standards, fail to establish any intent by Congress to exclude cigarettes and smokeless tobacco from the FDCA's "drug" and "device" definitions.

a. The Absence of Specific Evidence of Congressional Intent To Regulate Cigarettes and Smokeless Tobacco under the FDCA Does Not Create an Implied Exemption for Tobacco

Plaintiffs argue that cigarettes and smokeless tobacco are exempt from regulation because the legislative history of the FDCA fails to demonstrate a clear congressional intent to include such products. First Brief at 8-10. This argument rests on the erroneous premise

that tobacco products must be excluded absent an unambiguously expressed legislative intent to include them. Instead, the broad scope and remedial purpose of the FDCA require the opposite analysis: products meeting the FDCA's definition of "drug" or "device" are included within the scope of the FDCA unless Congress has clearly stated otherwise.

Certain products are exempt from regulation under the FDCA, and Congress has stated those exemptions expressly.[8/] No exemption is stated for tobacco. Instead, the sole provision in the FDCA that mentions tobacco--a provision added very recently as part of the Act's new treatment of "dietary supplements"--avoids exempting tobacco from the Act's "drug" definition. See 21 U.S.C. § 321(ff), created by the Dietary Supplement Health and Education Act ("DSHEA") of 1994, Pub. L. No. 103-417, 108 Stat. 4325, 4327 (1994).

Plaintiffs argue that, in enacting the DSHEA, Congress reaffirmed its "understanding that the definitions of 'drug' and 'device' in the FDCA do not include tobacco." First Brief at 44 n.34. This argument makes no sense because the DSHEA had exactly the opposite effect. Section 321(ff) defines a new class, "dietary supplements," and then defines such products, for most purposes, as "food." 21 U.S.C. § 321(ff). Because many of these products were regulated previously as "drugs," the effect of section 321(ff), by removing such products from the "drug" definition, was to eliminate FDA's authority to regulate them as drugs. However, by exempting tobacco from this new class of "dietary supplements,"

[8/] See 21 U.S.C. § 321(i) (excluding "soap" from definition of "cosmetic"); see also 21 U.S.C. § 321(s) (excluding pesticide chemicals, color additives, new animal drugs, and other substances from the definition of "food additive"). Cf. Jeldness v. Pearce, 30 F.3d 1220, 1225 (9th Cir. 1994) ("When a statute lists specific exemptions, other exemptions are not to be judicially implied.").

1/6

Congress effectively prevented tobacco manufacturers from taking advantage of this categorical exclusion and preserved FDA's authority to regulate tobacco products as drugs.[9/]

The fact that Congress has expressly exempted some products from the FDCA, but not cigarettes or smokeless tobacco, convincingly negates the argument that Congress has ever intended to exempt tobacco products from the Act. See Russello v. United States, 464 U.S. 16, 23-24, 104 S. Ct. 296, 300-01, 78 L. Ed. 2d 17 (1983). This conclusion is corroborated further by the fact that Congress has expressly exempted tobacco products in other statutes.[10/]

[9/] As plaintiffs acknowledge (First Brief at 44 n.34), FDA's current investigation into tobacco products was underway and publicly known in 1994 when Congress enacted the DSHEA. Nevertheless, Congress did not amend the FDCA to prohibit FDA from regulating tobacco as a drug or device; indeed, it amended the Act in a way that avoided that result.

[10/] See 15 U.S.C. § 2052(a)(1)(B) (excluding "tobacco and tobacco products" from the definition of "consumer products" in the Consumer Product Safety Act); 15 U.S.C. § 1261(f)(2) (excluding "tobacco and tobacco products" from the definition of "hazardous substance" in the Federal Hazardous Substances Act); 15 U.S.C. § 2602(2)(B)(iii) (excluding "tobacco or any tobacco product" from the definition of "chemical substance" in the Toxic Substances Control Act); 21 U.S.C. § 802(6) (excluding "tobacco" from the definition of "controlled substance" in the Controlled Substances Act); 15 U.S.C. § 1459(a)(1) (excluding "tobacco or tobacco product" from the definition of "consumer commodity" in the Fair Packaging and Labeling Act).

Plaintiffs argue that Congress exempted tobacco products from these laws only when it had warning that such products would be regulated. First Brief at 44. This argument fails to explain, among other things, why Congress did not exempt tobacco products in the 1938 FDCA when it knew that tobacco products were subject to regulation under the 1914 regulatory policy, see U.S. Department of Agriculture Service and Regulatory Announcements, No. 13 (1914) (AR: Vol. 535, Ref. 96); or in the 1994 DSHEA when Congress was on notice that FDA was reviewing its tobacco policy.

b. FDA Has Not Renounced Its Jurisdiction over Cigarettes and Smokeless Tobacco

Plaintiffs contend that FDA cannot regulate "customarily marketed" cigarettes and smokeless tobacco today because FDA in the past allegedly renounced its authority to regulate such products. First Brief at 1, 11-12, 17-20. This argument is incorrect both factually and legally.

For more than 80 years, FDA has consistently maintained that it has authority to regulate any tobacco or nicotine product (and has in fact taken regulatory actions against such products) where the evidence before the agency establishes that the product is a "drug" or "device" as defined in the FDCA. The fact that FDA has not previously asserted regulatory authority over cigarettes and smokeless tobacco generally is inconsequential because until now the agency has not had evidence to warrant such action. Now that such evidence exists, FDA is fully justified in asserting this authority.

As early as 1914, the Bureau of Chemistry, FDA's predecessor, asserted jurisdiction over tobacco products as drugs under the 1906 Act when such products were labeled for the cure, mitigation, or prevention of disease, but not when they were "not so labeled and . . . used for smoking or chewing or as snuff and not for medicinal purposes." See U.S. Department of Agriculture Service and Regulatory Announcements, No. 13 (1914) (AR: Vol. 535, Ref. 96). This view was consistent with the extent of FDA's authority at that time.[11/]

[11/] The "medicinal purposes" language reflected the language of the "drug" definition in the 1906 Pure Food and Drugs Act. As noted earlier, this statutory definition was expanded in 1938 to include "articles intended to affect the structure or any function of the body," the definitional provision at issue in this case. See 21 U.S.C. § 321(g)(1)(C).

Thereafter, FDA continued to assert jurisdiction over cigarettes marketed with claims that met the statutory definition of "drug." See, e.g., United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes containing tartaric acid to reduce the appetite for food were intended to affect the structure or function of the body); United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336, 338-39 (D.N.J. 1953) (cigarettes claimed to prevent respiratory ailments were intended to treat or prevent disease).

It is true, of course, that FDA has stated on various occasions that it would not regulate cigarettes and smokeless tobacco in the absence of express therapeutic or structure/function claims. Such statements, however, were expressions of FDA policy based on the evidence; they did not manifest an intent by FDA to categorically renounce or deny its authority to regulate tobacco for all time and under all circumstances. Rather, the statements reflected the fact that, at the time they were made, the agency lacked sufficient evidence from which to conclude, in the absence of express claims, that cigarettes and smokeless tobacco were "drugs" based on their intended use.

Plaintiffs' discussion of FDA's prior position on tobacco is particularly inaccurate in its characterization of FDA's response to the two late 1970s ASH petitions. In these petitions, ASH asked FDA to assert jurisdiction over cigarettes as "drugs" (in 1977) and "devices" (in 1978). Plaintiffs repeatedly assert that, in denying these petitions (in 1977 and 1980, respectively), FDA disclaimed jurisdiction over cigarettes marketed without claims "as a matter of law." First Brief at 19, 20, 33, 39 (emphasis omitted). This assertion is incorrect.

In responding to ASH's 1977 petition, FDA stated the view that "FDA can assert jurisdiction over,cigarettes containing nicotine (or nicotine separately) when a jurisdictional basis for doing so exists, e.g., health claims made by the vendors . . . ." See Letter from FDA Commissioner Kennedy to ASH Executive Director Banzhaf (Dec. 5, 1977), at 1 (AR: Vol. 28, Ref. 240). FDA, however, found that the evidence ASH presented--statements and citations "that cigarettes are used by smokers to affect the structure or any functions of their bodies"--did not, without more, establish the intent of cigarette manufacturers. Id. at 3. FDA's denial of the ASH petition in 1977 thus does not constitute a binding agency policy to abdicate or limit its jurisdiction over tobacco. As the Court of Appeals for the District of Columbia expressly found, after reviewing FDA's action on this petition:

> Unlike petitioners, we do not read [the petition denial] to mean either that the Commissioner will never consider evidence of consumer intent or that he simply ignored the evidence presented to him this petition.

ASH v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980). The import of FDA's decision, rather, was that ASH's petition had failed to "meet the high standard established in cases where the statutory 'intent' is derived from consumer use alone." Id.[12/]

[12/] Plaintiffs quote selectively from the government's appellate brief in ASH. First Brief at 7, 10, 19-20. Even if these quotes presented a balanced view of the government's litigating position (which they do not), they would be of no legal significance. Heckler v. Chaney, 470 U.S. 821, 836 n.5, 105 S. Ct. 1649, 1658 n.5, 84 L. Ed. 2d 714 (1985). Plaintiffs do not fairly acknowledge FDA's view that the evidence in the record was insufficient to establish manufacturers' intent. Brief for Appellees at 12 (Plaintiffs' Ex. 4). Furthermore, the government's brief took express issue with the argument plaintiffs now make--i.e., that FDA's decision to deny the ASH petition constituted a "holding that, in the absence of therapeutic claims by manufacturers or vendors, cigarettes are not a "drug" . . . ." Brief for Appellees at 9 n.7.

In 1980, responding to ASH's second petition, FDA again stated its view that evidence of consumer use could be used to support a finding of intended use, even in the absence of express claims:

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

Letter from FDA Commissioner Goyan to ASH Executive Director Banzhaf (Nov. 25, 1980), at 8-9 (AR: Vol. 28, Ref. 238).

As the extensive administrative record compiled by FDA now demonstrates, there is abundant new evidence--evidence not available to FDA when it denied the ASH petitions--that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body," and thus are subject to regulation under the FDCA. 61 Fed. Reg. 45219-52. Specifically:

> (1) At the time FDA considered the ASH petitions, not a single public health organization had declared nicotine to be an addictive drug and no definitive publicly available studies had been done on its addictive properties. 61 Fed. Reg. 45228. Since 1980, however, the addictive nature of nicotine in cigarettes and smokeless tobacco has become universally accepted in the scientific community and therefore foreseeable to, indeed, beyond dispute by, any reasonable tobacco manufacturer. 61 Fed. Reg. 45228-33.

> (2) In 1980, there were no scientific studies demonstrating the proportion of cigarette smokers who were addicted. 61 Fed. Reg. 45234-35. It has since been established that 77-92% of cigarette smokers use cigarettes to satisfy addiction and that an estimated 75% of young smokeless tobacco users are similarly addicted. 61 Fed. Reg. 45233-35.

> (3) In 1980, there was virtually no publicly available information showing that tobacco manufacturers believed that smokers used cigarettes for nicotine, or that manufacturers designed cigarettes to provide adequate doses of nicotine. 61 Fed. Reg. 45237. Today, there is a wealth of evidence establishing that tobacco

> manufacturers not only know that people use tobacco to obtain the pharmacological effects of nicotine, but also that the manufacturers design their products to be used as nicotine delivery devices. 61 Fed. Reg. 45235-38.

This new evidence fully supports FDA's decision to change its previous position, and to conclude that currently marketed cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body," even without express structure/function claims, and are, therefore, subject to regulation under the FDCA.

Plaintiffs contend that "most" of this new evidence was available to FDA when it acted on the 1977 ASH petition. First Brief at 18-19. Plaintiffs fail to acknowledge, however, that many of the allegations in the ASH petition were unsubstantiated and, more importantly, that the current jurisdictional determination rests on premises not even alleged in the ASH petition. For example, FDA has now determined that the use of tobacco for the pharmacological effects of nicotine is "foreseeable" to any reasonable manufacturer, not only because nicotine is addictive per se (as the ASH petition did contend), but also because its addictive nature has been universally accepted by the scientific community. FDA also has now found that consumer use can independently support a finding of intended use, not simply because "many" smokers are addicted, as contended in the ASH petition, but because studies now document that over 75% of cigarette and smokeless tobacco users are addicted and use nicotine to satisfy their addiction. Finally, FDA now has evidence that manufacturers are well aware that their products cause pharmacological effects, including nicotine addiction, and actively design their products to control and manipulate nicotine delivery. The ASH petition contained no allegations or evidence concerning tobacco manufacturers' actual intent.

Accordingly, FDA's denial of the ASH petitions, and other statements FDA made in the past to the effect that the agency lacked authority to regulate tobacco products absent express claims, do not, as plaintiffs claim, strait-jacket the agency and foreclose its current regulatory initiative. Rather, it is entirely appropriate, and indeed desirable, for the agency to adapt its position to the new evidence. See Rust v. Sullivan, 500 U.S. 173, 186-87, 111 S. Ct. 1759, 1769, 114 L. Ed. 2d 233 (1991) ("An agency is not required to establish rules of conduct to last forever, but rather must be given ample latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted); Chevron, 467 U.S. at 838, 104 S. Ct. at 2780 ("An agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."). Indeed, the possibility of such a change was expressly acknowledged by the court in ASH, which stated:

> Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.

ASH, 655 F.2d at 242 n.10.

c. Neither Unenacted Bills Nor Statements by Congressional Members or Committees Are Evidence of Legislative Intent Regarding the FDCA's Application to Cigarettes and Smokeless Tobacco

Plaintiffs ask this Court to infer Congress' intent to exempt tobacco from the FDCA based upon an alleged congressional "ratification of FDA's repeated statements over more than 80 years that the agency has no such authority." First Brief at 38. This argument fails on several grounds. As already shown, it is simply not the case that FDA has categorically

renounced its jurisdiction over cigarettes and smokeless tobacco. Instead, the historical record demonstrates that FDA, since at least 1914, has regulated tobacco products to the full extent supported by the available evidence.

Plaintiffs' argument is without merit for two additional reasons. First, plaintiffs point to no proper evidence that Congress ever "ratified" alleged prior positions taken by the agency. The unenacted legislation and isolated statements by later Congresses that plaintiffs rely upon are not evidence either of Congress' intent under the FDCA or of its ratification of previous FDA statements. Second, even if FDA had categorically renounced jurisdiction over tobacco products sold without express claims, and even if Congress had ratified that policy, plaintiffs' argument would still fail because Congress has done nothing to foreclose FDA from reevaluating and revising its position--as it has now done--in the face of new evidence.

i. Unenacted Bills

Plaintiffs cite numerous bills introduced in Congress over the years to specifically grant FDA authority over tobacco. First Brief, Attachment A. None of these bills, which plaintiffs claim Congress "rejected" (First Brief at 8, 26 n.17), was ever formally acted on by Congress; indeed, none was even reported out of committee. As the Supreme Court has stated, unenacted proposals are not proper evidence of Congress' intent:

> [F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute. . . . Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.

Central Bank of Denver v. First Interstate Bank of Denver, 511 U.S. 164, 187, 114 S. Ct. 1439, 1453, 128 L. Ed. 2d 119 (1994) (citations and internal quotation marks omitted); see also Brecht v. Abrahamson, 507 U.S. 619, 632, 113 S. Ct. 1710, 1719, 123 L. Ed. 2d 353 (1993) ("[a]s a general matter, we are reluctant to draw inferences from Congress' failure to act") (citations and internal quotation marks omitted).[13/]

Nevertheless, even had Congress formally "rejected" these proposals, as plaintiffs claim, that fact would not support the plaintiffs' argument that Congress intended to exclude customarily marketed tobacco products from the FDCA. Had Congress actually "rejected" such bills, it would show only that Congress did not intend to give FDA jurisdiction over tobacco products as a special class--i.e., when those products, based on the then-available evidence, were not "drugs" or "devices." Congress' alleged rejection of such proposals would not evidence any intent at all with respect to whether Congress intended cigarettes and smokeless tobacco to be regulated based on factual evidence showing that they are "drugs" and "devices" under the Act.

ii. Statements of Members or Committees

Isolated statements by members or committees of Congress similarly are not proper evidence of congressional intent. Such statements "simply represent[] the views of one informed person on an issue about which others may (or may not) have thought differently." Heintz v. Jenkins, 115 S. Ct. 1489, 1492, 132 L. Ed. 2d 395 (1995). Post-enactment

---

[13/] Bills have also been proposed, but not enacted, that would have explicitly excluded tobacco products from the reach of the Act. See, e.g., S. 1295, 104th Cong. (1995); H.R. 2265, 104th Cong. (1995); H.R. 2283, 104th Cong. (1995). Under plaintiffs' theory, the fact that such legislation was proposed but not enacted would mean that Congress intends FDA to have jurisdiction over tobacco products.

statements by members or committees are also of little help in determining Congress' intent under the FDCA. Central Bank, 114 S. Ct. at 1452 ("the interpretation given by one Congress (or a committee or Member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute") (citations and internal quotation marks omitted).

iii. Ratification of a Prior Agency Position

Even if (as was not the case) Congress ratified a past FDA policy renouncing jurisdiction over tobacco, that ratification would not preclude FDA from adopting a new policy based on the new evidence. As the Supreme Court has made clear:

> While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation . . . even an unequivocal ratification . . . of [a prior regulatory standard] would not connote approval or disapproval of an agency's later decision to rescind the regulation.

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 45, 103 S. Ct. 2856, 2867-68, 77 L. Ed. 2d 443 (1983) (citations omitted); see also Massachusetts v. Secretary of Health and Human Services, 899 F.2d 53, 61 (1st Cir. 1990) ("the ratification of one agency policy by Congress does not preclude a change in that policy"), vacated on other grounds sub nom. Sullivan v. Massachusetts, 500 U.S. 949, 111 S. Ct. 2252, 114 L. Ed. 2d 706 (1991); ASH, 655 F.2d at 242 n.10 (FDA is not "irrevocably bound by any long-standing interpretation [of its authority to regulate tobacco] and representations thereof to the legislative branch").

As demonstrated above, Congress intended to include within the coverage of the FDCA any product meeting the FDCA's definitions of "drug" or "device." That result is supported not only by the plain language of the statute, but also the history of the "drug" and "device" provisions added to the statute in 1938, and the statute's remedial purpose. The

FDCA does not expressly exempt cigarettes or smokeless tobacco, and there is no reliable evidence of any congressional intent to impliedly exempt these products when they are "drugs" or "devices" based on intended use. Because "the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43, 104 S. Ct. at 2781-82.

C. *Chevron*, Step Two: FDA's Application of the FDCA to Cigarettes and Smokeless Tobacco Is "Based on a Permissible Construction of the Statute"

Should this Court decide that the FDCA is ambiguous with respect to its application to tobacco products, the second step of the Chevron analysis would require the Court to determine "whether the agency's answer is based on a permissible construction of the statute." Chevron, 467 U.S. at 842-43, 104 S. Ct. at 2781-82. If the agency's interpretation is permissible, Chevron instructs the Court to defer to that interpretation. Chevron, 467 U.S. at 844, 104 S. Ct. at 2782 (court must give agency's interpretation "controlling weight" unless it is "arbitrary, capricious, or manifestly contrary to the statute"); see also Holly Farms Corp. v. NLRB, 116 S. Ct. 1396, 1401, 1406, 134 L. Ed. 2d 593 (1996); National R.R. Passenger Corp. v. Boston and Maine Corp., 503 U.S. 407, 417, 112 S. Ct. 1394, 1401, 118 L. Ed. 2d 52 (1992).

The deference due FDA's interpretation is not diminished, as plaintiffs contend (First Brief at 48), merely because FDA has not previously regulated cigarettes and smokeless tobacco marketed without therapeutic claims. The Supreme Court has expressly held that an agency's statutory construction must be deferred to under Chevron even if that construction "'represents a sharp break with prior interpretations . . . .'" Rust, 500 U.S. at 186-87, 111

S. Ct. at 1769 (quoting Chevron, 467 U.S. at 862, 104 S. Ct. at 2791); see also Smiley v. Citibank, 116 S. Ct. 1730, 1733, 135 L. Ed. 2d 25 (1996) ("neither antiquity [of the agency's interpretation] nor contemporaneity with the statute is a condition of validity"); id. at 1734 ("change is not invalidating, since the whole point of Chevron is to leave the discretion provided by the ambiguities of a statute with the implementing agency"); American Trucking Ass'ns, Inc. v. Atchison, Topeka & Santa Fe Ry. Co., 387 U.S. 397, 416, 87 S. Ct. 1608, 1618, 18 L. Ed. 2d 847 (1967) (agency, "faced with new developments or in light of reconsideration of the relevant facts and its mandate, may alter its past interpretation and overturn past administrative rulings and practice").

When an agency revises its position, it is required to support its revised position by a "reasoned analysis." Motor Vehicle Mfrs., 463 U.S. at 42, 103 S. Ct. at 2866. Here, FDA's determination that tobacco products are "drugs" and "devices" within the meaning of the FDCA is entirely reasonable given newly available factual evidence. Through its rulemaking process, FDA has developed reliable evidence demonstrating that cigarettes and smokeless tobacco are intended to affect the structure or a function of the body. The agency has analyzed this evidence and explained its findings in extraordinary detail. Based on this new evidence, FDA has concluded that these products are "drugs" and "devices" subject to regulation under the FDCA. As discussed in greater detail in response to plaintiffs' Second Brief, this determination is fully consistent with the text of the statute, and is supported as well by the statute's history and public health purpose. Thus, FDA's application of the statute is clearly permissible, is well-supported by evidence and reasoned analysis, and should be afforded deference by this Court.

Finally, even if FDA's application of the FDCA to cigarettes and smokeless tobacco constitutes a sharp break from prior legal interpretations of the statute, this policy should still be accorded Chevron deference because it is based on a permissible construction of the statute and is supported by "reasoned analysis" of the facts and law. Motor Vehicles Mfrs., 463 U.S. at 42, 103 S. Ct. at 2866; see also id. at 57, 103 S. Ct. at 2874 ("[a]n agency's view of what is in the public interest may change, either with or without a change in circumstances") (citations and internal quotation marks omitted); Rust, 500 U.S. at 187, 111 S. Ct. at 1769 (failure of prior policy, reevaluation of original intent of statute, and shift in attitude provided reasoned analysis).

II. The Federal Cigarette Labeling and Advertising Act, Comprehensive Smokeless Tobacco Health Education Act, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act Do Not Foreclose FDA from Regulating Cigarettes and Smokeless Tobacco under the FDCA

As explained above and discussed in more detail in response to plaintiffs' Second Brief, FDA is authorized under the FDCA to regulate any product, cigarettes and smokeless tobacco included, when such product is "intended to affect the structure or any function of the body." Plaintiffs argue that this authority is preempted or precluded by the Federal Cigarette Labeling and Advertising Act ("FCLAA"), the Comprehensive Smokeless Tobacco Health and Education Act ("CSTHEA"), and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Reorganization Act"). Here, too, plaintiffs are wrong.

A. No Statute, or Combination of Statutes, Can Override the FDCA in the Absence of Express Preclusion or Other Clearly Expressed Congressional Intent

There is a very strong presumption against the implied repeal of one statute by another. As the Fourth Circuit has recognized:

> The Supreme Court has frequently admonished that repeals of express statutory provisions by implication from later-enacted statutes are not favored, and will not be found unless congressional intent to repeal is clear and manifest. Instead, it is presumed that Congress legislates with knowledge of former related statutes, and will expressly designate the provisions whose application it wishes to suspend, rather than leave that consequence to the uncertainties of implication compounded by the vagaries of judicial construction.

United States v. Lund, 853 F.2d 242, 247-48 (4th Cir. 1988) (citations and internal punctuation omitted) (emphasis added); see also Connecticut Nat'l Bank, 503 U.S. at 253, 112 S. Ct. at 1149; Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1018, 104 S. Ct. 2862, 2880-81, 81 L. Ed. 2d 815 (1984); Mowbray v. Kozlowski, 914 F.2d 593, 598 (4th Cir. 1990).

For a court to find that one federal statute has repealed another:

> "[T]he intention of the legislature to repeal must be clear and manifest." . . . In practical terms, this "cardinal rule" means that "[i]n the absence of some affirmative showing of an intention to repeal, the only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable."

Tennessee Valley Auth. v. Hill, 437 U.S. 153, 189, 98 S. Ct. 2279, 2299, 57 L. Ed. 2d 117 (1978) (citations omitted). The "irreconcilable conflict" required is a conflict

> in the sense that there is a positive repugnancy between [the two statutes] or that they cannot mutually coexist. It is not enough to show that the two statutes produce differing results when applied to the same factual situation, for that no more than states the problem.

Radzanower v. Touche Ross & Co., 426 U.S. 148, 155, 96 S. Ct. 1989, 1993, 48 L. Ed. 2d 540 (1976) (emphasis added).

As demonstrated below, none of the statutes on which plaintiffs rely manifests an intent to restrict the FDCA's application to cigarettes and smokeless tobacco. The FCLAA and CSTHEA contain express preemption provisions that control this issue. Furthermore, there is no positive repugnancy between these statutes and the FDCA, nor any reason why FDA's Rule and these other statutes cannot mutually coexist.

B. Federal Cigarette Labeling and Advertising Act

The FCLAA requires cigarette manufacturers to include on packages and in advertising the now-familiar Surgeon General's health-hazard warnings, 15 U.S.C. § 1333; preempts certain governmental actions relating to cigarette labeling and advertising, 15 U.S.C. § 1334; bans broadcast advertising of cigarettes and little cigars, 15 U.S.C. § 1335; and provides for governmental research into the health effects of cigarette smoking, 15 U.S.C. §§ 1337, 1341.

Plaintiffs argue very generally that the preamble to the FCLAA,[14/] and the

---

[14/] The preamble states:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby--(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any

(continued...)

"comprehensiveness" of the statute, give it a broad preclusive effect foreclosing any regulation of cigarettes and smokeless tobacco under the FDCA. First Brief at 14, 30-31. A similar argument was raised and rejected in Banzhaf v. FCC, 405 F.2d 1082 (D.C. Cir. 1968), cert. denied, 396 U.S. 842 (1969). The petitioners in Banzhaf, like the plaintiffs here, contended that the "comprehensive Federal program to deal with cigarette labeling and advertising" described in the FCLAA's preamble "definitively balanced the conflicting interests of the health of the public and the health of the economy," thus precluding any other federal regulation. 405 F.2d at 1088. The D.C. Circuit disagreed: "On the contrary, there are positive indications that Congress's 'comprehensive program' was directed at the relatively narrow specific issue" of regulation of cautionary statements regarding smoking and health on cigarette packages. Id. at 1089.

The Banzhaf Court thus held that the FCLAA did not preclude the FCC from imposing requirements related to tobacco advertising that did not mandate particular statements in such advertising:

> Nothing in the Act indicates that Congress had any intent at all with respect to other types of regulation by other agencies--much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly--especially where it was careful to include a section entitled 'Preemption' specifically forbidding designated types of regulatory action.

405 F.2d at 1089.[15/]

[14/](...continued)
relationship between smoking and health.

15 U.S.C. § 1331.

[15/] While the FCLAA's preemption provisions were later amended, these amendments (continued...)

Banzhaf directly refutes plaintiffs' contention that "[e]xclusion of FDA from regulation of cigarettes was indispensable to Congress' program." First Brief at 14 (emphasis in original). If Congress had intended to foreclose FDA from regulating cigarettes in the FCLAA, it would have done so expressly. Banzhaf, 405 F.2d at 1089; see also Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517, 112 S. Ct. 2608, 2618, 120 L. Ed. 2d 407 (1992) ("the preemptive scope of the [FCLAA] is governed entirely by the express language of § 5 [section 1334]"). The FCLAA's preemption provision, however, does not mention FDA and does not foreclose FDA jurisdiction over cigarettes or any specific provision of its tobacco regulation.

The FCLAA's preemption provision, in relevant part, states as follows:

> (a) No statement relating to smoking and health, other than the statement required by section 1333 of this title [15 U.S.C. § 1333], shall be required on any cigarette package.

15 U.S.C. § 1334(a).[16/] This provision is drafted narrowly to prohibit government agencies from requiring any (1) statement, (2) relating to smoking and health, (3) on any cigarette package, other than those required by the FCLAA itself.

[15/](...continued)
were "limited entirely to State or local requirements or prohibitions in the advertising of cigarettes." S. Rep. No. 91-566 (1970), reprinted in 1970 U.S.C.C.A.N. 2652, 2663.

[16/] A second provision in the FCLAA refers to, and preempts, certain state laws. Therefore, it is not relevant to the Court's inquiry here. See 15 U.S.C. § 1334(b) ("No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.") (emphasis added).

Thus, section 1334(a) "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels . . . ." Cipollone, 505 U.S. at 518, 112 S. Ct. at 2618 (emphasis added); see also H.R. Rep. No. 89-449 (1965), reprinted in 1965 U.S.C.C.A.N. 2350, 2350 (FCLAA prohibits "the requirement of any other caution statement on the labeling of cigarettes under laws administered by any Federal, State, or local authority") (emphasis added). This provision does not bar regulations that do not mandate statements or that require statements on cigarette packages that are not related to smoking and health.

The bulk of FDA's Rule, which is not concerned at all with statements on cigarette packages, is not even arguably precluded by the FCLAA's preemption language. There is no basis, therefore, for plaintiffs' overblown claims (First Brief at 31) that these regulations "strike[] at the heart of," are "irreconcilable" with, or "collide with" the FCLAA.

FDA's Rule requires only two "statements" on cigarette packages. These two provisions are the requirements that cigarette packages state the "established name" of the product (e.g., "cigarettes," "cigarette tobacco"), 21 C.F.R. § 897.24, and that the packages bear the statement: "Nicotine-Delivery Device For Persons 18 or Older." 21 C.F.R. § 897.25. As FDA has explained, the purpose of the "established name" requirement is to provide basic information to consumers coming into contact with a regulated product. 61 Fed. Reg. 44462. The required statement that cigarettes are a "Nicotine-Delivery Device For Persons 18 or Older," similarly advises consumers about the intended use of cigarettes, specifically that the product is intended for purchasers who are at least 18 years of age. 61 Fed. Reg. 44464, 44544. Neither requirement is preempted because they do not relate to

smoking and health[17] and, thus, are not "particular cautionary statements" of the type precluded by the FCLAA.[18]

Plaintiffs argue that FDA's Rule is further precluded due to other alleged conflicts with the FCLAA, including FDA's asserted authority to ban tobacco products altogether. First Brief at 31-35. These alleged conflicts are either non-existent or purely hypothetical.

1. Plaintiffs argue that Congress, in the FCLAA, determined "that print advertising of tobacco products should remain lawful, so long as it carries the congressionally-mandated warnings." Id. at 32. The FCLAA says nothing of the sort. Section 1334(a), as noted, only preempts requiring statements relating to smoking and health, other than those prescribed by the FCLAA itself, on cigarette packages. Section 1334(b), as noted, restricts only cigarette advertising or promotion "requirement[s] or prohibition[s] . . . imposed under State law," and thus is inapplicable.

2. Plaintiffs argue that the "adequate directions for use" provision of the FDCA, 21 U.S.C. § 352(f)(1), also conflicts with the FCLAA. First Brief at 32-33. This conflict is

---

[17] For this same reason, section 1334(a) does not preclude tax regulations that require cigarette labels to describe the type and quantity of cigarettes in a package. See 27 C.F.R. § 270.215. Cf. Cipollone, 505 U.S. at 523-31 (holding that common law claims against a cigarette manufacturer for breach of express warranty, misrepresentation, intentional fraud, and conspiracy are not "based on smoking and health," and thus are not preempted by section 1334(b)).

[18] Furthermore, even if these two specific requirements were preempted by section 1334(a) that would be a basis for voiding these requirements only, not, as plaintiffs argue, for denying FDA's jurisdiction generally or voiding any other provision of FDA's Rule. Radzanower v. Touche Ross & Co., 426 U.S. at 155, 96 S. Ct. at 1994 ("'Repeal is to be regarded as implied only if necessary to make the (later enacted law) work, and even then only to the minimum extent necessary.'") (quoting Silver v. New York Stock Exchange, 373 U.S. 341, 357, 83 S. Ct. 1246, 1257, 10 L. Ed. 2d 389 (1963)) (emphasis added).

non-existent. FDA's rule exempts tobacco from the adequate directions for use requirement. This fact demonstrates how the Rule and the FCLAA can mutually coexist; it wholly fails to demonstrate a positive repugnancy that would require preemption. Plaintiffs also argue that FDA has no authority to exempt tobacco products from the "adequate directions" requirement, but that is wrong. The authority to exempt products from the adequate directions requirement does not apply solely to prescription drugs, as plaintiffs claim, nor, as FDA has explained (61 Fed. Reg. 44464), does it require further directions for use in circumstances where, as here, they would contribute nothing to the protection of public health. 21 U.S.C. § 352(f)(1).

3. Plaintiffs argue that FDA's asserted authority to require package inserts requires preclusion of FDA's Rule. First Brief at 33. This alleged conflict is currently non-existent, however, and thus fails to offer a positive repugnancy or other reason why the FDCA and FCLAA cannot mutually coexist. This argument, for the reasons given above, is also without merit in light of section 1334(a)'s narrow preemption language.

4. Finally, plaintiffs argue for preclusion based on a hypothetical FDA ban of tobacco products. Even if FDA did ban tobacco products, that action would not necessarily be precluded by the FCLAA, CSTHEA, or any other statute because the plaintiffs' claim that Congress intended to preclude such an action is unsupported. Cf. Banzhaf, 405 F.2d at 1090 ("While it is possible that had the FCC then anticipated its cigarette ruling, Congress would have expressly prohibited it, that possibility must remain in the realm of speculation. We must decide questions of legislative intent by the lights we have, not by those we might have had."). Congress' intent to give FDA broad authority to regulate "drugs" and "devices,"

coupled with the new evidence of the intended use of these products--evidence not available to Congress when it enacted the FCLAA--argues for just the opposite result.

For now, however, this alleged conflict is entirely hypothetical given FDA's conclusion that a ban on these products would not be "the appropriate public health response under the [A]ct." 61 Fed. Reg. 44398. The possibility of a future conflict, even if irreconcilable, would fail to demonstrate any positive repugnancy now, nor provide any reason why these statues cannot coexist.

As the foregoing demonstrates, the express preemption language in the FCLAA does not foreclose FDA jurisdiction over "customarily marketed" tobacco products in general, nor does it preempt any specific provision of FDA's Rule. There is no "positive repugnancy" between the FCLAA and the FDCA, nor any reason why these statutes "cannot mutually coexist." Radzanower v. Touche Ross & Co., 426 U.S. at 155, 96 S. Ct. at 1993. Thus, the FCLAA does not preempt or foreclose FDA's Rule.

C. Comprehensive Smokeless Tobacco Health Education Act

The CSTHEA regulates smokeless tobacco in essentially the same manner as the FCLAA regulates cigarettes. It prescribes health-hazard warnings, 15 U.S.C. § 4402; preempts only specified governmental actions relating to labeling and advertising regarding smoking and health, 15 U.S.C. § 4406; bans broadcast advertising, 15 U.S.C. § 4402(f); and provides for governmental research into health effects, 15 U.S.C. §§ 4401, 4407.

The CSTHEA also contains express preemption language, which is closely analogous to the preemption provision in the FCLAA. It states:

> No statement relating to the use of smokeless tobacco products and health, other than the statements required by [15 U.S.C. § 4402], shall be required by

any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

15 U.S.C. § 4406(a) (emphasis added).[19/]

Like the FCLAA's preemption clause, the CSTHEA's preemption provision only prevents federal agencies from requiring additional cautionary statements relating to the use of smokeless tobacco and health in smokeless tobacco packaging. It also preempts any additional such requirements in advertising. It does not preempt FDA jurisdiction generally, nor does it foreclose the Rule that FDA has adopted.

Only three provisions in the Rule relate to "statements" on the packaging or in the advertising of smokeless tobacco: 21 C.F.R. §§ 897.24, 897.25, and 897.32(c). The first two of these provisions are package label requirements that are identical to the requirements for cigarettes. Section 897.24 requires that packages of smokeless tobacco state the "established name" of the product; section 897.25 requires that smokeless tobacco package bear the statement: "Nicotine-Delivery Device For Persons 18 or Older." The third provision imposes these same requirements for smokeless tobacco advertising.

As explained above in the discussion of the FCLAA, none of these requirements "relat[es] to the use of smokeless tobacco and health." Thus, FDA's requirements are not preempted under section 4406(a) of the CSTHEA just as they are not preempted under the FCLAA.

[19/] The second preemption paragraph affects only state and local laws. 15 U.S.C. § 4406(b).

Plaintiffs' claim that the CSTHEA has broad preclusive effect over FDA's Rule is no more persuasive than its assertion with respect to the FCLAA. Like the FCLAA, the CSTHEA contains express preemption language, which is narrowly drawn and is controlling. Banzhaf, 405 F.2d at 1089. The narrow scope of the CSTHEA preemption provision leaves ample room for other federal requirements. See id. at 1089; see also 61 Fed. Reg. 44544-45.[20/]

Like the FCLAA, therefore, the CSTHEA neither manifests a clear congressional intention to repeal the FDCA, nor does the CSTHEA irreconcilably conflict with FDA's Rule. Thus, the CSTHEA does not preempt or foreclose FDA's Rule.

D. Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act

Plaintiffs argue that FDA is foreclosed from regulating tobacco products by the ADAMHA Reorganization Act, which, among other things, creates an incentive for states to enforce prohibitions on tobacco sales to minors. This argument is unsupported by the text, the legislative history, and the purpose of this legislation.

The ADAMHA Reorganization Act restructured several federal substance abuse and mental health programs in "an attempt to strengthen the federal effort to combat drug abuse, alcohol abuse and mental illness." S. Rep. No. 102-131 (1992), reprinted in 1992 U.S.C.C.A.N. 277, 278. A substantial part of this reorganization involved replacing the

---

[20/] In its supplemental brief, UST argues that the mere fact Congress enacted statutes relating specifically to tobacco proves that the FDCA does not cover tobacco. UST Brief at 6-7. If statutory redundancies were rare, there might be some logic to this argument; however, "[r]edundancies across statutes are not unusual events." Connecticut Nat'l Bank v. Germain, 503 U.S. at 253, 112 S. Ct. at 1149. Indeed, if plaintiffs were correct, FDA would not have jurisdiction over cigarettes and smokeless tobacco sold with express claims--jurisdiction that even plaintiffs do not question. See, e.g., First Brief at 1 n.2.

single federal block grant that previously had covered substance abuse and mental health services with "two discrete block grants, one limited to drug and alcohol abuse and the second for community mental health services." H.R. Rep. No. 102-464, at 54 (1992). The purpose of the reorganization was to help ensure that congressional appropriations intended for substance abuse were not instead allocated by the States to community mental health services. Id.

To receive funds under the substance abuse block grant program, States must conform to a number of conditions. Of these conditions, only a few relate to the availability of tobacco to children under the age of 18. They require States to:

(1) prohibit sales of tobacco to children under 18 (42 U.S.C. § 300x-26(a)(1));

(2) enforce that prohibition "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18" (42 U.S.C. § 300x-26(b)(1));

(3) conduct annual random, unannounced inspections of tobacco retailers (42 U.S.C. § 300x-26(b)(2)(A)); and

(4) make annual reports to HHS concerning the method and effects of the State enforcement efforts (42 U.S.C. § 300x-26(b)(2)(B)).

Plaintiffs contend that these ADAMHA tobacco conditions are more than just conditions States must satisfy in order to receive federal substance abuse block grant funds. According to plaintiffs, the ADAMHA Reorganization Act represents an all-encompassing, last-word pronouncement of federal policy on underage smoking, a policy which, in their view, delegates to the States exclusive responsibility for reducing underage smoking. Proceeding from this unsupported and illogical premise, plaintiffs then argue that FDA's Rule is invalid because it impermissibly conflicts with that delegation. See generally First

Brief at 35-37; Convenience Stores Brief at 3-14; Brief of Amicus Commonwealth of Virginia at 17-19.

Nothing in the text or legislative history of the ADAMHA Reorganization Act supports plaintiffs' argument. The statute and relevant congressional reports are silent as to any effect the tobacco provisions of the block grant would have on other federal statutes (such as the FDCA) or regulations adopted under those statutes. Because of this total absence of any evidence that Congress "had any intent at all with respect to other types of regulation by other agencies--much less that it specifically meant to foreclose all such regulation," Banzhaf v. FCC, 405 F.2d at 1089, plaintiffs' claim that the ADAMHA Reorganization Act forecloses FDA regulation of tobacco must be rejected.

The illogic of plaintiffs' contention that the ADAMHA Amendments essentially nullified any other federal regulation of tobacco is starkly revealed by the implications this argument would have for other aspects of the ADAMHA substance abuse block grant, or for other federal tobacco-control programs. For example, as a separate condition for receiving ADAMHA substance abuse funds, states must meet certain requirements for programs involving the treatment of intravenous drug abuse. See 42 U.S.C. § 300x-23. Surely plaintiffs would not contend that by establishing these requirements Congress foreclosed any other federal regulation of narcotics or other dangerous drugs. Similarly, it would be illogical to conclude, as plaintiffs' argument would suggest, that the ADAMHA Amendments impliedly repealed other block grants, such as the Preventive Health and Health Services Block Grant ("PHHSBG"), 42 U.S.C. § 300w, which have applications to tobacco use. See generally 61 Fed. Reg. 1492-93 (1996) (noting that "strategies to prevent tobacco use among

all populations, including minors," undertaken pursuant to the PHHSBG, would act to reinforce state activities under the ADAMHA tobacco conditions).

By emphasizing the flexibility the ADAMHA block grant affords States in meeting the conditions, plaintiffs highlight the illogic of their argument that the ADAMHA block grant statute impliedly preempts the FDA Rule. As a legal matter, a State may refuse altogether to accept a block grant or may choose to accept the penalty that results from the failure to meet the tobacco conditions. If a State simply follows one of those courses, there is no ADAMHA-directed tobacco policy in that State. This discretionary block grant scheme can hardly have the effect of impliedly precluding further federal requirements.

Plaintiffs also contend that FDA's Rule impermissibly conflicts with the ADAMHA Reorganization Act because the Rule may preempt states from undertaking certain tobacco policies in furtherance of the ADAMHA tobacco conditions. As FDA has observed, however, the Rule will not affect many aspects of state regulation of underage smoking.[21/] For example, FDA's Rule will not prevent states from separately enforcing their own laws prohibiting sales to children under 18; from restricting the places where tobacco may be sold; and from imposing other restrictions on access. See 61 Fed. Reg. 44548-50. Thus, in many circumstances, there will be no conflict between the ADAMHA Reorganization Act and FDA's Rule. As the Supreme Court has held, "[b]ecause giving effect to [two overlapping statutes] would not render one or the other wholly superfluous," neither should

---

[21/] The limited number of state and local requirements that will be preempted may qualify for an exemption from preemption under 21 U.S.C. § 360k(b). See 61 Fed. Reg. 44548; see also 61 Fed. Reg. 57685 (1996) (notice regarding the availability of exemptions from preemption).

be given preemptive effect over the other. Connecticut Nat'l Bank v. Germain, 503 U.S. at 253, 112 S. Ct. at 1149.[22/]

III. The Separation of Powers Doctrine Does Not Prohibit FDA's Regulation of Tobacco Products

As a variant of their theme that Congress has precluded FDA from regulating cigarettes and smokeless tobacco products, plaintiffs and certain amicus curiae maintain that FDA's assertion of jurisdiction violates the separation of powers doctrine. First Brief at 41-43; Brief of Amicus North Carolina at 8-11. Because, as already demonstrated, FDA has the authority under the FDCA to regulate tobacco products, the separation of powers argument must fail.

Under the Constitution, Congress is provided with the "law-making power," and the Executive Branch may not act unless authorized by the Constitution or by statute to do so. Youngstown Sheet and Tube Co. v. Sawyer, 343 U.S. 579, 585-88, 72 S. Ct. 863, 866-67, 96 L. Ed. 1153 (1952). Nevertheless, Congress may delegate its regulatory authority to agencies of the executive branch. Chrysler Corp. v. Brown, 441 U.S. 281, 302, 99 S. Ct.

[22/] Plaintiffs also assert that the Controlled Substances Act, 21 U.S.C. § 801, et seq. (CSA) somehow supports the argument that the FDCA's drug definition requires express claims by the manufacturer or vendor. First Brief at 16 n.13. Plaintiffs have failed to cite any authority in the CSA or its legislative history for their conclusion that "the FDCA does not reach [addictive drugs] in the absence of claims." Id. Indeed, Congress has always understood that the definition of "drug" under the FDCA includes psychoactive drugs (provided the other parts of the definition are met). The CSA was designed to combat drugs subject to abuse, see H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. 4566; by defining "controlled substance" to include "drug" under the FDCA, Congress demonstrated that it understood that the FDCA covered drugs subject to abuse. Furthermore, the FDCA specifically provides for FDA regulation of "habit-forming drug[s]." See 21 U.S.C. § 353(b)(1).

1705, 1718, 60 L. Ed. 2d 208 (1979). This grant of authority need not be specific. Id. at 308, 99 S. Ct. at 1720-21.[23/]

Plaintiffs' separation of powers argument, therefore, is nothing more than plaintiffs' statutory jurisdiction claim dressed in constitutional clothes; that is, either FDA has authority to regulate tobacco products under the FDCA or it does not. Because Congress exercised its lawmaking power to assign FDA the duty and authority to regulate any product that is a drug or device as defined under the FDCA and has not diminished that authority with respect to tobacco products, FDA may act to regulate tobacco products. Therefore, there is no violation of the separation of powers principle.

NICOTINE IN CIGARETTES AND SMOKELESS TOBACCO IS A DRUG AND CIGARETTES AND SMOKELESS TOBACCO ARE DRUG DELIVERY DEVICES UNDER THE FDCA

I. Cigarettes and Smokeless Tobacco Fall Squarely within the Act's Drug and Device Definitions

In its jurisdictional determination, FDA amassed hundreds of pages of evidence showing that cigarettes and smokeless tobacco meet the statutory definition of "drugs" and "devices" because they are "intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(C), (h)(3). The record contains very convincing evidence that: (A) the nicotine in these products "affect[s] the structure or any function of the body" by causing and sustaining addiction and by acting as a stimulant, sedative, and weight regulator; and (B) nicotine's effects are intended by cigarette and smokeless tobacco manufacturers.

[23/] In this case, Congress has delegated to the Secretary of Health and Human Services "[t]he authority to promulgate regulations for the efficient enforcement of [the FDCA]." 21 U.S.C. § 371.

Plaintiffs argue that the effects of nicotine are not effects "on the structure or any function of the body" because they are not "therapeutic." Plaintiffs' argument is inconsistent with the plain language of the Act and FDA's longstanding regulation of products that, like nicotine-containing cigarettes and smokeless tobacco, act as stimulants, sedatives, weight controlling agents, or substances (like methadone) used in the maintenance treatment of addiction.

Plaintiffs argue further that FDA is required to ignore all of the evidence of the intended use of cigarettes and smokeless tobacco because the statutory term "intend" precludes reliance on any evidence other than the promotional representations that manufacturers choose to make. Here, too, plaintiffs' narrow construction of the Act is inconsistent with the plain language of the statute, FDA's regulations defining "intended" use, and FDA's historical interpretation of the Act.

A. Cigarettes and Smokeless Tobacco "Affect the Structure or Any Function of the Body"

In the jurisdictional determination, FDA found that the nicotine in cigarettes and smokeless tobacco is an addictive and pharmacologically active drug that "affect[s] the structure or any function of the body" by causing and sustaining addiction and by acting as a stimulant, sedative, and weight regulator. 61 Fed. Reg. 44661, 44665-66. Moreover, FDA found that these effects are shared by a variety of products traditionally regulated by FDA, including stimulants, tranquilizers, appetite suppressants, and opiates used in the long-term treatment of addiction. 61 Fed. Reg. 44667-68.

In United States v. An Article of Drug . . . "Sudden Change", 409 F.2d 734, 742 (2d Cir. 1969), relied on by plaintiffs, the Court held that the structure-function provision

requires a "medical--or drug-type" effect. Here, FDA found that the nicotine in cigarettes and smokeless tobacco causes "quintessentially drug-like" effects. 61 Fed. Reg. 44666. Nonetheless, plaintiffs argue that nicotine's pharmacological effects are not effects on the structure or function of the body, within the meaning of the Act, because "manufacturers of tobacco products do not claim any medical or other health benefit from their use." Second Brief at 7 (emphasis added). This argument simply confuses the question of whether nicotine's effects are within the scope of the Act with the question of whether those effects are intended by the manufacturers.

While, as discussed below, manufacturers' claims may be relevant to the second part of the structure or function analysis (i.e., the "intended" use of the product), claims are not relevant to the first part of the analysis regarding the product's effects. The statutory phrase, "affect the structure or any function of the body," concerns only the kind of effect a product has, not whether therapeutic claims are made for that effect. And although the legislative history does not directly address the meaning of the phrase, it does show that, at FDA's request, Congress specifically rejected attempts to limit the drug definition to products with medical purposes. See, e.g., Hearings on S. 2800 Before the Senate Comm. on Commerce, 73d Cong. 2d Sess. 515 (1934) (testimony of Walter Campbell), reprinted in 2 Legislative History, at 518 (proposed amendment to add "intended for medicinal use" to drug definition would impose an "obligation that in a great many circumstances will result in the miscarriage of justice").

The courts have recognized that a product need not have a "medical" or "therapeutic" purpose to fall within the definitions of "drug" and "device." See Bacto-Unidisk, 394 U.S.

at 793, 89 S. Ct. at 1415 ("Congress intended to define 'drug' far more broadly than does the medical profession . . . . If Congress had intended to limit the statutory definition to the medical one, it could have so stated explicitly") (emphasis added); United States v. Undetermined No. of Unlabeled Cases, 21 F.3d 1026, 1029 (10th Cir. 1994) (lab test used for insurance coverage decisions and not for medical purposes was a device within FDA's jurisdiction); E.R. Squibb and Sons, Inc. v. Bowen, 870 F.2d 678, 682 (D.C. Cir. 1989) (structure-function definition applies to products having "only a physiologic, rather than a therapeutic, effect") (emphasis added); American Health Products Co. v. Hayes, 574 F. Supp. 1498, 1506 (S.D.N.Y. 1983) (structure-function provision enacted to reach those products that escaped regulation "because they were neither foods nor therapeutic agents") (emphasis added), aff'd, 744 F.2d 912 (2d Cir. 1984).

Consistent with the plain words of the Act and the courts' application of those words, FDA routinely regulates as drugs or devices many products that have recreational, cosmetic, and economic--as opposed to therapeutic--purposes. Such products include GHB, a black market alternative to anabolic steroids intended for muscle building, 61 Fed. Reg. 44680; products delivering a low level of oxygen to enhance athletic performance, United States v. . . . "Sports Oxygen", Civ. No. 89-2085 (D.N.J. Oct. 27, 1992); breast implants; collagen injections for cosmetic uses; creams for temporarily smoothing wrinkles, "Sudden Change", 409 F.2d 734; ingested drugs designed to eliminate pet odors (as veterinary drugs), United States v. Undetermined Quantities . . . "Pets Smellfree", 22 F.3d 235 (10th Cir. 1994); birth control drugs and devices; tanning booths; veterinary drugs to increase milk production, United States v. Pro-Ag, Inc., 796 F. Supp. 1219 (D. Minn 1991), aff'd, 968 F.2d 681 (8th

Cir. 1992); and veterinary drugs to euthanize animals, United States v. Articles of Drug . . . "Beuthanasia-D Regular", Civ. No. 77-0-396 (D. Neb. Aug. 1, 1979). All of these products arguably would be removed from FDA's jurisdiction under plaintiffs' theory.

Plaintiffs claim that if medical representations are not required, FDA will assert jurisdiction over a range of products that "could be used" to affect the structure or function of the body, such as exercise bicycles, mattresses, and hot tubs. Second Brief at 12. Although these products might fall within the literal language of the statute because of some physical effect on the structure or function of the body, FDA may, in its discretion, decline to regulate them and has in fact done so. An administrative agency must be allowed to apply reasonable discretion in deciding how to exercise its jurisdiction. "The scope [of the statute] is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications." United States v. Sullivan, 332 U.S. 689, 694, 68 S. Ct. 331, 335, 92 L. Ed. 297 (1948).

More to the point, plaintiffs' comparison between products at the margins of FDA's jurisdiction, because they may have a minor effect on the structure or function of the body, and nicotine-containing cigarettes and smokeless tobacco, is spurious. Nicotine is a well-known pharmacological agent with effects comparable to many prescription drugs regulated by FDA. Indeed, nicotine is already regulated as a drug by FDA in a variety of dosage forms. 61 Fed. Reg. 44665. Products that administer nicotine thus fall squarely in the category of products that Congress intended FDA to regulate.

B. Nicotine's Effects Are Intended by the Manufacturers

Plaintiffs' argument that promotional representations are required to establish that a use is "intended" is equally groundless. The agency found that the manufacturers' intended use of these products was independently demonstrated by each of the following types of evidence: (1) the addictive and other pharmacological effects of nicotine are so widely known and accepted that it would be foreseeable to any reasonable manufacturer that consumers would use tobacco to satisfy their addiction to nicotine, 61 Fed. Reg. 44698-806; (2) studies establish that more than 75% of tobacco consumers in fact use cigarettes and smokeless tobacco to satisfy their addiction to nicotine and for other pharmacological effects, 61 Fed. Reg. 44811-46; (3) tobacco manufacturers have known for decades that consumers use tobacco products primarily to obtain the pharmacological effects of nicotine, including satisfaction of addiction; and (4) tobacco manufacturers have intentionally designed their products to provide consumers with a "pharmacologically active nicotine level." 61 Fed. Reg. 44854-45150. Although any one of these findings would be sufficient to support a finding that these products are intended to have pharmacological effects, FDA found that the record supported all of them.[24/]

[24/] In the Jurisdictional Determination, FDA found that advertisements for cigarettes and smokeless tobacco that promise "satisfaction" contain an implied claim that the products will provide pharmacological satisfaction of the desire for nicotine. Both tobacco company documents and evidence from consumers establish a link between the term "satisfaction" and nicotine delivery. See 61 Fed. Reg. 45171-78. Plaintiffs have conceded that implied claims can establish intended use. (Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. II. at 91.) Accordingly, for purposes of summary judgment, those cigarettes and smokeless tobacco products that are advertised or promoted as providing "satisfaction" must be treated as "intended" to affect the structure or function of the body, and this finding alone is sufficient to preclude granting summary judgment to plaintiffs.

FDA's interpretation that the term "intend" permits reliance on these categories of evidence is based on the plain language of the statute, longstanding agency regulations, and case law. FDA's interpretation is also supported by a history of administrative precedents.

1. The Plain Language of the Statute Directs FDA to Consider All Relevant Evidence to Establish the Intended Use of a Product

The Supreme Court has held that "[w]hen terms used in a statute are undefined, we give them their ordinary meaning." Asgrow Seed Co. v. Winterboer, 115 S. Ct. 788, 793, 130 L. Ed. 2d 682 (1995). Congress did not provide an independent definition of "intend" for purposes of the Act, nor did it limit in any way the types of the evidence that could be relied upon to establish intended use. Thus, the term should be construed "as broad[ly] as the literal language indicates." Bacto-Unidisk, 394 U.S. at 798, 89 S. Ct. at 1418 (interpreting the scope of the drug definition) (emphasis added).

There are two well-established ordinary meanings of the term "intend," both of which refer to the purpose of the actor. First, the dictionary defines "intend" as "to have in mind; plan. . . . [t]o design for a specific purpose. . . . [t]o have in mind for a particular purpose."[25/] Second, the ordinary legal usage of "intend," well-understood in 1938 at the time the Act was passed, includes the principle that one intends the readily foreseeable consequences of one's actions. Agnew v. United States, 165 U.S. 36, 53, 17 S. Ct. 235, 242, 41 L. Ed. 624 (1897) ("[t]he law presumes that every man intends the legitimate consequences of his own acts") (emphasis added); accord Fanning v. United States, 72 F.2d 929, 932 (4th Cir. 1934).

[25/] The American Heritage Dictionary of the English Language, 2d ed. (Boston: Houghton Mifflin Co., 1991), 668 (AR: Vol. 526, Ref. 95, vol. V).

Accordingly, the plain language of the Act permits FDA to consider all evidence relevant to whether: (a) the manufacturer has in mind that its product will be used for pharmacological purposes; (b) the manufacturer designs its product so that it may be used for pharmacological purposes; and (c) use of the product by the vast majority of consumers for its pharmacological effects is a readily foreseeable consequence of marketing the product.

FDA's determination that cigarettes and smokeless tobacco are intended to affect the structure or any function of the body is based on abundant evidence establishing each of these points. Specifically, FDA found that:

(a) Tobacco manufacturers have known for decades that the nicotine in tobacco is a "powerful pharmacological agent,"[26/] an "addictive drug,"[27/] and the "primary reason" people use tobacco.[28/] Industry officials view their own industry as "a specialized . . . segment of the pharmaceutical industry . . . based upon design, manufacture and sale of attractive dosage forms of nicotine."[29/] FDA found that hundreds of tobacco company statements like these, 60 Fed. Reg. 41583-620, 41740-78 and 61 Fed. Reg. 44854-912, 45100-08, demonstrate that tobacco manufacturers intend (have "in mind") that cigarettes and

---

[26/] Charles JL (Philip Morris Inc.), "Nicotine Receptor Program-University of Rochester" (Mar. 18, 1980) (AR: Vol. 14, Ref. 175a).

[27/] Yeaman A (Brown & Williamson Tobacco Co.), "Implications of Battelle Hippo I and II and the Griffith Filter" (Jul. 17. 1963), at p. 4 (AR: Vol. 21, Ref. 221).

[28/] Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-Named Table, at 1 (AR: Vol. 531, Ref. 122).

[29/] Teague, CE (R.J. Reynolds Tobacco Co.), "Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein (Apr. 14, 1972), at p. 1 (AR: Vol. 531, Ref. 125).

smokeless tobacco will be used for the purpose of delivering the pharmacological effects of nicotine to consumers. 61 Fed. Reg. 44993, 45125.

(b) The research and product development activities of tobacco manufacturers related to nicotine delivery, as well as analyses of the design of cigarettes and smokeless tobacco, show that tobacco manufacturers have studied the dose of nicotine that must be delivered to consumers to provide the desired pharmacological effects, and have manipulated the delivery of nicotine from cigarettes and smokeless tobacco to ensure that consumers receive an adequate dose. 60 Fed. Reg. 41644-740 and 61 Fed. Reg. 44915-92, 45108-25. FDA found that this evidence shows that tobacco manufacturers intend ("design") cigarettes and smokeless tobacco for the purpose of delivering adequate doses of nicotine to affect the structure and function of the body. 61 Fed. Reg. 44993-94, 45125.

(c) As discussed in the statement of facts, there is now virtually universal scientific consensus that nicotine is a highly addictive substance, similar in its addictive effects to cocaine and heroin. Based on this evidence, FDA determined that no reasonable manufacturer could fail to foresee that cigarettes and smokeless tobacco would be used by the vast majority of consumers to obtain pharmacological effects. 61 Fed. Reg. 44750.

Ignoring the ordinary meaning of "intend" and the fact that Congress placed no limitations on the evidence that may be adduced to establish intended use, plaintiffs argue that FDA is authorized to consider only the manufacturer's express or implied promotional representations and is precluded from reviewing other relevant evidence. In effect, plaintiffs ask the Court to substitute the words "represented" or "advertised" for the statutory term "intended." Although Congress expressly referred to "representations," "labeling," and

"advertising" in other sections of the Act,[30/] these terms are absent from the drug and device definitions. As the Supreme Court recently observed, "it is generally presumed that Congress acts intentionally and purposely" when it includes particular language in one section of a statute but omits it in another. Keene Corp. v. United States, 508 U.S. 200, 208, 113 S. Ct. 2035, 2040, 124 L. Ed. 2d 118 (1993). Thus, there is no basis in the statutory language to interpret "intended" as "represented" or "advertised."

Plaintiffs make no attempt to argue that the statutory language supports their view, turning instead to some sparse and ambiguous legislative history to support their interpretation. Second Brief at 8-9. Where the language of a statute is clear on its face, however, it is inappropriate to resort to legislative history. Kofa v. INS, 60 F.3d at 1088.

Even if legislative history could override the plain language of the Act, the passage relied on by plaintiffs (Second Brief at 8) does not support their position. The passage is introduced with the statement that "[t]he use to which the product is to be put will determine the category into which it will fall." S. Rep. No. 74-361, at 4 (1935), reprinted in 3 Legislative History, at 663 (emphasis added). This is consistent with FDA's position that the use of the product can establish intended use. The later sentence relied on by plaintiffs, that the manufacturer of an article "through his representations in connection with its sale, can determine the use to which the article is to be put" has been taken out of context. The passage was not designed to restrict the types of evidence that could be relied on to establish

---

[30/] See, e.g., 21 U.S.C. § 321(n) (whether a drug or device is misbranded depends on the manufacturer's "representations" made in "labeling or advertising"); 21 U.S.C. § 352(n) (a drug is misbranded unless its "advertisements and other descriptive printed matter" contain certain statements).

intended use, but to explain that when a product fell within the definitions of both "food" and "drug," it would "escape" dual regulation as a food and a drug if "unequivocal" drug claims were made for it. Nothing in this passage purports to limit the types of evidence that can be relied on to establish the intended use of a product, nor does the passage even suggest that a product containing a powerful drug ingredient could be removed from the drug definition simply by promoting the product as a food, or could escape regulation altogether by avoiding therapeutic representations.

Furthermore, in the legislative history of the Medical Device Amendments of 1976, Congress specifically rejected a proposition nearly identical to that advocated by plaintiffs here, finding that a device that was actually used in humans could not escape regulation by being promoted "for veterinary use." FDA "may consider the ultimate destination of a product in determining whether or not it is for human use just as [it] may consider actual use of a product in determining whether or not it is a device." H.R. Rep. No. 94-853, at 14 (1976).

2. FDA's Interpretation is Reasonable and Consistent with Longstanding Administrative Interpretations of the Statute

Contrary to plaintiffs' assertion that FDA's interpretation is a departure from the past, FDA regulations in effect since the 1950's, as well as a history of similar administrative actions show that the agency has consistently held that "intended" use may be proven by many different types of evidence, including foreseeable uses, actual uses, and the statements and actions of the manufacturer.[31/] The regulations expressly authorize the agency to look

[31/] Even if the statute were not plain on its face, the agency's interpretation of the statute (continued...)

at these sources of evidence even when the manufacturer has made no claims in its promotion of the product.

The full text of the primary regulation on intended use (which is selectively edited in plaintiffs' brief) demonstrates its breadth:

> The words "intended use" or words of similar import in [various FDA regulations] refer to the objective intent of the persons legally responsible for the labeling of drugs. 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 labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may 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. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with other such uses to which the article is to be put.

21 C.F.R. § 201.128 (emphasis added); see also 21 C.F.R. § 801.4 (defining intended use for devices in identical language).[32/]

[31/](...continued)
would be entitled to deference and must be upheld because it represents a reasonable construction of the statute. Holly Farms Corp. v. NLRB, 116 S. Ct. 1396, 1401, 134 L. Ed. 2d 593 (1996); Young v. Community Nutrition Inst., 476 U.S. 974, 981, 106 S. Ct. 2360, 2365, 90 L. Ed. 2d 959 (1986); Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 845, 106 S. Ct. 3245, 3254, 92 L. Ed. 2d 675 (1986) (an agency's longstanding regulation interpreting the scope of its jurisdiction is owed "substantial deference").

[32/] A companion regulation that requires "adequate directions" for all intended uses of a product lists as examples of intended uses both: (1) "uses for which it is prescribed,
(continued...)

Plaintiffs seek to obscure the breadth of the evidence that these regulations treat as probative by reading into the regulations words that are not there. They argue, for example, that the provision that intended use "may 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," means that a distributor, retailer, or "others not subject to the control of the manufacturer" must first offer the product for a drug use. Second Brief at 13. The text of the regulation belies this claim. The manufacturer's responsibility for the uses intended by a packer, distributor, or seller other than the manufacturer is dealt with in the two sentences following the passage in question.

Similarly unsupported is plaintiffs' contention that the final sentence of the regulation, holding the manufacturer responsible for uses when he "knows, or has knowledge of facts that would give him notice that a drug . . . is to be used for . . . purposes . . . other than the ones for which he offers it," applies only to additional uses of a product that is already marketed as a drug or a device. Second Brief at 13 n.11. The regulation contains no such limitation, and FDA regularly applies this provision to establish whether products should be regulated as drugs or devices in the first instance. See, e.g., United States v. Kasz Enter., 855 F. Supp. 534, 539 (D.R.I.), modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); United States v. Undetermined Quantities . . . "Exachol", 716 F. Supp. 787, 791 (S.D.N.Y. 1989).

[32/](...continued)
recommended, or suggested in its oral, written, print, or graphic advertising;" and (2) "uses for which the drug is commonly used." 21 C.F.R. § 201.5 (emphasis added); 21 C.F.R. § 801.5 (same, for devices).

FDA's prior administrative practice also shows that the agency has consistently interpreted its statute and regulations as permitting the agency to rely on evidence other than promotional claims. The jurisdictional analysis describes a number of relevant precedents. 60 Fed. Reg. 41527-31. For example, FDA took enforcement actions against imitation cocaine products, often sold as "incense,"[33/] and against imported "khat," on the strength of its use as a stimulant narcotic in many countries, without any information about claims by vendors.[34/]

3. FDA May Rely on Foreseeable Uses, Consumer Use, and the Statements, Knowledge, and Actions of the Manufacturers to Establish Intended Use

Plaintiffs are unable to cite a single case in which a court has held that intended use could be established only by promotional representations. In fact, courts have repeatedly held that while promotional claims are one source of evidence of intended use, the agency is authorized to rely on "any other relevant source" of evidence. See, e.g., "Sudden Change", 409 F.2d at 739; ASH, 655 F.2d at 239 (FDA may consider evidence of consumer use to establish that cigarettes are drugs even in the absence of promotional claims); National Nutritional Foods Ass'n ("NNFA") v. FDA, 504 F.2d 761, 789 (2d Cir. 1974) (in

---

[33/] FDA determined that the products were "intended" as drugs based upon laboratory analyses showing that the products contained drug ingredients, the outlets in which the products were sold (e.g., "head shops"), and "street" information that the products provide a "cheap high." 60 Fed. Reg. 41528; 61 Fed. Reg. 45167, 45186. Contrary to plaintiffs' claim, most of the imitation cocaine cases involved no promotional claims. 61 Fed. Reg. 45186.

[34/] There is no basis for plaintiffs' contention that FDA exercised jurisdiction solely because the Drug Enforcement Agency (DEA) considered khat a "drug of abuse." FDA regulated khat as a drug under the Federal, Food, Drug, and Cosmetic Act for over a decade before the Drug Enforcement Agency asserted jurisdiction. 61 Fed. Reg. 45190.

considering whether high potency vitamins without therapeutic representations are drugs, FDA is "free to pierce . . . a manufacturer's . . . misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence"), cert. denied, 420 U.S. 946 (1975); United States v. Storage Spaces Designated Nos. "8" and "49", 777 F.2d 1363, 1366 (9th Cir. 1985), cert. denied, 479 U.S. 1086 (1987); Hanson v. United States, 417 F. Supp. 30, 35 (D. Minn.), aff'd, 540 F.2d 947 (8th Cir. 1976); United States v. 250 Jars . . . U.S. Fancy Pure Honey, 218 F. Supp. 208, 211 (E.D. Mich. 1963) (to find intended use, a "court is not limited to the labels on such article or to the labeling which accompanies it, but may look at all relevant sources"), aff'd, 344 F.2d 288 (6th Cir. 1965). Indeed, ASH v. Harris, on which plaintiffs heavily rely, would be nonsensical if plaintiffs were correct. In that case, the court stated that even in the absence of any promotional representations by a manufacturer, evidence that consumers use cigarettes "predominantly" or "nearly exclusively" for a pharmacological purpose could be used to establish that cigarettes are "intended" as drugs. 655 F.2d at 240; see also NNFA v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977); NNFA v. Weinberger, 512 F.2d 688, 703 (2d Cir.), cert. denied, 423 U.S. 827 (1975). And in United States v. Ten Cartons . . . Ener-B Vitamin B-12, 72 F.3d 285, 287 (2d Cir. 1995), the court expressly held that an article can be a "drug" under 21 U.S.C. § 321(g)(1)(C) for reasons other than claims made in the label or labeling, such as "method of intake." 72 F.3d at 287. The court noted that the Dietary Supplements Health Education Act, which prohibits dietary supplements from being regulated as drugs under 21 U.S.C. § 321(g)(1)(C) "solely" on the basis of promotional claims, plainly implies that other evidence beyond promotional claims can be relevant to establishing intended use. Id.

a. Foreseeable Use and Actual Consumer Use

The courts have upheld reliance on evidence of foreseeable uses and actual consumer use. These two concepts are closely related. Reliance on consumer use to "justify an inference as to the vendor's intent," ASH, 655 F.2d at 239, presumes that because there is actual use of the product for a drug or device purpose, a reasonable manufacturer should know (foresee) that its product is being used as a drug or device. See United States v. Focht, 882 F.2d 55, 60 (3d Cir. 1989) (knowledge of consumer use attributed to the manufacturer in establishing intended use). Courts have recognized that a foreseeable drug effect or use is persuasive evidence that the product is "intended" as a drug. See "Pets Smellfree", 22 F.3d at 240 (presence of chlortetracycline, a drug ingredient, at doses sufficient to have physiological effects on pets was relevant evidence of "intended use"); United States v. Articles of Food & Drug . . . Apricots, 444 F. Supp. 266, 271 (E.D. Wis. 1977) (in light of widespread publicity surrounding the use of Laetrile (amygdalin) to treat cancer, simply representing that a product is or contains amygdalin can establish that it is a drug intended to treat cancer).

Cases interpreting "intended use" under other public health statutes that focus on consumer products also support reliance on reasonably foreseeable uses. See Focht, 882 F.2d at 60 (under the Federal Hazardous Substances Act ("FHSA"), "[i]ntended use . . . , objectively defined, necessarily encompasses foreseeability") (emphasis added); N. Jonas & Co. v. EPA, 666 F.2d 829, 832-33 (3d Cir. 1981) (a product was "intended for use" as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") based on its foreseeable consumer use, even though the manufacturer did not promote the product as a

pesticide and even disclaimed use as a pesticide on the label); United States v. Articles of Banned Hazardous Substances . . . Baby Rattles, 614 F. Supp. 226, 231, 232 n.9 (E.D.N.Y. 1985) (baby rattles labeled as party favors were "toys intended to be used by children" under FHSA based on "evidence of its use as a toy and the common sense observation that children would be likely to use it as a toy").

Despite these cases, plaintiffs argue that FDA may not rely on evidence of foreseeable uses because the word "foreseeable" does not appear in the Act. Second Brief at 15. The word does not appear in FIFRA either, yet the Third Circuit relied on foreseeable use to establish intended use under that statute. N. Jonas, 666 F.2d at 833. Foreseeability concepts are, moreover, incorporated in the Act and longstanding regulations. See, e.g., 21 U.S.C. § 321(n) (labeling or advertising may be misleading for failing to reveal "consequences which may result from . . . such conditions of use as are customary or usual"); 21 C.F.R. § 201.5 (intended use may be based on common uses), 21 C.F.R. § 201.128 (intended use based on knowledge and notice); United States v. Park, 421 U.S. 658, 671-72, 95 S. Ct. 1903, 1911, 44 L. Ed. 2d 489 (1975) (the Act imposes "requirements of foresight and vigilance" on manufacturers and the duty to act as "society might reasonably expect . . . from one who assumed his responsibilities").[35/]

[35/] Plaintiffs also argue that the agency may not rely on the interpretation of "intended use" in other statutes to interpret the Act. Courts, however, have already treated the case law on "intended use" under the Act as applicable to the same phrase in these other public health statutes. See, e.g., N. Jonas, 666 F.2d at 833 (relying on cases interpreting the phrase "intended use" under the Act in holding that intended uses under FIFRA encompass readily foreseeable consumer uses).

As noted, courts that have upheld reliance on consumer use under the Act have based such holdings on the principle of foreseeability. In ASH, the Court recognized that while "the vendors' intent . . . is the key element in [the] statutory definition," the "requisite statutory intent can be inferred" if "consumers . . . use the product predominantly and in fact nearly exclusively with the appropriate intent." 655 F.2d at 239-40; see also NNFA v. Weinberger, 512 F.2d at 703. Thus, where consumer use of a product for pharmacological purposes is nearly exclusive, the manufacturer may be held to intend that use solely on the basis of consumer use. In the present case, FDA found that consumers use cigarettes and smokeless tobacco "predominantly" for the pharmacological effects of nicotine. 61 Fed. Reg. 44812-13. FDA's finding was based primarily on evidence that as many as 92% of cigarette smokers are addicted to nicotine and estimates that approximately 75% of young smokeless tobacco users are also addicted. Id.

Courts have also recognized that where, as here, there is other evidence of manufacturer intent, evidence of consumer use may provide relevant corroborative evidence of intended use, even if the extent of use is not quantified. See, e.g., Kasz Enters., 855 F. Supp. at 539 (intended use "can be demonstrated by . . . evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised") (emphasis added); United States v. 789 Cases . . . Latex Surgeons' Gloves, 799 F. Supp. 1275, 1285, 1294-95 (D.P.R. 1992) (intended use determined by all the facts, including "actual use"); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Ill. 1991) ("a court should examine a wide range of evidence, including . . . actual use of the product"), aff'd, 984 F.2d 814 (7th Cir. 1993). Contrary to plaintiffs' assertion,

Second Brief at 18, courts have expressly relied on actual use to establish intended use. See, e.g., United States v. An Article of Device . . . Toftness Radiation Detector, 731 F.2d 1253, 1257 (7th Cir.), cert. denied, 469 U.S. 882 (1984); United States v. 22 . . . Devices . . . "The Ster-o-lizer MD-200", 714 F. Supp. 1159, 1165 (D. Utah 1989); United States v. An Article of Device . . . "Cameron Spitler Amblyo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966).

Plaintiffs make no attempt to distinguish these cases. Instead, they selectively quote from past FDA statements to suggest misleadingly that FDA has taken the position that consumer use cannot support jurisdiction over tobacco. Second Brief at 18. In fact, in 1980 the agency expressly recognized that "evidence of consumer use [of cigarettes] can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act" but found that there was not sufficient evidence of consumer use to "impute the requisite intent."[36/] Indeed, looking at the very language quoted by plaintiffs, the Court of Appeals in ASH said, "we do not read these statements to mean . . . that the Commissioner will never consider evidence of consumer intent." 655 F.2d at 239.

b. Statements, Knowledge, and Actions of the Manufacturers

FDA's administrative record contains hundreds of tobacco company statements and research reports which show that tobacco industry officials actually intend their products to be used for the pharmacological effects of nicotine, including satisfaction of addiction. The

---

[36/] Letter from Goyan, JE to Banzhaf, JF, III and Georgiades, PN (Nov. 25, 1980), at 8-9 (AR: Vol. 28, Ref. 238).

evidence showed overwhelmingly the industry's keen appreciation that nicotine is a powerful and addictive drug and that consumers use tobacco primarily to obtain nicotine. 60 Fed. Reg. 41583-620, 41740-78; 61 Fed. Reg. 44854-912, 45100-08. The record further demonstrated that the industry intentionally designs cigarettes and smokeless tobacco to deliver adequate doses of nicotine to the user. 60 Fed. Reg. 41644-740; 61 Fed. Reg. 44915-92, 45108-25.

Plaintiffs, nevertheless, take the striking position that what a manufacturer actually intends its product to be used for is legally irrelevant. Second Brief at 19. In effect, they argue that the Court should close its eyes to their admissions. Case law contradicts their position. See, e.g., American Health Prods. Co. v. Hayes, 574 F. Supp. at 1508 (evidence that the manufacturer formulated the product in a manner that was more conducive to its use as a drug than as a food relied on to establish that it was "intended" as a drug); Latex Surgeons' Gloves, 799 F. Supp. at 1294-95 (circumstances surrounding manufacturer's storage and handling of the product are relevant to establishing intended use); "Cameron Spitler Amblyo-Syntonizer", 261 F. Supp. at 245 (manufacturer's admission in litigation that devices were actually used to treat eye diseases was sufficient to conclude that they were devices despite lack of representations).

Plaintiffs again make no effort to distinguish the case law. They argue instead that the manufacturers' statements and research must be ignored because FDA's regulations interpreting intended use refer to "objective intent." Second Brief at 19-20. According to plaintiffs, what is in the mind of the manufacturer constitutes "subjective intent" which must be disregarded under an objective intent standard.

There is simply no support for plaintiffs' argument. The fact that the regulation refers to an objective intent standard in no way precludes consideration of what is in the mind of the manufacturer. Objective intent encompasses all relevant evidence, including what is in the mind of the manufacturer. As described above, the regulation expressly authorizes reliance on evidence of what is in the mind of the manufacturer. 21 C.F.R. §§ 201.128, 801.4 (what the manufacturer "knows" about the unpromoted uses of its product is evidence of intended use).[37/]

Implicitly conceding that courts have in fact relied on evidence other than promotional representations to establish intended use, plaintiffs argue that FDA should not be permitted to rely on non-promotional evidence because every case in which a court relied on non-promotional evidence also involved some express or implied promotional claim. Plaintiffs' assertion is not correct. See, e.g., "Ener-B", 72 F.3d at 287; ASH, 655 F.2d at 239 (intended use can be established by evidence of consumer use "alone," in the absence of any manufacturer representations); NNFA v. Weinberger, 512 F.2d at 703.

In the cases relied on by plaintiffs, courts were never presented with the question of whether promotional claims are required to establish intended use. They were simply cases in which manufacturers made drug claims for products without any known pharmacological effects and claims were sufficient to establish intended use. See, e.g., United States v.

[37/] Objective and subjective intent are not, as plaintiffs suggest, opposites. Rather, they refer to different types of evidence relevant to proving the same ultimate fact. Actual intent is no less relevant than labeling claims for this purpose. And even if plaintiffs' arguments concerning "subjective intent" evidence were correct, they would not disturb FDA's finding (61 Fed. Reg. 44993-94, 45125) that tobacco manufacturers "design" their products for use as nicotine delivery devices and thus intend them to affect the structure and function of the body.

Articles of Drug for Veterinary Use, 50 F.3d 497 (8th Cir. 1995) (component of cow's breast milk represented to have wide range of pharmacological effects); "Sudden Change", 409 F.2d 734 (cosmetic represented to give "face lift without surgery"); Bradley v. United States, 264 F. 79 (5th Cir. 1920) (pharmaceutical claims made for mineral water). In these cases, the representations of the manufacturer that the product will have desired pharmacological effects are highly relevant because without such representations consumers have no reason to purchase or use the products for pharmacological purposes. These cases do not, however, purport to require promotional representations for products that contain known drug ingredients and that are widely used for pharmacological effects.

In particular, plaintiffs' reliance on United States v. Articles of Drug for Veterinary Use, is misplaced. That case, like the others cited by plaintiffs, was brought by FDA solely on the strength of promotional representations made about an innocuous substance (cow's breast milk). The court explicitly recognized that intended use "may be derived from any relevant source." The court held that if promotional representations are the source on which FDA relies, they are "relevant" only if there is evidence that they are being distributed with the product or that past representations are still relied on by consumers. 50 F.3d at 500. Nothing in the court's opinion even suggests that promotional representations are required to establish intended use; that issue was not before the court.

It is noteworthy that FDA found that "[m]anufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of

nicotine." 61 Fed. Reg. 44630. Promotional claims are not necessary to successfully sell a product which is designed to provide the drug effects that consumers seek.[38/]

II. FDA's Application of the Medical Device Provisions to Cigarettes and Smokeless Tobacco Does Not Affect FDA's Jurisdiction over these Products

Despite the overwhelming evidence and precedent showing that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body," and are therefore subject to FDA jurisdiction, plaintiffs contend that the manner in which FDA has chosen to regulate these products, under the Act's device authorities, "provide[s] further evidence that tobacco products cannot be regulated under the FDCA." Second Brief at 25.

The jurisdictional inquiry, however, ends with the conclusion that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body" within the meaning of the Act. Questions regarding the manner in which FDA has chosen to regulate these products do not affect jurisdiction, but instead go to whether FDA is applying

---

[38/] If correct, plaintiffs' argument that, in the absence of promotional claims, other evidence of intended use no matter how persuasive, must be ignored would also create a loophole in the Act that defies logic. While drugs and devices with therapeutic claims are subject to careful FDA scientific review, many drugs and devices currently subject to FDA regulation could escape that regulation with no satisfactory regulatory alternative simply by eliminating any medical or therapeutic claims from their promotion. Such well-recognized products as aspirin, acetaminophen, ibuprofen, and other over-the counter drug products, as well as widely recognized prescription products such as estrogen, tranquilizers and anti-depressants, nitroglycerin, crutches, contact lenses and syringes, to name a few, could all find ready markets without any need for promotional claims. For this reason, FDA has stated in several contexts that including a known drug ingredient in a product can be sufficient to make the product a drug despite the absence of drug claims. See, e.g., 58 Fed. Reg. 47611, 47612 (1993) (skin creams containing hormones are drugs); 59 Fed. Reg. 6084, 6088 (1994) (dentifrices containing fluoride are drugs). FDA found in the jurisdictional determination that to the extent these are implied drug claims, similar implied claims are made for cigarettes and smokeless tobacco because they contain nicotine, a known drug ingredient, and frequently advertise that fact. 61 Fed. Reg. 45187.

the Act in a permissible manner. FDA's regulatory approach for cigarettes and smokeless tobacco is reasonable and consistent with the Act.

A. Cigarettes and Smokeless Tobacco Are Combination Drug/Device Products and, As Such, May Be Regulated under the Act's Device Authorities

FDA found that, in addition to containing the drug nicotine, cigarettes and smokeless tobacco products contain device components, i.e., the tobacco blend, filter, and ventilation system used in cigarettes, and the processed tobacco and porous pouch (where present) used in smokeless products. Because each of these components is an "instrument, . . . implement, . . . contrivance . . . or other similar or related article," 21 U.S.C. § 321(h), that is intended to "affect[] the structure and function of the body by delivering a controlled amount of nicotine to the body," 61 Fed. Reg. 45209, 45213-15, each is a device in its own right.

FDA also found that the drug nicotine in cigarettes and smokeless tobacco products, and the device components that deliver nicotine, "'are physically, chemically, or otherwise combined or mixed and produced as a single entity.'" 61 Fed. Reg. 45205 (quoting 21 C.F.R. § 3.2(e)(1), the regulation defining the term "combination product"). Cigarettes and smokeless tobacco, therefore, are "combination products" within the meaning of 21 U.S.C. § 353(g). Id.

Finally, FDA found that the "primary mode of action" of these combination products is that of a drug. See 61 Fed. Reg. 45209-18, 44400-03; 60 Fed. Reg. 41348. The "primary mode of action of [a] combination product" determines which agency component will be assigned the administrative responsibility for premarket review of the product. 21 U.S.C. § 353(g). Here, because the primary mode of action of cigarettes and smokeless tobacco is that of a drug, the Act requires that the "persons charged with premarket review

of drugs," namely those in the agency's Center for Drug Evaluation and Research ("CDER"), are to be assigned responsibility for these products. Id.

FDA further decided that CDER should apply the Act's device provisions to these products. 61 Fed. Reg. 44404. That decision was based on FDA's judgment that regulation of these products as devices "is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed. Reg. 44398, 44404.

1. Cigarettes and Smokeless Tobacco Are Combination Products

Plaintiffs have essentially three objections to FDA's finding that cigarettes and smokeless tobacco are combination products that may be regulated solely under the Act's device provisions. Each objection, however, is based on either a misreading of the Act or a misreading of the agency's findings.

Plaintiffs first contend that the drug delivery components of cigarettes and smokeless tobacco are not devices because those components "do not in themselves have any effect on a structure or function of the body . . . [because they] can affect the structure or function of the body only through the [effect] of nicotine." Second Brief at 26-27. This argument fails because it relies on the assumption--nowhere to be found in the Act--that in order for a product to be a "device," it must have a direct effect on the structure or function of the body.

FDA concluded that the device components of cigarettes and smokeless tobacco affect the structure and function of the body indirectly--by delivering the drug nicotine to the body which affects the structure and function of the body. See 61 Fed. Reg. 45209, 45214-15. This finding is not only a reasonable application of the plain language of the statute,

21 U.S.C. § 321(h), it is also consistent with FDA's conclusions--reached in numerous other instances--that products that do not themselves have a direct effect on the structure or function of the body, but instead deliver an agent or substance that has such a direct effect, may be regulated under the Act's device authorities. See, e.g., 21 C.F.R. § 878.4635 (ultraviolet lamps that deliver ultraviolet light which causes tanning); 21 C.F.R. § 878.4800 (surgical stapler that delivers staples that affect body tissues by holding them together); 21 C.F.R. § 880.5475 (jet lavage that delivers sterile fluid that cleans wounds); 21 C.F.R. § 880.5570 (hypodermic needle that delivers drug substance to site on the body); 21 C.F.R. § 868.5580 (oxygen mask that delivers oxygen for absorption by the lungs).

FDA's interpretation of its device authority has been repeatedly upheld by the courts. See, e.g., United States v. 23, More or Less, Articles, 192 F.2d 308, 309 (2d Cir. 1951) (phonograph records that "produce[]" sounds intended to induce sleep are devices because "sleep is a function of the body"); United States v. Relaxicizor, Inc., 340 F. Supp. 943, 944, 947 (C.D. Cal. 1970) (device that "provides electrical currents which cause intermittent contraction of the muscles" "is a device . . . because it is intended to affect the structure and functions of the body as a girth reducer and exerciser"); United States v. An Article of Device . . . Dynatone, 315 F. Supp. 588, 589 (D. Minn. 1970) (facial exerciser that sends electrical current "into and through the facial anatomy" is a device because it is "designed to affect the 'structure or any function of the body of man'").

Plaintiffs next argue that cigarettes and smokeless tobacco cannot be "devices" because FDA found that those products "achieve their primary intended purposes through chemical action." Second Brief at 27; UST Brief at 15; see also 61 Fed. Reg. 45218. This

argument not only confuses the components of a combination product with the combination product itself, but also misstates one of FDA's core findings. Contrary to plaintiffs' statement that FDA declared cigarettes and smokeless tobacco to be "devices," Second Brief at 26, FDA found that these products are "combination products" consisting of device components and a drug component. For administrative purposes, FDA determined that the primary mode of action of each of the combination products as a whole was that of a drug.

Under the Act, a device or device component cannot achieve its primary purpose by chemical action within or on the body, 21 U.S.C. § 321(h), but a combination product consisting of a drug and a device very well may do so. See 21 C.F.R. § 3.2(e)(1) (definition of "combination product"). Indeed, when Congress enacted section 353(g), it expressly intended to address issues related to the regulation of "drug delivery systems," S. Rep. No. 101-513, at 31 (1990), i.e., products that contain one or more device components that deliver a drug to the body.

The tobacco blend, filter, and cigarette ventilation system "release a nicotine-containing aerosol, i.e., the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as a vehicle for nicotine delivery." 61 Fed. Reg. 45209. The processed tobacco in a smokeless tobacco product "deliver[s] the nicotine to the cheek and gum tissue for absorption," 61 Fed. Reg. 45213, and the porous pouch (if used) in those products "hold[s] the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa." 61 Fed. Reg. 45214. Consistent with the statutory definition of a device, none of these functions relies on "chemical actions within or on the body." See 61 Fed. Reg 45210, 45214-15. Thus, the components of cigarettes and

smokeless tobacco products which deliver nicotine to the body fully satisfy the Act's device definition, even though nicotine, the drug component in those combination products, "achieves its primary intended purpose through a series of chemical actions inside the body." 61 Fed. Reg. 45210; see also 61 Fed. Reg. 45215.

Plaintiffs' third objection is that cigarettes and smokeless tobacco are not combination products because "a combination product must consist of two products, each of which could be separately regulated." Second Brief at 29 (emphasis omitted). Plaintiffs further contend that "[n]either the filter nor the ventilation system . . . is a 'device' that could be used or regulated apart from the cigarette," and that the tobacco in a cigarette or smokeless tobacco product "cannot be used or regulated as a 'device' separate from the nicotine . . . because nicotine is an inherent part of it." Second Brief at 29-30; UST Brief at 14-15.

Plaintiffs are correct that a combination product is "comprised of two or more regulated components, i.e., drug/device." 21 C.F.R. § 3.2(e)(1). However, plaintiffs' insistence that the drug and device components of a combination product must be "distinct physical entities," see UST Brief at 15, has no basis in the law. A combination product is one that "constitute[s] a combination of a drug, device, or biological product." 21 U.S.C. § 353(g). Thus, if a product contains components that meet at least two of those definitions, the product is a combination product. As shown above, cigarettes and smokeless tobacco have components that meet the definitions of two product categories (i.e., drugs and devices) and cigarettes and smokeless tobacco are therefore properly categorized as combination products. See 61 Fed. Reg. 45208-18.

Further, plaintiffs are incorrect that a filter or cigarette ventilation system could not be regulated apart from the cigarette. Since these products are intended to be used as devices, i.e., as drug delivery components of cigarettes and smokeless tobacco, they are devices even when they are not part of the finished product. See 21 U.S.C. § 321(h). Each of the drug delivery components of cigarettes and smokeless tobacco remains an "instrument, implement, . . . contrivance or similar or related article," that is intended to "affect[] the structure and function of the body by delivering a controlled amount of nicotine to the body," 61 Fed. Reg. 45209, 45213-15, even when it is separated from the rest of the nicotine delivery system.

2. FDA's Choice of Authorities Is Consistent with the Act

Once again reading a constraint into the Act that does not exist, plaintiffs argue that cigarettes and smokeless tobacco cannot be regulated using the Act's device authorities because "the FDCA requires the agency to review a combination product according to its 'primary mode of action.'" Second Brief at 26, 31-32. As discussed above, FDA found for administrative review purposes under the combination product provision that the "primary mode of action" of cigarettes and smokeless tobacco products is that of a drug.

The language and the legislative history of section 353(g) make clear that it was intended to provide consistent direction regarding which group of individuals within FDA has administrative responsibility over particular types of products for pre-market review purposes: the intent was to provide manufacturers with a single contact point within the agency. The legislative history does not support plaintiffs' contention that section 353(g) is intended to limit FDA's discretion to regulate drug-device combination products under the

authorities--drug, device, or both--that are otherwise applicable to the product under the language of the statute. See, e.g., H.R. Rep. No. 101-959, at 29 (1990) (Conference Report), reprinted in 1990 U.S.C.C.A.N. 6327, 6334 (the combination product provision "describe[s] the general procedures for determining the appropriate component of the FDA to review" a combination product) (emphasis added); see also 61 Fed. Reg. 44400-03.[39/]

The Act's combination product provision also expressly provides that "[n]othing in [the provision] shall prevent [FDA] from using any agency resources . . . necessary to ensure adequate review . . . of an article." 21 U.S.C. § 353(g) (emphasis added). Contemporaneous with the enactment of section 353, FDA interpreted this phrase to include administrative resources and all applicable statutory authorities, and expressly recognized that the combination product provision "grant[s] the agency discretion to choose the premarket approval authority that provides the best public health protection." 61 Fed. Reg. 44402; see also 61 Fed. Reg. 44401-03; Young, 476 U.S. at 979-81, 106 S. Ct. at 2364-65.

In an attempt to support their argument that cigarettes and smokeless tobacco cannot be regulated using the Act's device provisions, plaintiffs argue that nicotine patches, nicotine gum, nicotine nasal spray, and metered dose inhalers are all regulated under the Act's drug authorities. Second Brief at 27-28; UST Brief at 15. Plaintiffs are correct that the agency generally applies the Act's drug provisions to a combination product that contains both a

---

[39/] Notably, an earlier version of the Safe Medical Devices Act arguably would not have allowed FDA discretion with respect to which statutory authorities to apply. See 136 Cong. Rec. S. 12493, 101st Cong., 2d Sess., Aug. 4, 1990 (proposing, in S. 3006, that if the primary mode of action of a combination product is that of a drug "neither the combination article nor any part of the article shall be treated as a device or as a biological product for market clearance purposes"). However, Congress chose not to enact that limitation.

drug substance and a delivery system and that has as its primary mode of action a drug effect. 61 Fed. Reg. 44402-03. That the agency generally employs the Act's drug authorities in regulating drug delivery systems, however, does not negate the discretion section 353 provides the agency in regulating combination products. See id. (citing 1991 FDA Intercenter Agreement). In view of the unique health and safety concerns raised by cigarettes and smokeless tobacco products, and the flexibility afforded by the Act's device provisions to develop "careful, tailored solutions" to these concerns, the agency's decision to employ these provisions "is the [option] most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed. Reg. 44398, 44404.

B. FDA's Application of Device Provisions to Cigarettes and Smokeless Tobacco Is Reasonable

Plaintiffs raise two objections to the regulatory scheme FDA has promulgated for cigarettes and smokeless tobacco. First, they claim that FDA is disregarding mandatory statutory provisions (Second Brief at 31, 33-37) and, second, they claim that FDA is not authorized under the FDCA to impose restrictions on the advertising of tobacco products (Second Brief at 38-47). Neither assertion is correct.

FDA is not disregarding or misapplying the device provisions of the FDCA in its regulation of these products. FDA's regulatory approach for cigarettes and smokeless tobacco is both authorized under the Act and reasonable in light of the unique circumstances presented by these products. Because the agency's construction of the Act is reasonable, it should be upheld by this Court. See Chevron, 467 U.S. at 842-43, 104 S. Ct. at 2781-82; accord Young, 476 U.S. at 981, 106 S. Ct. at 2364-65; Kofa, 60 F.3d at 1088.

1. FDA Is Fully Applying the Device Provisions to Cigarettes and Smokeless Tobacco

Plaintiffs allege that FDA has evaded three mandatory provisions of the FDCA. Second Brief at 33-36. In fact, FDA's application of the FDCA to tobacco products is fully consistent with the Act.

a. Classification

Plaintiffs' first complaint is that FDA is "evading" the classification process for devices. Second Brief at 34. FDA, however, has expressly stated that "[a]s required by [21 U.S.C. § 360c, the agency] will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in [that section] of the [A]ct." 61 Fed. Reg. 44412. Plaintiffs' argument appears to be that FDA's issuance of the Rule restricting cigarettes and smokeless tobacco, prior to classifying these products, should somehow be interpreted as evidence that the agency does not intend to classify these products.

The approach followed by the agency is consistent with both the statutory framework for device regulation and the agency's regulation of other devices. After a product becomes subject to the device provisions, it must be classified into one of three classes. The purpose of classification is to determine, based on the safety and efficacy issues specific to a particular device, whether that device should be subject to special controls (Class II) or premarket approval (Class III) in addition to the general controls applicable to all devices. Classification, while an important part of device regulation, is not a prerequisite to device regulation, and does not occur immediately.

Other regulatory controls for devices, often called "general controls," apply regardless of whether classification has occurred. "[C]ertain of the general controls," like the

adulteration and misbranding provisions, became applicable to all devices "immediately upon enactment of the . . . [Medical Device Amendments of 1976]." H.R. Rep. 94-853, at 17 (1976). Other general controls, such as restrictions on sale, distribution, and use, pursuant to section 360j(e), apply only where FDA concludes that they are necessary to provide reasonable assurance of the safety and effectiveness of a particular device. Id.

The statutory scheme for device regulation does not contemplate, much less require, that a device be classified before it is subject to the general controls applicable to all devices. Nor must a device be classified before the agency may apply general controls, such as restrictions, to that device.

Indeed, the agency ordinarily does not complete the classification process before regulating a device under the general controls of the Act. 61 Fed. Reg. 44404. Rather, each of the thousands of devices that have been classified by rulemaking under 21 U.S.C. § 360c was subject to the general controls of the Act prior to the completion of classification rulemaking proceedings. Id.; see generally Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2247, 135 L. Ed. 2d 700 (1996) (recognizing that devices are not classified immediately); Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 603 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986). In fact, the one device other than cigarettes and smokeless tobacco that FDA has restricted by regulation (hearing aids) was restricted in 1977, but not classified until 1986. See 42 Fed. Reg. 9286 (1977) (promulgating restrictions); 51 Fed. Reg. 40389 (1986) (classifying).[40/]

[40/] Contrary to plaintiffs' assertions, hearing aids were restricted under 21 U.S.C. § 360j(e) (restricted device authority), despite the fact that the hearing aid rulemaking was (continued...)

Plaintiffs allege that "FDA's expressed views about the health effects of tobacco products would require FDA to place them in class III and demand that they undergo premarket approval." Second Brief at 34. Although it is impossible at this point to predict into which class these products will eventually be placed, see 21 U.S.C. § 360c (describing the classification process), it is not necessarily true that cigarettes and smokeless tobacco would have to be placed into Class III.

A device is to be classified into the class that will "provide [a] reasonable assurance of . . . safety and effectiveness." 21 U.S.C. § 360c(a)(1). The "reasonable assurance" standard is not an absolute one. Instead, the determination as to whether there is a "reasonable assurance of safety" involves consideration of not only the risks presented by a product, but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed. Accordingly, the statute provides that, with respect to safety and effectiveness, the agency must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

The reasonableness standard "is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury" and that "[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits to be derived." H.R. Rep. No. 94-853, at 16, 17 (1976); see also

---

[40/](...continued)
begun (but not completed) shortly before the restricted device authority was enacted. Compare Second Brief at 35 with 42 Fed. Reg. 9294 (citing section 520(e) of the Act (21 U.S.C. § 360j(e)) as authority for the hearing aid regulations).

United States v. Rutherford, 442 U.S. 544, 555-56, 99 S. Ct. 2470, 2477, 61 L. Ed. 2d 68 (1979) (stating that "a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit").

FDA has stated that classification of cigarettes and tobacco products will involve consideration of both the "known risks of tobacco products and the public health concerns that could be raised by withdrawal from the market of cigarettes and smokeless tobacco to which many adults are addicted." 61 Fed. Reg. 44412. FDA noted that the "restrictions on access and advertising in [the] final rule . . . will need to be factored in as well." Id. Without prejudging the classification proceeding, the agency has concluded that "the best public health result is one that prevents access to tobacco products by children and adolescents while allowing their continued availability for adults." Id.

b. Recall and Misbranding

Plaintiffs' argument that, if FDA is to regulate tobacco products, the Act requires the agency to issue a mandatory recall order with respect to these products and to find these products to be misbranded (Second Brief at 35-36), is also misplaced.

As described previously, the agency has concluded that, because of the unique circumstances surrounding the use of these products, a regulatory approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while allowing the sale to adults, is most appropriate. Application of either the recall provision or a misbranding provision that would result in removal of these products from the market would be inconsistent with this regulatory approach. Neither the recall authority nor the

misbranding provisions require the agency to remove products from the market where the agency concludes such action would be contrary to the public health.

The FDCA provides that "[i]f [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, [the agency] shall issue an order requiring" recall of that device. 21 U.S.C. § 360h(e)(1) (emphasis added). The recall authority is a regulatory tool that provides FDA with authority to require recalls of devices. Plaintiffs' assertion that section 360h(e) is mandatory overlooks the fact that, by its terms, the provision is dependent on the agency making the requisite finding. Thus, the agency has the discretion to apply this section to a particular device if it determines that a recall is appropriate under the circumstances. FDA is not required to order a recall every time the agency has information indicating that a formal recall finding could be made. As the legislative history makes clear, it was Congress' intention, in adding the recall provision to the statute, to empower, but not require, FDA to conduct recalls. See 21 U.S.C. § 360h(e) (entitled "Recall authority") (emphasis added); H.R. Rep. 101-959 (1990) (Conference Report) (discussing the fact that the bill "provide[s] [FDA] with explicit authority to order the recall of a device") (emphasis added); S. Rep. No. 101-513, at 20, 14, 37 (1990) (discussing the recall authority as a useful tool that "provides the Secretary authority to recall devices") (emphasis added); 136 Cong. Rec. S17459 (daily ed. Oct. 27, 1990) (statement of bill conferee Senator Kennedy) ("If the Secretary finds that there is a reasonable probability that a device could cause serious health consequences or death, the Secretary can remove or recall the device.") (emphasis added).

Contrary to plaintiffs' protestations, the agency has said that it intends to apply the misbranding provisions of the Act to cigarettes and smokeless tobacco consistent with the regulatory approach it has adopted for these products. See 61 Fed. Reg. 44410. Thus, for example, the agency could take enforcement action to remedy false or misleading labeling of these products. Id. As the agency noted in the Federal Register, the misbranding provisions, like the adulteration provisions, are "largely self-executing." 61 Fed. Reg. 44410. Therefore in its Federal Register notice, the agency did not, and did not have to, individually analyze the applicability of each one of the numerous adulteration and misbranding provisions to tobacco products. Id.[41/]

2. FDA Has Reasonably Interpreted Its Restricted Device Authority

Plaintiffs' final protest is that FDA does not have authority under the restricted device provision to impose the restrictions contained in the Rule. Plaintiffs claim that FDA's restrictions are unauthorized because: (1) they do not make cigarettes and smokeless tobacco "safe," or they do not make those products safe for some groups; (2) the only restriction FDA can impose on tobacco products is a prescription-like requirement; and (3) FDA does

---

[41/] The consequence of an FDA determination that tobacco products are misbranded would be an enforcement action. A decision whether or not to take such action would be unreviewable by the Court because "[t]he Act's enforcement provisions . . . commit complete discretion to [FDA] to decide how and when they should be exercised." Heckler v. Chaney, 470 U.S. 821, 835, 105 S. Ct. 1649, 1658, 84 L. Ed. 2d 714 (1985).

It is worth noting that plaintiffs are not seriously contending that FDA's regulation of tobacco products is not stringent enough. Rather, plaintiffs maintain that the way in which FDA is regulating cigarettes and smokeless tobacco is not fully in compliance with the FDCA, and therefore FDA does not have jurisdiction over tobacco products. This confuses jurisdiction with the manner of regulation. Even if, for example, plaintiffs were right--and they are not--that there are provisions of the FDCA that FDA is obliged to apply to tobacco products but is not applying, the proper remedy would be for FDA to apply those provisions, not for a court to rescind FDA's jurisdiction over those products.

not have authority to restrict device advertising (Second Brief at 38-47). None of these claims is supportable.

Under section 360j(e), FDA is authorized to determine whether device restrictions are necessary because "there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness." 21 U.S.C. § 360j(e). As described above, the agency determined that, in light of the unique circumstances surrounding the use of tobacco products, the only way to provide a reasonable assurance of the safety of these products is to prevent children and adolescents from using and becoming addicted to them, while allowing their sale to adults. Accordingly, the agency concluded that, without the restrictions contained in the Rule, there cannot be a reasonable assurance of the safety and effectiveness of these products. See 61 Fed. Reg. 44406-07.

Plaintiffs assert that this is the wrong standard to apply, arguing instead that a restriction under 360j(e) must itself "make a marketed device safe." Second Brief at 38 (emphasis added). The plain language of the restricted device provision refutes plaintiffs' claim. Only certain kinds of restrictions authorized by section 360j(e)--those that "restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities"--must be based on a finding "that such a restriction is required for the safe . . . use of a device." 21 U.S.C. § 360j(e). Section 360j(e) does not require FDA to make such a finding when it establishes other types of restrictions under that section. The statutory requirement of a specific safety finding for certain restrictions would be wholly superfluous if FDA were required to make that same finding for all restrictions. See Bailey

v. United States, 116 S. Ct. 501, 506-07, 133 L. Ed. 2d 472 (1995) ("Judges should hesitate to treat as surplusage statutory terms in any setting.") (internal quotations omitted).

Plaintiffs' argument that the Act "requires that products be safe" (Second Brief at 38-41) is also based on a misreading of the Act. As described in the preceding section, the ultimate goal of the device provisions is to provide a "reasonable assurance of safety" (and effectiveness) of devices. 21 U.S.C. § 360c (emphasis added). The reasonableness standard is not absolute, but rather is a balancing test designed to "eliminate those risks which are unreasonable in relation to the benefits to be derived." H.R. Rep. No. 94-853, at 16, 17 (1976). On this basis, the agency found that its regulatory approach "is consistent with the statutory standard of reasonable assurance of safety." 61 Fed. Reg. 44413.

As even plaintiffs appear to recognize, it is not necessary that individual restrictions--or a set of restrictions--on the sale, distribution, or use of a device under 360j(e), be sufficient to provide a reasonable assurance of safety. Instead, "[t]he FDCA . . . contemplates that any restrictions based on section 360j(e)--together with other applicable requirements of the FDCA--will provide "'reasonable assurance of [the device's] safety.'" Second Brief at 39 (emphasis added). Thus, devices that are restricted under 360j(e) are subject to the other general controls under the Act, as well as to special controls if they are classified into Class II, or premarket approval if they are classified into Class III. The many available regulatory controls for devices are designed to work together to provide a reasonable assurance of safety and effectiveness.

There is also no support in the statutory language for plaintiffs' argument (Second Brief at 38) that "the only purpose for which [the restricted device] provision authorizes any

restrictions is to make a marketed device safe (and effective) for those who use it," and therefore that restrictions cannot be related to those who will not use a device. The section of the device authorities that plaintiffs cite to support this argument, see 21 U.S.C. § 360c(a)(2)(A) (the safety and effectiveness of a device is to be determined "with respect to the persons for whose use the device is represented or intended"), is, by its own terms, applicable to only three sections of the statute (classification, performance standards, and premarket approval), and does not apply to the restricted device provision under which the Rule was promulgated.

The restricted device provision was designed to be a flexible authority, allowing FDA to tailor restrictions on sale, distribution, and use according to the individual circumstances posed by the particular device being regulated. Under the provision, FDA may prevent the use of a device by those not competent to use it safely. Thus, in accordance with this provision, FDA may adopt regulations that ensure that children and adolescents, who by state law are not competent to use cigarettes and smokeless tobacco, will not obtain them. See 21 U.S.C. § 360j(e).

Plaintiffs' assertion that the restricted device authority allows only "limitations on access to a device to medical professionals specifically trained in the use of a device or to specific medical settings" (Second Brief at 41, 41-43) is also groundless. In fact, the statute explicitly provides to the contrary. The second sentence of section 360j(e) makes clear that restrictions relating to "persons with specific training or experience" and "for use in certain facilities" are a subset of the possible authorized restrictions. See 21 U.S.C. § 360j(e)(1)(B) ("upon such other conditions as the Secretary may prescribe in such regulation").

Plaintiffs' claim that the restricted device provision was intended to be nothing more than "the device counterpart of FDA's authority to confine potent drugs to prescription sale" (Second Brief at 41), cannot be squared with the legislative history of that provision. The restricted device provision was intended to "supersede[ ] and add[] to existing authority [that was being] utilized by [FDA] to require that certain devices be dispensed only upon prescription." H.R. Rep. No. 94-853, at 24-25 (1976) (emphasis added); see also In re Establishment Inspection Portex, Inc., 595 F.2d 84, 86 (1st Cir. 1979) ("[w]hen . . . 21 U.S.C. § 360j(e) was enacted, many devices . . . were already subject to FDA's prescription device regulation").[42/] In fact, Congress considered merely creating statutory language that explicitly recognized the existence of "prescription devices," but instead created the broader "restricted device" category. See Becton, Dickinson & Co. v. FDA, 589 F.2d 1175, 1181 (2d Cir. 1978) (discussing the history of the legislation).

Plaintiffs next assert that the restricted device authority does not authorize FDA to regulate the advertising of restricted devices because "[s]ection 360j(e) nowhere mentions advertising." Second Brief at 43, 43-48. This assertion, like most of plaintiffs' other attacks on the device provisions, is based on reading a limitation into the Act that simply does not exist.

[42/] Plaintiffs' citation of an out-of-context statement from an FDA proposed rule which they claim is contrary to this interpretation (Second Brief at 42 n.33), bears no weight. See Public Citizen v. Shalala, 932 F. Supp. 13, 18 n.6 (D.D.C. 1996) ("tentative conclusion in a nonfinal, proposed rule does not command deference from the Court nor is it binding on the agency") (citing Public Citizen Health Research Group v. FDA, 740 F.2d 21, 32 (D.C. Cir. 1984)). The proposed rule cited by plaintiffs was withdrawn; indeed, when FDA withdrew the proposal, the agency noted that "comments stated that the proposed rule had not gone far enough" in the application of the restricted device authority. 46 Fed. Reg. 57569 (Nov. 24, 1981).

Advertising restrictions are permissible under section 360j(e) because, as FDA stated, advertising is an "offer for sale" and is part of the sale of a product. See 61 Fed. Reg. 44406; Edenfield v. Fane, 507 U.S. 761, 767, 113 S. Ct. 1792, 1798, 123 L. Ed. 2d 543 (1993) (commercial transactions are "linked inextricably" with the commercial speech that proposes the transaction). Under 360j(e), the sale of a device is "linked inextricably" to the advertising that promotes the sale, giving FDA authority to impose necessary restrictions on advertising. Moreover, the agency's authority is especially clear where, as here, a narrow reading of the statute would thwart its effectiveness. See Bacto-Unidisk, 394 U.S. at 798, 89 S. Ct. at 1418 ("the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health"). If the restricted device provision were read to exclude advertising restrictions, tobacco advertising could entice children in such a way as to undermine all the other conditions on sale, distribution, or use that the agency has adopted under that provision. Plaintiffs point to nothing, nor is there anything, in the FDCA that limits the aspects of sale that FDA can restrict by regulations promulgated under 360j(e).

Plaintiffs also attempt to draw the inference that because the statutory misbranding section, 21 U.S.C. § 352, contains certain specific provisions with respect to the advertising of restricted devices, e.g., 21 U.S.C. §§ 352(q), (r), the restricted device provision cannot be used to regulate advertising. Second Brief at 43-44. The misbranding section cited by plaintiffs covers many violations that are also covered by other sections of the FDCA. Compare, e.g., 21 U.S.C. § 352(a) (a device is misbranded if its labeling is false or misleading in any particular) and 21 U.S.C. § 352(f) (a device is misbranded if it does not

bear adequate directions for use on the label of a device) with 21 U.S.C. § 360e(d)(2)(D) (FDA shall deny approval of a premarket approval application if the proposed labeling is false or misleading in any particular) and 21 U.S.C. § 360d(a)(2)(C) (a performance standard can include labeling requirements). The misbranding provisions often correspond to, or are incorporated in, substantive requirements under various other provisions of the Act. However, that redundancy has never been read to limit the scope of the substantive requirements, and should not be so read here.

Finally, plaintiffs attempt to defeat FDA's regulation of advertising based on an alleged "primacy of the [Federal Trade Commission] in the general regulation of advertising for medical devices." Second Brief at 44. Plaintiffs rely on irrelevant historical material and miss the fundamental point that federal agencies, including FDA and the FTC, often have overlapping and concurrent jurisdiction. See Thompson Medical Co. v. FTC, 791 F.2d 189, 192-93 (D.C. Cir. 1986) (finding that FDA and the FTC have concurrent jurisdiction over the regulation of over-the-counter medicine and noting that "the cases recognize that ours is an age of overlapping and concurring regulatory jurisdiction"), cert. denied, 479 U.S. 1086 (1987); see also Bristol-Myers Co. v. FTC, 738 F.2d 554, 559-60 (2d Cir. 1984) (FDA and FTC jurisdiction "overlap"), cert. denied, 469 U.S. 1189 (1985).

Congress intended for FDA and the FTC to share authority over restricted device advertising. One of the linchpins of FTC advertising authority is 15 U.S.C. § 52, which prohibits, in part, disseminating "any false advertisement . . . which is likely to induce . . . the purchase of . . . devices." The FDCA similarly declares that a restricted device is misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. § 352(r).

Except for the limitations contained in section 352(r), both FDA and the FTC may regulate the advertising of restricted devices based on their particular statutory mandates and areas of expertise. FDA's regulation is aimed at protecting the public health, while the activities of the FTC are aimed at protecting the public's economic interests. The activities of both agencies serve important, yet distinct, consumer protection objectives. See 42 Fed. Reg. 9286 (1977) (hearing aid regulation). This extensive overlap of FDA and FTC authority demonstrates that plaintiffs' "primacy" argument avails them no more than any of their other arguments attacking FDA's use of its device authorities to regulate cigarettes and smokeless tobacco.

THE RESTRICTIONS IMPOSED BY FDA ON ADVERTISING AND OTHER PROMOTION OF CIGARETTES AND SMOKELESS TOBACCO ARE FULLY CONSISTENT WITH THE FIRST AMENDMENT

Plaintiffs contend that FDA's restrictions on tobacco advertising and promotion violate the First Amendment. Specifically, plaintiffs argue that FDA has not sufficiently tailored its advertising restrictions to make certain that they do not limit more speech than is necessary. They also assert that this Court must hold a trial to determine whether the restrictions adopted by FDA will directly advance the interest in lowering tobacco consumption by juveniles.

These arguments must be rejected in light of Supreme Court and Fourth Circuit precedent relating to government regulation of commercial speech. FDA has preserved plaintiffs' ability to provide relevant commercial information to adults, such as the price of tobacco products, where such products can be obtained, what such products contain, and any other fact consumers would want to know about tobacco products, such as any asserted

brand-specific superiority. With respect to adult publications and adult-only facilities, FDA also has not restricted the plaintiffs in any way, leaving them free to utilize the full range of modern advertising techniques, including the use of colors and images. As the agency explained: "FDA's concerns are about the ability of manufacturers to use images, color, and peripheral presentations (such as sponsorship) in their advertising and promotion of their products to create particular appeal for children and adolescents under 18." 61 Fed. Reg. 44472 (emphasis added).

I. The Agency's Regulations Must Be Judged Pursuant to the Supreme Court's *Central Hudson* Standard

A. The *Central Hudson* Standard and the Proper First Amendment Analysis

Because commercial speech is at issue, this case is governed by the framework set out by the Supreme Court in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980). The Central Hudson analysis asks as a threshold question ("first prong") whether the regulated speech is "related to unlawful activity" or is misleading. Id. at 564, 100 S. Ct. at 2350. If so, the speech can be freely regulated by the Government; if not, the next issues to be considered are: "whether the asserted governmental interest is substantial" ("second prong"); "whether the regulation directly advances the governmental interest asserted" ("third prong"); and "whether [the regulation] is not more extensive than is necessary to serve that interest" ("fourth prong"). Id. at 566, 100 S. Ct. at 2351.

Under Central Hudson, the Government bears the burden of justifying a restriction on commercial speech. See Rubin v. Coors Brewing Co., 115 S. Ct. 1585, 1592, 131 L. Ed.

2d 532 (1995). However, this burden is lower than it is for restrictions on other types of expression, such as political speech. The Supreme Court has

> always been careful to distinguish commercial speech from speech at the First Amendment's core. Commercial speech enjoys a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values, and is subject to modes of regulation that might be impermissible in the realm of noncommercial expression.

Florida Bar v. Went For It, Inc., 115 S. Ct. 2371, 2375, 132 L. Ed. 2d 541 (1995) (internal quotation marks and citations omitted).

This limited degree of First Amendment protection is particularly appropriate in this case for an important reason. The FDA regulations are directed at, and tailored to, restricting the flow of commercial speech to minors, a group of persons who may not legally purchase the product being advertised. The advertising at issue encourages the sale of tobacco products. In proposing this commercial transaction, the advertisers do not differentiate between adult and minor purchasers. Even assuming they are not so intended, these advertisements at the very least are perceived by minors as offers or inducements to buy and use tobacco products. Thus, such advertising in part "relates to," and encourages, an illegal transaction. The Supreme Court has repeatedly said that commercial speech "related to" unlawful activity is not entitled to First Amendment protection. See, e.g., Florida Bar, 115 S. Ct. at 2376.

It is not our position that this point by itself would permit FDA to ban tobacco advertising altogether, because such advertising also relates to lawful activity: the purchase of tobacco products by adults. However, FDA has attempted to tailor its regulations to restrict advertising in a manner directly related to the "unlawful" aspect of tobacco

advertising; it has restricted advertising that reaches minors, who have no right to receive such advertising. The agency would be able to do this without any constitutional constraint were it not for the incidental effect that such restrictions have on receipt by adults of such advertising. That incidental effect does necessitate a Central Hudson analysis. But in performing that analysis, this Court should keep in mind that the restrictions are aimed at the Government's wholly legitimate and compelling interest in curtailing minors' use of tobacco products, rather than at restricting adults' rights to receive information about their consumer choices.

B. The Recent Rulings by the Supreme Court in *44 Liquormart*, and by the Fourth Circuit in *Anheuser-Busch* and *Penn Advertising*

In Anheuser-Busch, Inc. v. Schmoke, 63 F.3d 1305, 1311-14 (4th Cir. 1995) ["Anheuser-Busch I"], and Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore, 63 F.3d 1318, 1323 (4th Cir. 1995) ["Penn Advertising I"], the Fourth Circuit, applying Central Hudson, upheld against a First Amendment challenge restrictions imposed by the City of Baltimore on outdoor alcohol and tobacco advertising. The Supreme Court remanded these cases for further consideration by the Fourth Circuit following the Court's decision in 44 Liquormart, Inc. v. Rhode Island, 116 S. Ct. 1495, 134 L. Ed. 2d 711 (1996), which struck down Rhode Island's total ban on price advertising for certain alcohol products. On remand, the Fourth Circuit again upheld Baltimore's restrictions on the outdoor advertising of alcohol and tobacco products. See Anheuser-Busch, Inc. v. Schmoke, 1996 WL 657711 (4th Cir. Nov. 13, 1996) ["Anheuser-Busch II"], and Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore, 1996 WL 657723 (4th Cir. Nov. 13, 1996) ["Penn Advertising II"] (relying primarily upon the Anheuser-Busch II analysis).

The decision in 44 Liquormart, while fragmented among several opinions, retained the constitutional framework adopted in Central Hudson. The opinions of Justices O'Connor and Scalia, which speak for a majority of the Court, explicitly declined to depart from Central Hudson. See 44 Liquormart, 116 S. Ct. at 1521 (O'Connor, J., joined by Rehnquist, C.J., and Souter & Breyer, JJ., concurring in the judgment); id. at 1515 (Scalia, J., concurring in part and concurring in the judgment). Furthermore, while other members of the Court identified hypothetical circumstances in which they would apply stricter First Amendment scrutiny, id. at 1507-08 (Stevens, J., joined by Kennedy & Ginsburg, JJ.) (Part IV); id. at 1516-20 (Thomas, J., concurring in part and concurring in the judgment), those circumstances are far different from those posed by the restrictions on the promotion of cigarettes and smokeless tobacco adopted by FDA.[43/]

[43/] In particular, as is explained more fully in the text: (1) The FDA's advertising restrictions -- unlike the restriction in 44 Liquormart -- are not imposed in order to be "paternalistic" to adult consumers. See 116 S. Ct. at 1507, 1510 (Stevens, J.); id. at 1517 (Thomas, J.). It is entirely legitimate under the First Amendment for the Government to act "paternalistically," as it has done here, in order to protect children. See, e.g., Denver Area Educational Telecommunications Consortium, Inc. v. FCC, 116 S. Ct. 2374, 2386 (1996) (opin. of Breyer, J.). (2) The FDA restrictions--again, unlike the 44 Liquormart restriction --are not a "complete ban[]" that "entirely prohibits" commercial speech regarding a product or service. 116 S. Ct. at 1507 (Stevens, J.). Justice Stevens reasoned that "complete speech bans . . . are particularly dangerous," and hence deserving of additional scrutiny, "because they all but foreclose alternative means of disseminating certain information." 116 S. Ct. at 1507. That danger is not present where -- as is true of the FDA tobacco product advertising restrictions -- a regulation leaves open alternative avenues for advertisers to communicate commercial messages to their legitimate audience. (3) The opinions in 44 Liquormart did not suggest that heightened scrutiny would be required when a commercial speech restriction is directed at reducing unlawful activity, such as the sale of tobacco products to minors. To the contrary, Justice Stevens cited with approval the Court's earlier decision in United States v. Edge Broadcasting Co., 509 U.S. 418 (1993), which employed the Central Hudson test to uphold a federal statute restricting broadcast advertisements for state lotteries, which are legal in some states, but unlawful in others. See 116 S. Ct. at 1511. Justice Stevens

(continued...)

In Anheuser-Busch II, the Fourth Circuit analyzed the Supreme Court's somewhat splintered 44 Liquormart holding, stating: "[e]ight justices thus concluded that keeping legal users of alcoholic beverages ignorant of prices through a blanket ban on price advertising does not further any legitimate end." 1996 WL 657711 at *3. The court then noted that, in contrast to the Rhode Island blanket ban on price advertising struck down by the Supreme Court, "Baltimore's ordinance expressly targets persons who cannot be legal users of alcoholic beverages," and is not a complete ban on advertising. Id.

In addition, because sales of alcohol products to minors are illegal, the Fourth Circuit found that the Baltimore provision is not an attempt "to undermine democratic processes and circumvent public scrutiny by substituting a ban on advertising for a ban on the product . . . ." Id. In light of the prohibition on sale to minors, "Baltimore's restrictions thus reinforce the democratic decisionmaking mechanism's conclusion as to the dangerousness of underage drinking by protecting children from exposure to advertising which the legislature reasonably considers harmful in itself to children's maturation." Id. The Fourth Circuit strongly contrasted the attempt by Rhode Island "to enforce adult temperance through an artificial budgetary constraint" with "Baltimore's interest . . . to protect children who are not yet independently able to assess the value of the message presented." Id. at *4.

The Fourth Circuit in Penn Advertising II similarly affirmed its earlier holding that Baltimore's restrictions on tobacco advertising were consistent with the First Amendment,

---

[43/](...continued)
reasoned that the statute in Edge "was designed to regulate advertising about an activity that had been deemed illegal in the jurisdiction in which the broadcaster was located," while the statute in 44 Liquormart "targets information about entirely lawful behavior." Id.

"[f]or the reasons given in [Anheuser-Busch II] . . . ." Penn Advertising II, 1996 WL 657723 at *1.

C. In Applying the *Central Hudson* Test, the Court's Decision Should be Based on the Record Created by the Agency, and the Reasonable Determinations Made by FDA Are Not to be Disregarded

In ruling on the First Amendment issues here, the Court must determine for itself if the Government has gone too far in restricting speech. See Sable Communications of California, Inc. v. FCC, 492 U.S. 115, 129, 109 S. Ct. 2829, 2838, 106 L. Ed. 2d 93 (1989). Nevertheless, judicial review in this area should not disregard the informed views of the other branches of government. See Columbia Broad. Sys., Inc. v. Democratic Nat'l Comm., 412 U.S. 94, 103, 93 S. Ct. 2080, 2087, 36 L. Ed. 2d 772 (1973) (in the First Amendment context, "when we face a complex problem with many hard questions and few easy answers we do well to pay careful attention to how the other branches of Government have addressed the same problem").

Plaintiffs contend (Third Brief at 4 n.3) that there is a need for a trial regarding the third Central Hudson factor, addressing whether the new advertising restrictions directly advance the substantial governmental interest asserted. In a similar vein, they suggest that if they do not receive summary judgment under the fourth prong of Central Hudson, they would be "entitled to present testimony and additional evidence in court" on the question of narrow tailoring. Id. at 6 n.5. Because these suits challenge final administrative action by FDA, however, plaintiffs are mistaken in claiming that this Court must hold some sort of trial, with development of even more factual material.

The record compiled by FDA--the largest ever assembled by the agency--provides a reviewing court with ample material from which it can determine whether the Government has satisfied its Central Hudson burden. This record was compiled with full participation by all of the plaintiffs. With rare exceptions not present here, review of an agency's action is limited to the record developed in administrative proceedings. See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743-44, 105 S. Ct. 1598, 1606-07, 84 L. Ed. 2d 643 (1985); James Madison Ltd. v. Ludwig, 82 F.3d 1085, 1095 (D.C. Cir. 1996), petition for cert. filed, 65 U.S.L.W. 3295 (U.S. Oct. 1, 1996) (No. 96-525). This rule defining the scope of the record applies even when constitutional claims--including First Amendment arguments--are made against agency rules. See, e.g., Action for Children's Television v. FCC, 58 F.3d 654 (D.C. Cir. 1995) (en banc) (analyzing record developed by administrative agency in ruling on First Amendment challenge to FCC regulations governing broadcast of indecent material), cert. denied, 116 S. Ct. 701 (1996); Plaquemines Port, Harbor and Terminal Dist. v. Fed. Maritime Comm'n, 838 F.2d 536, 551 (D.C. Cir. 1988) ("This court may reach constitutional issues not reached by the agency. We must rely, however, on the factual record transmitted to us by the agency.").

As the D.C. Circuit explained in White House Vigil for the ERA Comm. v. Clark:

> [G]overnment regulations which restrict the exercise of free speech are subject to closer scrutiny than other types of administrative decisions, and . . . courts, not agencies are the ultimate arbiters of constitutionality. It by no means follows, however, that courts are required or permitted to duplicate the extensive factual inquiries undertaken by agencies when they draft regulations. Not only is such duplication highly inefficient, it reflects a lack of judicial recognition for the unique expertise of administrative agencies.

746 F.2d 1518, 1531 n.96 (D.C. Cir. 1984) (emphasis in original).[44/]

In the distinct situation concerning review of legislative determinations but no factual record, the Supreme Court in Turner Broad. Sys., Inc. v. FCC, 114 S. Ct. 2445, 120 L. Ed. 2d 497 (1994), ruled that the First Amendment issue required development of an evidentiary record by the district court regarding the asserted economic necessity for "must carry" rules in the cable industry. Justice Kennedy explained there that "Congress is not obligated, when enacting its statutes, to make a record of the type that an administrative agency or court does to accommodate judicial review." Id. at 2471. Thus, because of the lack of a record for the Court to review, the Turner Broadcasting Court remanded that matter for factfinding by the district court on the key First Amendment points. But, Justice Kennedy contrasted that situation to one in which an agency has already developed a record, making judicial review possible. Id.

Significantly for the case at bar, the Justices in Turner Broadcasting emphasized that "courts must accord substantial deference to the predictive judgments of Congress." Id. (plurality opinion); id. at 2473-74 (Stevens, J., concurring). As Justice Kennedy explained, "[t]his obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence de novo, or to replace Congress' factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress

---

[44/] Moreover, even if this Court were to find that the record developed by FDA were insufficient to support the agency's action, the proper remedy would not be to have a trial to find more facts. Rather, the matter would be remanded to the agency to determine whether further necessary facts can be adduced. See Florida Power, 470 U.S. at 744, 105 S. Ct. at 1607.

has drawn reasonable inferences based on substantial evidence." Id. at 2471; accord id. at 2473-74 (Stevens, J., concurring).

This point in the Turner Broadcasting opinion by Justice Kennedy is revealing because it cites as support Century Communications Corp. v. FCC, 835 F.2d 292 (D.C. Cir. 1987), a case that decided a First Amendment challenge to an agency rule on the basis of the rulemaking record developed by the FCC. Turner Broadcasting, 114 S. Ct. at 2471. Accordingly, Justice Kennedy's opinion equated a reviewing court's role in examining legislative findings made by Congress with its role in ruling on a First Amendment challenge to an agency rule.

Thus, in evaluating FDA's advertising restrictions for compliance with the First Amendment, this Court is not to create its own factual record, or to make its own entirely new judgments about whether advertising contributes to the use of tobacco products by minors and whether the restrictions at issue represent a desirable and effective means of limiting the effects of cigarette and smokeless tobacco product advertising. Rather, on the basis of the record compiled by the agency with the participation of the plaintiffs, this Court should determine whether the Government has amply justified the existence of a real concern, and whether the Government has chosen appropriate means to address that concern. See Anheuser-Busch I, 63 F.3d at 1311-15. As demonstrated below, the FDA has satisfied these Central Hudson requirements.

II. The Government's Interest Here Is Plainly Substantial

There can be no doubt that the Government has a sufficiently substantial interest in discouraging the use of tobacco products by minors, and plaintiffs appear to concede this point. The Supreme Court has instructed that

> [i]t is evident beyond the need for elaboration that a State's interest in safeguarding the physical and psychological well-being of a minor is compelling. A democratic society rests, for its continuance, upon the healthy, well-rounded growth of young people into full maturity as citizens. Accordingly, we have sustained legislation aimed at protecting the physical and emotional well-being of youth even when the laws have operated in the sensitive area of constitutionally protected rights.

New York v. Ferber, 458 U.S. 747, 756-57, 102 S. Ct. 3348, 3354, 73 L. Ed. 2d 1113 (1982) (internal quotation marks and citations omitted).

Tobacco products are dangerous to health, yet millions of minors use them. The states and the Federal Government have a clear and substantial interest in restricting and discouraging activities that result in sales of such products to, and use of such products by, minors. See Penn Advertising I, 63 F.3d at 1325. Accordingly, the second Central Hudson prong is met without question.

III. FDA Has Demonstrated That Advertising Affects Tobacco Use By Minors, To the Detriment of the Public Health, And That The Agency's Restrictions On Advertising Of These Products Should Alleviate That Problem To A Material Degree

Under the third Central Hudson prong, the reviewing court must look to whether the challenged regulation of commercial speech advances the Government's stated interest "in a direct and material way." Edenfield v. Fane, 507 U.S. 761, 767, 113 S. Ct. 1792, 1798, 123 L. Ed. 2d 543 (1993). That burden "is not satisfied by mere speculation and conjecture; rather a governmental body seeking to sustain a restriction on commercial speech must

demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Id. at 770-71, 113 S. Ct. at 1800.

The Government has met that burden here. The reality of the harm at stake is manifest; millions of minors are using tobacco products. Minors not only start using cigarettes and smokeless tobacco as children, they become addicted as children. This usage has severe and long-term adverse health consequences for these minors when they become adults. And, FDA has found that advertising of tobacco products has a considerable impact on this use by minors.

In 1993 alone, the cigarette and smokeless tobacco industries spent over $6.1 billion to promote their products through magazines, newspapers, and outdoor advertising; at the point of purchase, in stores, and through direct mail; by dissemination of non-tobacco items with brand names and logos; and by sponsorship of cultural and sporting events. FDA concluded that significant evidence, including studies from the National Academy of Sciences' Institute of Medicine and the federal Centers for Disease Control and Prevention, indicates that this advertising is an important factor in tobacco use by minors. See 61 Fed. Reg. 44466, 44475-88.[45/] FDA also based its findings on the numerous studies and surveys showing that "children are exposed to substantial and unavoidable advertising, that exposure to tobacco advertising leads to favorable beliefs about tobacco use, that advertising plays a role in leading young people to overestimate the prevalence of tobacco use, and that these factors are related to young people's tobacco initiation and use." 61 Fed. Reg. 44488; see

[45/] As the agency observed, the two named studies "represent mainstream scientific consensus and are appropriately entitled to a great deal of deference." 61 Fed. Reg. 44488.

also 61 Fed. Reg. 44475-76. In addition, empirical studies based on multi-country data showed that advertising tends to increase consumption of tobacco products among young people. See 61 Fed. Reg. 44483, 44487-88, 44489-93; 60 Fed. Reg. 41333-34.

There is insufficient space here to describe the breadth of support for FDA's conclusions on this point, as well as the agency's discussion of precisely how advertising affects minors. However, these matters are fully addressed and supported in FDA's explanation for the advertising restrictions it has imposed. See 61 Fed. Reg. 44466-95. Those pages review the extensive evidentiary record compiled by the agency, and cogently explain the bases for its action. In brief, FDA found that advertising in a wide variety of media has an impact on minors, and, in particular, that the use of color and imagery in advertising is especially effective in reaching youth. 61 Fed. Reg. 44466-68. This advertising helps tobacco companies overcome the fact that, as documents from R.J. Reynolds show, there is no natural craving for nicotine. 61 Fed. Reg. 44489. One forceful example of the effectiveness of youth-directed advertising is R.J. Reynolds' massive "Joe Camel" campaign. Camel's share of the youth cigarette market rose from about 3% before the campaign started to 13-16% within six years. 60 Fed. Reg. 41330; 61 Fed. Reg. 45246. In addition, FDA cited evidence demonstrating that company officials in the smokeless tobacco industry deliberately set out to create a youth market through advertising. 61 Fed. Reg. 44479-82, 44484.

Even if there were not such an extensive record on this point, the Supreme Court has recognized that, as a matter of "common sense" and "reason," promotional advertising and subsequent consumption are linked, and that reducing the former will reduce the latter. See

44 Liquormart, 116 S. Ct. at 1506 ("the Court [in Central Hudson] recognized . . . that there was an immediate connection between advertising and demand for electricity") (quoting Central Hudson, 447 U.S. at 569, 100 S. Ct. at 2353). Accord Rubin, 115 S. Ct. at 1592 ("It is assuredly a matter of 'common sense' that a restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait"). The Court expanded on this theme in Edge Broadcasting: "If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand . . . is correspondingly advanced." 509 U.S. at 434, 113 S. Ct. at 2707.

Not surprisingly, this appeal to common sense has been relied upon by the Fourth Circuit and other appellate courts as well. For example, in Anheuser-Busch I, 63 F.3d at 1314-15, the Fourth Circuit relied upon Central Hudson in upholding Baltimore's judgment that restrictions on outdoor advertising would affect alcohol use by minors, despite a factual predicate far short of that found in this case. One of the cases used by the Fourth Circuit to reach this conclusion was Dunagin v. City of Oxford, Miss., 718 F.2d 738 (5th Cir. 1983), where the Fifth Circuit upheld a ban on certain types of advertising for alcohol products, stating:

> Money talks: it talks to the young and the old about what counts in the marketplace of our society, and it talks here in support of Mississippi's concerns. . . . We simply do not believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors. . . . [W]e hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban [on advertising for alcohol], whether or not 'concrete scientific evidence' exists to that effect.

Id. at 749-50.

Thus, under existing Supreme Court and Fourth Circuit precedent, the link between advertising and consumption of tobacco products--and the consequent reduction in consumption to be expected from restrictions on advertising--cannot be disputed. Since minors are subject to the effects of advertising by the tobacco industry to at least the same degree as adults,[46/] there can be no dispute that the consumption of tobacco products by minors is affected by this advertising.

Further, FDA examined the issue raised by the Fifth Circuit in Dunagin: whether advertising of tobacco products merely increases the market share of the particular product brand being advertised, or whether such advertising, when combined with all other tobacco product advertising, raises the overall level of consumption by minors. FDA quoted one "well-known advertising executive," who commented: "'I am always amused by the suggestion that advertising, a function that has been shown to increase consumption of virtually every other product, somehow miraculously fails to work for tobacco products.'" 61 Fed. Reg. 44494. The agency did not simply rely upon common sense and anecdotes on this point, however; it also cited, for example, an econometric study showing that "advertising for low tar cigarettes did increase overall market size." 61 Fed. Reg. 44483.

FDA addressed the argument raised in the rulemaking proceedings that the tobacco products market is a "mature" one, and that advertising therefore only promotes brand loyalty and does not induce anyone to begin using tobacco products. The agency found this

---

[46/] As FDA found: "Children are not isolated from tobacco advertising's attractiveness or inducements. There is no 'magic curtain around children and teenagers who seek to learn how to fit into the adult world,' nor is there any evidence to support a claim that young people are immune from advertising's blandishments." 61 Fed. Reg. 44494.

theory simplistic because even in mature markets, producers must replenish their customer base as older consumers leave the market; indeed, approximately one million new young smokers enter the tobacco market each year. 61 Fed. Reg. 44494. There is no evidence establishing that these new smokers are predestined. As was recognized in a R.J. Reynolds marketing memorandum: "'If we are to attract the nonsmoker or the presmoker, there is nothing in this type of product that he would currently understand or desire. . . . Instead, we somehow must convince him with wholly irrational reasons that he should try smoking.'" Id. This statement further demonstrates the likelihood that restrictions on tobacco advertising will be effective in reducing youth smoking rates.

Moreover, FDA noted that even in a so-called mature tobacco market, previous advertising campaigns have resulted in increased smoking rates within targeted groups; for example, smoking rates for teenage girls rose dramatically when major promotional campaigns targeted women. 61 Fed. Reg. 44495. FDA found that the ability of tobacco advertising to expand total demand for a particular product by targeting particular consumer desires is similar to the use of advertising in other mature markets to create new segments of the market, such as the breakfast cereal industry's promotion of the health benefits of its products. Id.

FDA also found strong support in international experience showing that comprehensive restrictions on advertising decreased consumption by minors of tobacco products: "The experience of other countries that have adopted advertising restrictions shows that when those restrictions are enforced, they have resulted in reductions in the level of tobacco use." 61 Fed. Reg. 44490. The evidence FDA relied on included one multi-country

analysis finding that advertising restrictions resulted in an aggregate decrease in cigarette consumption. For example, in Norway, the percentage of 15- to 16-year-old youth who smoked daily dropped by 7% among boys and by 11% among girls after an advertising ban went into effect. 61 Fed. Reg. 44490-91.[47/]

In short, FDA concluded that the tobacco companies have not been spending billions of dollars fruitlessly or only to shift brand choices among cigarette and smokeless tobacco product users; advertising of tobacco products helps persuade minors to use these products. As empirical evidence from other countries demonstrates, significantly limiting the amount of tobacco product advertising with powerful use of color and imagery that minors see will help to reduce demand in that group, and thereby benefit public health.

The agency therefore found that "advertising plays an important role in creating new customers, including young people." 61 Fed. Reg. 44495. Like the Fifth Circuit in Dunagin, FDA concluded: "It is beyond our ability to understand why an industry would spend billions a year merely to acquire market share at the expense of its competitors, when it has a much harder job of convincing young people to start a habit that is neither easy to acquire nor pleasant." 61 Fed. Reg. 44495 (citing 718 F.2d at 750). Accordingly, the FDA has satisfied the third prong of the Central Hudson inquiry.

[47/] FDA's conclusions on these points are summarized in two pages that discuss expert opinions, advertising theory, empirical studies, anecdotal evidence, and tobacco industry statements. 61 Fed. Reg. 44488-89. We urge the Court to consult that concise discussion, which further demonstrates the validity of the agency's conclusion that advertising leads to an increase in youth consumption of tobacco products.

IV. FDA's Advertising Restrictions Are Narrowly Tailored

A. The Restrictions Are Designed To Preserve The Flow Of Information To Lawful Consumers

The final question under Central Hudson is whether the regulation is "more extensive than is necessary to serve that interest." 447 U.S. at 566, 100 S. Ct. at 2351. In Board of Trustees of the State Univ. of N.Y. v. Fox, the Court held squarely that this inquiry does not amount to a "least restrictive means" test. 492 U.S. 469, 109 S. Ct. 3028, 106 L. Ed. 2d 388 (1989). Instead, the Court's decisions require

> a "'fit' between the [government's] ends and the means chosen to accomplish those ends," 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[]"; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective. Within those bounds we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.

Id. at 480, 109 S. Ct. at 3035 (citations omitted).

The Supreme Court has elaborated on this approach in subsequent decisions, but it has never retreated from Fox's firm rejection of a "least restrictive means" test. To the contrary, it has repeatedly reaffirmed that holding. See Edge Broadcasting, 509 U.S. at 429-30, 113 S. Ct. at 2704-05; City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 416-17 nn.12-13, 113 S. Ct. 1505, 1510 nn.12-13, 123 L. Ed. 2d 99 (1993); Florida Bar, 115 S. Ct. at 2380. Accordingly, a commercial speech restriction will fail the narrow-tailoring requirement only if it "burden[s] substantially more speech than necessary." Edge Broadcasting, 509 U.S. at 430, 113 S. Ct. at 2705 (emphasis added); Anheuser-Busch I, 63 F.3d at 1315. The existence of "numerous and obvious less-restrictive alternatives" is a "relevant consideration," although not necessarily a dispositive one, in assessing the fit

between the Government's regulatory means and ends. Discovery Network, 507 U.S. at 417 n.13, 113 S. Ct. at 1510 n.13. Conversely, the continued availability of alternative channels to communicate the regulated speech weighs in favor of sustaining the regulation. See Florida Bar, 115 S. Ct. at 2380-81.

In the pages that follow, we apply these standards to each element of FDA's advertising regulations. First, however, we address plaintiffs' characterization of those regulations as a whole.

According to plaintiffs, the FDA regulations constitute "the most wide-ranging restrictions on commercial speech ever imposed by any governmental body in the United States." Third Brief at 1. Plaintiffs insist that the regulations here "are far more sweeping--and prohibit far more speech to adults--than the Rhode Island alcohol price advertising laws" struck down by the Supreme Court in 44 Liquormart. Id. at 17.[48/] This rhetoric is dramatic, but it disregards what FDA's regulations actually do. Far from being an unprecedented incursion on commercial speech, the regulations represent a carefully limited exercise in regulation that has been shaped by close attention to the constitutional values underlying Central Hudson.

[48/] Amicus curiae Washington Legal Foundation's assertion in its brief (at 4) that "no government entity has ever attempted to impose a set of speech restrictions of the magnitude, scope, or detail as the FDA regulations here" is mistaken. The enactment of the FCLAA in 1970, which ended all cigarette advertising on television when cigarette advertising was the largest advertiser on that medium, had a larger economic impact. That statute was upheld in Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582 (D.D.C. 1971), aff'd, Capital Broadcasting v. Kleindeinst, 405 U.S. 1000, 92 S.Ct. 1289, 31 L. Ed. 2d 472 (1972).

"The First Amendment's concern for commercial speech is based on the informational function of advertising." Central Hudson, 447 U.S. at 563, 100 S. Ct. at 2350. At its core, advertising serves to "'disseminat[e] . . . information as to who is producing and selling what product, for what reason, and at what price.'" 44 Liquormart, 116 S. Ct. at 1505 (principal opinion) (quoting Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 765, 96 S. Ct. 1817, 1827, 48 L. Ed. 2d 346 (1976); Bates v. State Bar of Arizona, 433 U.S. 350, 364, 97 S. Ct. 2691, 2699, 53 L. Ed. 2d 810 (1977) (advertising "inform[s] the public of the availability, nature, and prices of products and services."). Advertising thus "serves individual and societal interests in assuring informed and reliable decisionmaking." Bates, 433 U.S. at 364, 97 S. Ct. at 2699. It is this informational function that the First Amendment's protection of commercial speech is "designed to safeguard." Edenfield, 507 U.S. at 766, 113 S. Ct. at 1798.

The FDA regulations have been carefully tailored to preserve, rather than impair, this informational function. The regulations do not attempt to restrict tobacco manufacturers, distributors, or retailers from conveying information about their products to lawful purchasers. To the contrary, plaintiffs remain entirely free to "inform the public of the availability, nature, and prices" of their products. Bates, 433 U.S. at 364, 97 S. Ct. at 2699. Moreover, with the sole exception of outdoor advertising within 1,000 feet of schools and playgrounds, which poses special concerns, the regulations do not limit the media through which product information may be conveyed. To the extent that the regulations affect the form of tobacco advertising, for example by restricting the use of images and colors, they do so not to limit the flow of information to adults, but rather solely to reduce

the effect of the advertising on children, an audience that plaintiffs have no First Amendment interest in reaching, and one that plaintiffs publicly disavow any desire to sell to.

Because FDA's regulations are not intended to impede the free flow of commercial information to lawful purchasers, but instead are designed to preserve that flow, they differ fundamentally from the principal Supreme Court cases invoked by plaintiffs. In 44 Liquormart, for example, Rhode Island's statutes were specifically designed to prevent liquor advertisers from conveying information about the price of their products. See 116 S. Ct. at 1501; see also Bates, 433 U.S. at 367-68, 97 S. Ct. at 2701 (ban on price advertising by lawyers); Virginia State Board of Pharmacy, 425 U.S. at 749-50, 96 S. Ct. at 1819 (ban on price advertising by pharmacists). Likewise, in Coors, the Alcohol Administration Act sought to minimize lawful purchasers' knowledge of a basic characteristic of beer--its alcohol content--by excluding content information from beer labels. See 115 S. Ct. at 1587-89. And in Central Hudson itself, the regulatory orders at issue prohibited all promotional advertising by electrical utilities. See 447 U.S. at 558-60, 100 S. Ct. at 1347-48. In each of these cases, the challenged regulation undertook to keep truthful commercial information out of the hands of legal purchasers. In this most fundamental sense, FDA's regulations, which are aimed at advertising received by unlawful purchasers, are less restrictive than the laws in cases like 44 Liquormart, not more so.

B. The Availability Of Non-Speech Related Regulatory Alternatives Does Not Invalidate FDA's Regulations

Plaintiffs argue at considerable length that FDA's advertising regulations are unconstitutional because the Government has alternative, non-speech related means to reduce underage smoking. The Fourth Circuit's recent decisions in Penn Advertising II and

Anheuser-Busch II, which were issued after plaintiffs' opening brief, effectively dispose of this argument. In Penn Advertising and Anheuser-Busch, the court of appeals sustained the constitutionality of restrictions on tobacco and alcohol advertising despite the existence of non-speech alternatives for reducing underage consumption of those products. These decisions cannot be squared with a rule that non-speech alternatives render speech restrictions per se invalid as a means of discouraging consumption by minors.

Plaintiffs profess to find support for their per se rule in 44 Liquormart. There, a majority of the Supreme Court held that Rhode Island's liquor price advertising restrictions were invalid because the state had alternative non-speech restrictions available to it that would be more effective than advertising restrictions in increasing liquor prices and reducing liquor consumption. See 116 S. Ct. at 1510-11 (principal opinion); id. at 1521-22 (concurring opinion). The majority identified a number of possible non-speech restrictions, none of which was being pursued by Rhode Island. Id. In particular, the opinions of Justice Stevens and Justice O'Connor identified the alternatives of setting minimum prices and raising sales taxes as obviously more effective ways for the state to increase liquor prices and reduce consumption. Id.[49/]

[49/] While 44 Liquormart makes clear that the availability of effective non-speech-related regulatory alternatives is relevant to the final prong of Central Hudson, that decision does not hold that the bare existence of such alternatives will always be dispositive. In practice, there are any number of practical constraints on the effective scope of regulatory alternatives. Central Hudson and its progeny have never required the Government or the courts to disregard such constraints, and 44 Liquormart does not purport to change the law in this regard. If it were construed to require the Government to exhaust all conceivable regulatory alternatives to commercial speech restrictions, Central Hudson and Fox would be dead letters.

44 Liquormart's reasoning casts no doubt on the constitutionality of FDA's advertising regulations, for two related reasons. First, unlike Rhode Island in 44 Liquormart, and like Baltimore in Penn Advertising and Anheuser-Busch, the Federal Government and the states are pursuing non-speech related means of reducing underage smoking. The advertising regulations at issue here are being employed as a complement to non-speech restrictions, rather than as an alternative to them, as in 44 Liquormart. Second, an attack on underage smoking that is confined to non-speech related restrictions, as plaintiffs demand, cannot be expected to be as effective as one in which non-speech restrictions and advertising restrictions are used together. See 61 Fed. Reg. 44487-88. As shown above, the limited advertising restrictions here directly address a critical component of underage cigarette and smokeless tobacco use that is largely beyond the reach of non-speech restrictions: the development of the desire of children to use tobacco. Accordingly, the addition of advertising restrictions to FDA's regulatory initiative can be expected to result in less underage smoking now and fewer tobacco-related deaths in the future. As we now show, nothing in 44 Liquormart or any other decision demands that these important public health gains be sacrificed to the interest of unrestricted tobacco advertising.

Plaintiffs themselves acknowledge the breadth of the non-speech restrictions that are already employed by the Federal Government and the states to combat underage smoking. See Third Brief at 20-22. Every state now prohibits the sale of tobacco products to minors, and many states have taken additional steps to restrict sales to minors, such as limiting vending machine sales and conducting point-of-sale inspections. 61 Fed. Reg. 44548-49. Pursuant to the ADAMHA Reorganization Act of 1992, the Federal Government has encour-

aged these measures by requiring states, as a condition for obtaining specified federal block grants, to prohibit tobacco sales to minors and "enforce the law . . . in a manner that can reasonably be expected to reduce the extent to which tobacco products are available" to minors. 42 U.S.C. § 300x-26; 45 C.F.R. §§ 96.123(a)(5), 96.130 (implementing regulations). Finally, FDA itself has promulgated a variety of access restrictions as part of the present Rule--non-speech restrictions whose enforcement plaintiffs are asking this Court to enjoin. See 21 C.F.R. §§ 897.14(a)-(d), 897.16(b)-(d).

Contrary to plaintiffs' claim, FDA gave careful attention to the likely effect of non-speech restrictions. See 61 Fed. Reg. 44426-30, 60 Fed. Reg. 41322-29. FDA recognized that non-speech measures, if implemented in a consistent and vigorous fashion, can be expected to contribute to a material reduction in tobacco use by children. But there is no reason to think that, standing alone, they will reduce underage smoking nearly as effectively as a coordinated approach. To the contrary, without speech restrictions, there is every reason to expect that tobacco advertising will continue to contribute to the decisions of a significant percentage of young people to use tobacco products, thereby undermining the effectiveness of the agency's non-speech (access) restrictions and resulting in continued sales to, and use by, minors. See 61 Fed. Reg. 44465-66.

The ADAMHA amendments are a case in point. The amendments and implementing regulations contemplate that state access restrictions may be able to eliminate 80 percent of sales to minors. See 45 C.F.R. § 96.130(g). An 80 percent reduction would indeed be a significant accomplishment, but it would mean that as much as 20 percent of all efforts by minors to purchase cigarettes from retailers--one out of every five attempts--would still be

successful. In California, a state that has mounted a vigorous effort to curtail tobacco sales to minors, attempts by minors to purchase cigarettes from retail outlets during 1996 succeeded nearly 30 percent of the time. Third Brief, Ex. 9.[50/]

Plaintiffs quote HHS' statement, in its notice of proposed rulemaking for the ADAMHA regulations, that "[e]liminating virtually all sales to minors does not even present particularly difficult enforcement problems." 58 Fed. Reg. 45165 (1993). At the same time that it made this remark, however, HHS concluded that the most realistic target for reduction in sales to minors was 80 percent, rather than a higher figure. Id.; 61 Fed. Reg. 1492 (1996) (final rule) (adhering to 80 percent goal). HHS' decision to accept a 20 percent failure rate reflects its judgment that, while eliminating "virtually all sales to minors" is theoretically possible, that outcome cannot be expected in practice.

Moreover, reducing retail sales to minors by a given percentage does not mean that there will be a corresponding reduction in underage access to tobacco products, since minors can obtain tobacco products through a variety of means--such as sales to older friends and siblings--that do not involve direct sales to minors themselves. See 61 Fed. Reg. 1501 (1996). Thus, as HHS observed when promulgating the final version of the ADAMHA regulations, "[i]t is probable . . . that the reduction in tobacco use by youth and children would be much less than the reduction in illegal sales measured by the State's failure rate."

[50/] In drafting the ADAMHA regulations, HHS noted that Woodbridge, Illinois, achieved a dramatic reduction in tobacco sales to minors by enforcing access restrictions. 58 Fed. Reg. 45161 (1993). Plaintiffs take pains to quote HHS's description of Woodbridge's success (Third Brief at 22). However, they neglect to quote HHS's response: "it would not be prudent to rely on the experience of one community in setting a national policy . . . ." 58 Fed. Reg. 45161 (1993).

Id. at 1502 (emphasis added). HHS estimated that the ADAMHA regulations would result in a reduction in youth smoking rates that "would exceed one-tenth, but fall short of one-third." Id. at 1503.[51/]

Advertising restrictions are a vital complement to access and other non-speech restrictions because they attack a problem that non-speech restrictions cannot directly address: the demand for tobacco products by minors created by advertising. See Anheuser-Busch I, 63 F.3d at 1316. As described above, there is ample evidence that exposure to tobacco advertising contributes strongly to the decision of minors to use cigarettes and smokeless tobacco. Tobacco advertising employs images and other visual techniques that appeal to adolescents' need to belong and to appear adult, and this breaks down their resistance to tobacco use. 61 Fed. Reg. 44466-68. Conversely, restrictions on types of tobacco advertising that are particularly effective on children will diminish the perceived attractiveness of smoking to that group. FDA's advertising restrictions are designed to discourage demand that non-speech regulations cannot adequately forestall. Moreover, these restrictions are necessary to prevent advertising from undercutting the effectiveness of access restrictions. See 61 Fed. Reg. 44406-07.[52/]

[51/] When plaintiffs compare the relative efficacy of advertising restrictions and non-speech restrictions, they gloss over the distinction between sales and use. For example, they attempt to contrast the ADAMHA goal of an 80 percent reduction in sales with FDA's goal of a 50 percent reduction in use (Third Brief at 22). As explained above, sales and use are not synonymous; an 80 percent reduction in sales, standing alone, is expected to translate into far less than a 50 percent reduction in use.

[52/] Interest in smoking by minors also may be diminished by comprehensive anti-smoking educational campaigns. FDA did not mandate an educational campaign as part of the present Rule, but it announced that it intends to pursue implementation of an educational campaign

(continued...)

Plaintiffs nevertheless argue that, if 44 Liquormart bars the Government from using advertising restrictions in lieu of equally effective non-speech alternatives, then the Government cannot use advertising restrictions in addition to non-speech restrictions, even if the cumulative effect of advertising restrictions and non-speech restrictions is greater than that of non-speech restrictions alone. Third Brief at 25. As the Fourth Circuit's decisions in Penn Advertising and Anheuser-Busch demonstrate, this argument is a non sequitur. It finds no support in 44 Liquormart, a case in which the state had closed its eyes to non-speech related alternatives, such as raising liquor prices, and was faulted for its one-track approach. Indeed, plaintiffs' argument reflects a basic misunderstanding of the logic of 44 Liquormart and Central Hudson.

When the Government restricts commercial speech instead of using an equally effective non-speech alternative, the availability of the unexercised non-speech alternative enables the Government to give up the speech restriction without losing ground in the pursuit of its ultimate goal. As a result, the speech restriction is necessarily more extensive than is necessary in an obvious and straightforward sense. In contrast, when the Government employs a commercial speech restriction as a complement to non-speech regulation, and where (as here) the speech restriction promises to provide additional benefits beyond those

---

[52/](...continued)
using the notification provision of Section 518(a) of the Act. 61 Fed. Reg. 44538. The tobacco industry, which disputed the efficacy of educational campaigns in the administrative proceedings before FDA, see id., now asserts that educational campaigns would be as effective as advertising restrictions in reducing underage demand (Third Brief at 23-24). As FDA pointed out, however, the efficacy of educational campaigns would be undermined if children continued to be exposed to unrestricted tobacco advertising. See 61 Fed. Reg. 44499. Educational campaigns and advertising restrictions are complementary initiatives rather than alternatives.

that can be realized by non-speech alternatives alone, forcing the Government to abandon the speech restriction necessarily means leaving the Government further from achieving its public health goal. In these circumstances, the mere existence of non-speech alternatives does not render the speech restriction more extensive than necessary for the simple reason that the speech restriction is necessary to advance the Government's interests beyond the point that non-speech regulations can carry it. In addition, the fact that the Government is pursuing non-speech restrictions as well as speech restrictions demonstrates that the Government is not using speech regulations "to undermine democratic processes and circumvent public scrutiny" of its underlying policies. Anheuser-Busch II, 1996 WL 657711 at *3.

Invoking Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983), plaintiffs argue that the additional impact of advertising restrictions on underage smoking does not pass muster under the fourth prong of Central Hudson. Third Brief at 26. However, nothing in Bolger supports that proposition. There, the Supreme Court invalidated a federal law that prohibited the unsolicited mailing of contraceptive advertising. The Court determined that the law provided "only the most limited incremental support" for the goal of parental control over access to birth control information, because parents already exercised "substantial control" over the disposition of mail, and because children could obtain the same information from a variety of other advertising media. 463 U.S. at 73 & n.26, 103 S. Ct. at 2884. At the same time, because the restriction in Bolger completely prohibited the mailing of commercial information about contraception to the home, the law "'reduce[d] the adult population . . . to reading only what is fit for children,'" a cost that outweighed the "marginal degree of [additional] protection" achieved by the

statute. Id. at 73-74, 103 S. Ct. at 2884 (quoting Butler v. Michigan, 352 U.S. 380, 383, 77 S. Ct. 524, 526, 1 L. Ed. 2d 412 (1957)).

The incremental value of the advertising restrictions in this case is far greater than that in Bolger because FDA's regulations cover a wide array of advertising media over which parents can exercise little if any control, such as billboards near schools and playgrounds. At the same time, in stark contrast to Bolger, FDA's regulations impose no restriction on the information that can be conveyed to adults; far from "reduc[ing] the adult population . . . to reading only what is fit for children," the regulations leave adults free to read whatever information the tobacco industry wishes to publish.

Plaintiffs also assert (Third Brief at 26) that in "virtually every case" in which commercial speech restrictions have been struck down, including 44 Liquormart, the speech restrictions "arguably might have advanced the State's interests" beyond what could be achieved by non-speech alternatives. That is incorrect. In 44 Liquormart, for example, it could not seriously be contended that prohibiting liquor price advertising could significantly increase liquor prices (and thereby reduce consumption) beyond the levels that could be achieved by direct price regulation or tax increases. Similarly, in Coors, it could not credibly be claimed that excluding alcohol content information from beer labels would provide a meaningful additional deterrent to "strength wars" beyond that provided by direct regulation of alcohol content.

Plaintiffs assert (Third Brief at 24) that the Government must wait until non-speech means of reducing underage smoking have been shown to be ineffective before it can resort to advertising restrictions. We emphatically disagree. FDA's advertising regulations are not

based on the assumption that access restrictions will fail, and their constitutional justification turns not on the failure of those restrictions, but rather on the value of advertising restrictions in buttressing those restrictions. More fundamentally, the First Amendment does not require the Government to stand aside and wait while thousands of youths, influenced by advertising and undeterred by access restrictions, start down a road that will ultimately lead to their deaths. The Government's object is to save lives; it does not have to postpone the use of reasonable advertising restrictions while yet more lives are lost.[53/]

C. Each Of FDA's Individual Advertising Restrictions Is Narrowly Tailored

Despite the undeniably significant role that tobacco advertising plays in underage smoking, and despite the drastic consequences that follow a child's decision to use tobacco products, FDA rejected proposals to ban tobacco advertising altogether. See 61 Fed. Reg. 44509. Instead, FDA undertook an intensive effort to identify aspects of tobacco advertising that are particularly influential on children, but do not play a significant role in the informational function of advertising that the First Amendment protects. To the greatest extent practicable, the individual regulations adopted by FDA are directed to these youth-influencing aspects. As a result, the scope of the regulations "is 'in proportion to the interest served'"

[53/] In re R.M.J., 455 U.S. 191, 102 S. Ct. 929, 71 L. Ed. 2d 64 (1982), is not to the contrary, despite the plaintiffs' suggestion (Third Brief at 24-25). In R.M.J., the Supreme Court invalidated an "absolute prohibition," 455 U.S. at 206, 102 S. Ct. at 939, on direct mailing of lawyer advertising because the state had not shown that less restrictive alternatives would be less effective. When the Supreme Court observed that "[t]here is no indication in the record of a failed effort to proceed along such a less restrictive path," id., it was not imposing a substantive requirement, but rather making the unremarkable evidentiary point that the state was not able to demonstrate the need for its prohibition by pointing to "failed effort[s] along . . . a less restrictive path." Here, there is ample evidence in this record showing that existing access restrictions alone are not working effectively. See 61 Fed. Reg. 44419-20, 60 Fed. Reg. 41322-29.

and their "means [are] narrowly tailored to achieve the desired objective." Fox, 492 U.S. at 480, 109 S. Ct. at 3034 (citation omitted). Moreover, they reflect "a 'carefu[l] calculat[ion of] the costs and benefits associated with the burden on [commercial] speech imposed by [the] prohibition[s].'" 44 Liquormart, 116 S. Ct. at 1521 (concurring opinion) (quoting Discovery Network, 507 U.S. at 417).

1. Image and Color Restrictions (§ 897.32(a))

a. FDA's advertising regulations restrict the use of images and color in tobacco advertising. As a general matter, the regulations provide that "labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background." 21 C.F.R. § 897.32(a). This restriction does not apply to advertising in "adult publications" or in facilities that are restricted to adults. 21 C.F.R. § 897.32(a)(2); see also 21 C.F.R. § 897.16(c)(2)(ii). An "adult publication" is one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii).

FDA's adoption of this restriction reflects a careful effort to reduce the special appeal of tobacco advertising to minors without intruding unduly on the ability of the tobacco industry to provide adults with relevant factual information about their products. 61 Fed. Reg. 44508. FDA's administrative record demonstrates that the use of images and colors in advertising is particularly effective in capturing the attention of children and increasing the appeal of the advertised products to children. 61 Fed. Reg. 44467-68, 44509. As noted earlier, the effectiveness of advertising images among young people is confirmed by marketing data: the three most heavily advertised brands of cigarettes, all of which are promoted with attractive imagery, account for 86 percent of underage smoking. 61 Fed.

Reg. 44509. Restricting the use of images and color will significantly reduce the attention that children pay to tobacco advertising and the attraction that such advertising will exert on them. At the same time, the regulation does not prevent the tobacco industry from conveying information about the taste, price, and other characteristics of their products to adults who are interested in such information. Id.

Plaintiffs assert that the use of images and colors in advertising "can convey information," "often more effectively and efficiently than words alone." Third Brief at 29. As a generalization, this may well be correct: commercial images (and, to a far lesser degree, color) can convey information. See Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 647, 105 S. Ct. 2265, 2279-80, 85 L. Ed. 2d 652 (1985); Qualitex Co. v. Jacobson Products Co., 115 S. Ct. 1300, 1303, 131 L. Ed. 2d 248 (1995). However, plaintiffs are notably silent about precisely what information is conveyed by the images ordinarily used in their own advertising. The images utilized in the typical cigarette advertisement convey virtually no information about the taste, price, or other features of the advertised products. It is unclear what information about cigarettes is being conveyed, for example, by a picture of Joe Camel playing pool or by a photograph of men and women frolicking on a beach while holding cigarettes. See 61 Fed. Reg. 44468-69.[54/]

Plaintiffs invoke the Supreme Court's decision in Zauderer for the proposition that images and colors, like text, are a form of speech for purposes of the commercial speech

---

[54/] Pictures can convey one piece of information about cigarettes: the appearance of the product. Unlike most consumer products, however, cigarettes come in a highly standardized and unadorned shape, and, with limited exceptions, tobacco manufacturers do not use differences in appearance to distinguish their products.

doctrine. Third Brief at 30. We have no quarrel with that proposition, at least with respect to images. However, Zauderer signifies only that restrictions on the use of images in advertising are subject to review under Central Hudson, rather than being outside the scope of the commercial speech doctrine altogether. Zauderer does not mean, as plaintiffs suggest, that restricting the use of images in advertising makes a commercial speech regulation ipso facto overbroad. FDA's restriction on the use of images and color eliminates the features of tobacco advertising that are most attractive to and influential on children, without preventing the tobacco industry from conveying information about its products to adults. By striking this balance, the restriction is "narrowly tailored to achieve the desired objective." Fox, 492 U.S. at 480, 109 S. Ct. at 3034.

Plaintiffs argue that FDA's restriction on the use of images and color represents an impermissible attempt by the Government to evaluate the relative "importance" of commercial information. Third Brief at 31. That is simply incorrect. Section 897.32(a) does not restrict substantive information, but simply affects the form in which it is conveyed. The Government here is not trying to draw a "line between publicly 'interesting' or 'important' commercial advertising and the opposite kind," Virginia State Bd. of Pharmacy, 425 U.S. at 765, 96 S. Ct. at 1827; nor is it trying to second-guess the judgments of consumers about "the value of the information presented," Edenfield v. Fane, 507 U.S. at 767, 113 S. Ct. at 1798.

Plaintiffs also argue that the use of images and color serves another constitutionally protected function, that of "attract[ing] attention." Third Brief at 29. See Zauderer, 471 U.S. at 647, 105 S. Ct. at 2279. FDA is well aware of the attention-getting function of

images and color. Indeed, that function lies at the heart of FDA's rationale for excluding images and color from advertising media to which children are exposed.

But the fact that images and colors can attract attention, like the fact that they can (in some cases) convey information, begs the constitutional question here. The issue, once again, is not whether images and colors are protected at all under Central Hudson, but whether FDA's restriction on their use is impermissible under the fourth prong of Central Hudson. For the reasons set forth above, it is not: Section 897.32(a) is carefully tailored to eliminate a feature of tobacco advertising that has particular appeal for children without impeding "the free flow of commercial information," Coors, 115 S. Ct. at 1589, from the tobacco industry to lawful consumers. While interested adults may have to look more closely at tobacco advertisements to gain the desired information, plaintiffs do not seriously suggest that they will be unable or unwilling to do so, nor do plaintiffs claim that they will be unable to design text-only advertisements that attract the attention of adults.

Plaintiffs assert that Virginia State Board of Pharmacy makes it impermissible for FDA to adopt a regulation that imposes added "search" costs on interested adults. Third Brief at 32. However, Virginia State Board of Pharmacy says nothing of the sort. In that case, the majority rejected an argument by the dissent that the First Amendment interests of consumers are not implicated at all as long as there is some means by which they can obtain the commercial information in question. See 425 U.S. at 757 n.15, 96 S. Ct. at 1823 (majority); id. at 782-83, 96 S. Ct. at 1835-36 (dissent). It was in that context that the majority dismissed "[the] principle that freedom of speech may be abridged when the speaker's listeners could come by his message by some other means." Id. at 757 n.15, 96 S.

Ct. at 1823. In this case, FDA is not contending that the ability of adults to "find" black-and-white text ads removes section 897.32(a) from the scope of Central Hudson. Instead, the point is that the ease with which adults can still obtain the desired information reflects favorably on the extent of the burden that the regulation places on commercial speech.[55/]

Plaintiffs also quote Shapero v. Kentucky Bar Ass'n, 486 U.S. 466, 108 S. Ct. 1916, 100 L. Ed. 2d 475 (1988), an attorney discipline case, to support their claim that the Government "may claim no substantial interest in restricting truthful and nondeceptive . . . solicitations to those least likely to be read by the recipient." 486 U.S. at 479, 108 S. Ct. at 1924 (plurality opinion). In Shapero, however, the Government's goal was to reduce the effect of the regulated advertising on an audience that was legally entitled to purchase the service. See id. at 478-79, 108 S. Ct. at 1924-25. Here, in contrast, the Government is regulating the use of images and color solely because of their effect on an audience (minors) to whom sale of the advertised product is entirely illegal, and for whom color and imagery are particularly powerful. Here, the effect on adults is incidental and unavoidable, not (as in Shapero) the very point of the regulation.

Finally, plaintiffs argue that a categorical restriction on the use of images and colors is impermissible because FDA "has not found that every use of color or imagery in tobacco advertising" appeals to minors. Third Brief at 32. It is true that FDA has not made such a

---

[55/] In this respect, FDA's regulation stands in obvious contrast to the anti-solicitation ordinances struck down by the Ninth Circuit in Project 80's, Inc. v. City of Pocatello, 942 F.2d 635 (9th Cir. 1991), another case on which plaintiffs rely. Under the ordinances in Project 80's, consumers who wished to receive in-home solicitations were compelled to "post a 'Solicitors Welcome' sign." Id. at 639. This case does not involve the imposition of any remotely comparable "affirmative obligations," id., on consumers: they need only continue to look for the advertisements in the same publications that they currently read.

finding, but Central Hudson and its progeny do not require the agency to do so. The commercial speech doctrine requires "a fit that is not necessarily perfect, but reasonable." Florida Bar, 115 S. Ct. at 2380. Merely positing the hypothetical existence of particular images or colors that might be relatively less attractive to minors falls far short of establishing that the regulation "burden[s] substantially more speech than necessary." Edge Broadcasting, 509 U.S. at 430, 113 S. Ct. at 2705 (emphasis added); see also Anheuser-Busch I, 63 F.3d at 1315. In demanding a predicate finding that every possible image and color will attract children, plaintiffs are employing precisely the kind of "least restrictive means" test that the Supreme Court has repeatedly rejected. Moreover, while some images and colors may be more likely to exert an attraction for children than other images, it remains the case that all images and colors serve to increase the attention-getting function of tobacco advertising, and thereby necessarily increase the exposure of children.

Plaintiffs attach several examples of advertisements whose use of images and color does not, in plaintiffs' view, warrant the restrictions in section 897.32(a). Plaintiffs do not claim that the use of images and colors in these particular advertisements are typical or characteristic of tobacco advertising as a whole. Moreover, removing images and color from these advertisements would have no impact on the information that they convey, such as (in plaintiffs' words) "the message that adult smokers can send away for a catalogue offering home furnishings" or the message "that [a particular cigarette brand] is lower in 'tar' and nicotine than other brands but still offers flavor." Third Brief at 32. Those messages are purely a product of the text in print advertising, which FDA is not restricting in any way.

Plaintiffs' examples thus confirm, rather than rebut, the carefully limited reach of section 897.32(a).

b. As noted above, FDA has further refined and limited the scope of its restrictions on the use of images and color by exempting adult publications. As a result of this exception, tobacco advertisements in adult publications may contain any images and colors that the manufacturer wishes to use. FDA's adoption of this "adult publication" exception is further evidence that the agency has "carefully calculated the costs and benefits associated with the burden on [commercial] speech" imposed by its regulations. Discovery Network, 507 U.S. at 417, 113 S. Ct. at 1507 (citation and internal quotations omitted).

Plaintiffs do not object to the existence of the adult publication exception, but they argue that it is impermissibly narrow. The regulation defines an adult publication as one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii). Plaintiffs argue that the 85 percent figure is too low (by an unspecified percentage) and the two million figure is too high (by an unspecified amount).

The numerical benchmarks for adult publications were chosen with care by FDA, rather than being pulled out of the air, as plaintiffs suggest. Because children between five and 17 constitute approximately 15 percent of the total population, a publication whose youth readership is proportionately higher than 15 percent (i.e., one whose adult readership is less than 85 percent) can fairly be characterized as having greater appeal to younger readers. 61 Fed. Reg. 44516. To test this approach, FDA also identified magazines that were publicly perceived to be of interest to children under 18, and an 85 percent figure proved to distinguish those magazines from others that were not publicly perceived as interesting to

children. 61 Fed. Reg. 44513. FDA supplemented the 85 percent figure with a limit of two million young readers because youth readership of more than two million "is so great that the publication can no longer be considered to be of no interest to those under 18 . . . ." 61 Fed. Reg. 44514.

These are eminently reasonable judgments, and plaintiffs conspicuously fail to offer a different set of benchmarks. The fact that a magazine that barely exceeds the specified figures is treated differently from one that barely falls short of them is an inevitable byproduct of line-drawing; the same difference in treatment would occur with any readership-based definition of adult publications, and indeed any quantity-based regulation, regardless of where the line was drawn.

Plaintiffs also claim that section 897.32(a)(2) violates the First Amendment and the Due Process Clause by placing the burden on manufacturers, distributors, and retailers to demonstrate that a particular publication qualifies as an "adult publication." Third Brief at 34-35. This claim rests on a misunderstanding of the regulation. Section 897.32(a)(2) is not intended to require an advertiser to assume the burden of proof on this issue in a criminal prosecution or other judicial proceeding. While an advertiser who wishes to take advantage of the adult publication exception must obtain the information needed to determine whether a particular publication meets the criteria of the regulation, the burden of proof in any enforcement proceeding would rest with the Government.

c. Finally, plaintiffs argue that section 897.32(a) is invalid to the extent that it prohibits the use of images and color in direct mail. Third Brief at 35-36. Plaintiffs assert that the Supreme Court invalidated a similar restriction in Bolger. There, however, the

statute in question prohibited the unsolicited mailing of any information regarding contraceptive products. See 463 U.S. at 61-62, 103 S. Ct. at 2877. Here, in contrast, FDA's regulations do not prohibit the direct mailing of all advertisements concerning tobacco products, nor do they restrict the information that such advertisements can convey. And because direct mail advertising is a "high involvement" medium, forbidding the use of images and color is particularly unlikely to impede the ability of tobacco manufacturers to communicate their messages to adults. See 61 Fed. Reg. 44510.

Plaintiffs argue that, since FDA permits the direct mailing of tobacco products to adults, it is irrational for the agency not to permit the direct mailing of tobacco advertisements with images and color to adults as well. Third Brief at 36. However, tobacco products by their nature are far more likely to be kept out of the hands of children than are advertising materials. Moreover, as FDA pointed out, a significant portion of tobacco direct mail advertising is sent to children, directly exposing them to the images and color contained in such advertising. 61 Fed. Reg. 44510. The application of section 897.32(a) to direct mail is a reasonable product of these considerations.[56/]

2. Outdoor Advertising (§ 897.30(b))

Section 897.30(b) prohibits the outdoor advertising of tobacco products within 1,000 feet of any elementary or secondary school or any playground in a public park. The rationale for prohibiting outdoor tobacco advertising in close proximity to schools and playgrounds is straightforward. See generally 61 Fed. Reg. 44502-06. Children spend a

---

[56/] FDA also indicated that it based its decision on the fact that young people do not currently purchase by mail. The agency indicated that it would monitor the situation and would propose amending the rule if direct mail sales became a youth access issue.

great deal of time in schools and playgrounds, and outdoor advertising that is visible from those locations, particularly billboards, exposes children to tobacco advertising on a continuous and prolonged basis. 61 Fed. Reg. 44502-03, 44506. Evidence in FDA's administrative record indicated that billboards play a particularly strong role in the development of children's familiarity with tobacco products. 61 Fed. Reg. 44504, 44505. And with respect to other kinds of outdoor signage, such as storefront signs, the administrative record indicated that such displays tend to be significantly more widely used within 1,000 feet of schools than elsewhere. 61 Fed. Reg. 44504. Because it results in prolonged exposure to an effectively captive audience, outdoor advertising in the vicinity of schools and playgrounds intrudes on children in a way that other advertising media do not. FDA therefore determined that the less restrictive alternative of image and color restrictions would not suffice to overcome the message conveyed to children by such advertising. As FDA noted, the rationale behind its regulation has been recognized and accepted by the tobacco industry itself: the industry's own voluntary advertising code calls for tobacco advertisements to be excluded from all billboards within 500 feet of primary and secondary schools. See 61 Fed. Reg. 44502, 44504.

In Penn Advertising, the Fourth Circuit recently sustained the constitutionality of a similar outdoor advertising restriction adopted by Baltimore. The Baltimore ordinance generally prohibited tobacco advertising in "publicly visible location[s]" within the city, while adopting certain exceptions to this restriction, most notably an exception for signs in specified commercial and industrial areas. See Penn Advertising I, 63 F.3d at 1321. In Penn Advertising I, the Fourth Circuit held the Baltimore ordinance was narrowly tailored

and therefore passed muster under the fourth prong of Central Hudson, and the court reaffirmed that holding in Penn Advertising II. See Penn Advertising I, 63 F.3d at 1325-26; Penn Advertising II, 1996 WL 657723 at *1. The Fourth Circuit followed the reasoning of the companion Anheuser-Busch case, in which the court reasoned that "Baltimore's efforts to tailor the ordinance by exempting commercial and industrial zones from its effort renders it not more extensive than is necessary to serve the governmental interest . . . ." Anheuser-Busch I, 63 F.3d at 1317. The court also noted that "'[i]n the face of a problem as significant as that which the City seeks to address, the City must be given some reasonable latitude.'" Penn Advertising I, 63 F.3d at 1326 (quoting Anheuser-Busch I, 63 F.3d at 1316).

The Penn Advertising decisions effectively dispose of plaintiffs' challenges to section 897.30(b). FDA's regulation has the same basic features as the Baltimore ordinance: a general prohibition on outdoor tobacco advertising that is geographically tailored to areas in which children are particularly exposed to such advertising. Just as Baltimore's exception for commercial and industrial areas rendered the city's ordinance "not more extensive than is necessary to serve the governmental interest," Anheuser-Busch I, 63 F.3d at 1317, FDA's limitation to billboards within 1,000 feet of schools and playgrounds accomplishes the requisite narrow tailoring. And here, as there, "there [are] numerous other means of advertising to adults that d[o] not subject the children to 'involuntary and unavoidable solicitation [while] . . . walking to school or playing in their neighborhood.'" Anheuser-Busch II, 1996 WL 657711 at *1 (quoting Anheuser-Busch I, 63 F.3d at 1314).

Plaintiffs propose a variety of assertedly less restrictive alternatives to section 897.30(b) (Third Brief at 37-38), but Penn Advertising disposes of most of them, and even without Penn Advertising, none of them shows that section 897.30(b) burdens substantially more speech than necessary. A "directional" limitation would be less effective in accomplishing FDA's ancillary goal of protecting children as they travel to and from their schools and playgrounds. 61 Fed. Reg. 44503. The proposed exception for densely populated urban areas, where the 1,000 foot limit excludes most outdoor tobacco advertising, would strike at the heart of the regulation; the influence of tobacco billboards on individual children is no less in urban centers than in less densely populated areas, and such advertising actually affects more children in such areas. Plaintiffs also suggest vaguely that FDA could limit "the number or type of billboards and signs" in school and playground areas (Third Brief at 37), but they fail to identify any practical limits, or to explain how such limits would result in a material increase in the flow of information to adults. Finally, while storefront signs "stating that tobacco products are for sale," id. at 37-38, may lie at the margin of the concerns underlying section 897.30(b), and while such signs were permitted in Penn Advertising, the inclusion of such signs in FDA's regulation hardly makes the regulation as a whole "substantially excessive." Fox, 492 U.S. at 479, 109 S. Ct. at 3034.[57]

---

[57] Basiardanes v. City of Galveston, 682 F.2d 1203 (5th Cir. 1982), is not to the contrary. In Basiardanes, the Fifth Circuit invalidated an ordinance that prohibited any publicly visible advertising for adult bookstores and theaters. Id. at 1218. The object of the ordinance was to "shield the public from lurid advertisements for sexually explicit films." Id. at 1219. Unsurprisingly, the Fifth Circuit held that a citywide ban on all outdoor advertising was an impermissibly broad means to pursue this goal. Id. Here, restriction on outdoor advertising is more carefully tailored to the Government's goals than the ordinance in Basiardanes, for it applies only within 1,000 feet of schools and playgrounds, and the (continued...)

Plaintiffs also assert that the purpose behind section 897.30(b) is an unconstitutional one. Third Brief at 38-39. According to plaintiffs, it is constitutionally impermissible for FDA to restrict outdoor advertising in order to prevent such advertising from giving children a sense of "normalcy and acceptability" regarding the use of tobacco products. 61 Fed. Reg. 44506. However, neither of the cases cited by plaintiffs for this proposition comes close to supporting it. Kingsley Int'l Picture Corp. v. Regents of the Univ. of the State of N.Y., 360 U.S. 684, 688-89, 79 S. Ct. 1362, 1365-66, 3 L. Ed. 2d 1512 (1959), did not involve commercial speech at all, and Carey v. Population Services International, 431 U.S. 678, 701-702, 97 S. Ct. 2010, 2024-25, 52 L. Ed. 2d 675 (1977), concerned commercial speech regarding "products and services that are not only entirely legal . . . but constitutionally protected." Neither decision even remotely suggests that the Government may not use advertising restrictions to influence children's perceptions of an addictive product when sales of that product to children are legally prohibited. See Anheuser-Busch II, 1996 WL 657711 at *4 (approving government's interest in "protect[ing] children who are not yet independently able to assess the value of the [commercial] message presented").

3. Sponsorship (§ 897.34(c))

Section 897.34(c) generally prohibits manufacturers from sponsoring athletic, social, and cultural events "in the brand name" of a tobacco product. See 61 Fed. Reg. 44527-36. This restriction is intended to "reduce the 'friendly familiarity' [among children] that sponsorship generates for a [tobacco] brand." 61 Fed. Reg. 44527. It is also designed to

---

[57](...continued)
Government's concern is not simply "lurid" advertising, but all advertising that exposes children to the promotion of tobacco use.

break the link sponsorship creates that "associates tobacco use with exciting, glamorous, or fun events such as car racing and rodeos." Id. Contrary to plaintiffs' claim, the restriction is not a "blanket ban on sponsorships," nor does it "end[] decades of support for cultural, musical, athletic, and other events." Third Brief at 39. Manufacturers remain entirely free to sponsor such events; the regulation simply requires them to do so in their own corporate name rather than in the name of their tobacco products, a practice that they already pursue with respect to certain cultural events. See 61 Fed. Reg. 44528, 44535.

The First Amendment interests at stake with respect to this regulation are peripheral at best. Brand name sponsorship conveys virtually no information about the characteristics of the product whose brand name is being used. Cf. Friedman v. Rogers, 440 U.S. 1, 11-12, 99 S. Ct. 887, 894-95, 59 L. Ed. 2d 100 (1979). Thus, section 897.34(c) has very little impact on the "informational function of advertising," Central Hudson, 447 U.S. at 563, 100 S. Ct. at 2350, that the First Amendment seeks to protect. Plaintiffs do not identify any information about their products that section 897.34(c) prevents them from conveying.

Plaintiffs fault the regulation for failing to allow brand name sponsorship of events that are said to be attended largely by adults, such as seniors golf tournaments. Third Brief at 39. FDA considered this possibility, but declined to adopt such an exception because brand name sponsorship reaches a wide audience of children through television, even when direct attendance is largely confined to adults. 61 Fed. Reg. 44529. Limiting the regulation based on youth attendance would fail to deal with this broader audience problem.

Alternatively, plaintiffs suggest that FDA should confine itself to restricting brand name advertising and promotional activities at sponsored events, rather than prohibiting

brand name sponsorship itself. Third Brief at 39-40. But these alternatives are not "'far less restrictive and more precise,'" Fox, 492 U.S. at 479, 109 S. Ct. at 3034; indeed, for First Amendment purposes, they can hardly be described as less restrictive at all. To the extent that brand name sponsorship serves any informational function, it is through the display of the brand name at the sponsored event in posters, logos, promotional paraphernalia, and the like. Any additional impact on the free flow of commercial information that comes from prohibiting brand name sponsorship is virtually nil.

4. Branded Merchandise (§ 897.34(a))

Section 897.34(a) prohibits manufacturers and distributors from marketing non-tobacco products and services under tobacco brand names. This restriction is designed to reach items such as tee shirts, caps, sporting goods, and other items bearing tobacco brand names. 61 Fed. Reg. 44521. FDA found that branded paraphernalia are a particularly effective form of advertising among young people, both because of the attractiveness of the paraphernalia and because such articles turn their users into image-laden, "walking bill-boards." 61 Fed. Reg. 44521, 44523-24, 44527. At the same time, branded paraphernalia provide relatively little informational value, since they convey no information about the tobacco product other than the brand name itself. 61 Fed. Reg. 44524.

Plaintiffs argue that the reach of this prohibition should be confined to products and services that are likely to be used or viewed by children. Third Brief at 41. As FDA pointed out, however, there is no practical way to limit the distribution of any branded item to adults only, and the extent of the appeal of such items makes it virtually impossible to distinguish among them. 61 Fed. Reg. 44525. Moreover, there is no meaningful way to

narrow the restriction without reviving the "walking billboard" problem: even if an item is worn or used by adults, its tobacco logo will inevitably be viewed on a repeated basis by children. As a result, plaintiffs' proposed alternative is neither as workable nor as effective as the regulation adopted by FDA.

5. Product Names (§ 897.16(a))

Section 897.16(a) generally prohibits manufacturers from using a trade or brand name of a nontobacco product as the trade or brand name of a tobacco product. The object of this provision, like that of the advertising restrictions, is "to ensure that the restrictions on sale and distribution to children and adolescents are not undermined by how the product is presented to the public." 61 Fed. Reg. 44444. Section 897.16(a) contains a grandfather clause for any trade or brand name that was used domestically both for tobacco and non-tobacco products as of January 1, 1995, such as Harley-Davidson cigarettes. Id.

Plaintiffs assert that section 897.16(a) is impermissibly overbroad under the fourth prong of Central Hudson. Third Brief at 42. As a threshold matter, it is extremely doubtful that this claim presents a ripe "case or controversy" under Article III, for plaintiffs do not allege that they currently use any nontobacco brand names that would be affected by section 897.16(a), nor do they allege that they intend to do so in the future.[58/] But even if plaintiffs' challenge were ripe, it is without merit.

[58/] A challenge to an administrative action is not ripe "unless [its] effects . . . have been 'felt in a concrete way by the challenging parties.'" Reno v. Catholic Social Services, Inc., 509 U.S. 43, 57, 113 S. Ct. 2485, 2495, 125 L. Ed. 2d 38 (1993) (citation omitted). "[T]he constitutional requirement for ripeness is injury in fact," and "'[i]f the injury be a future one[,] the occurrence of the injury must be reasonably certain and clearly describable. . . .'" DKT Memorial Fund Ltd. v. Agency for Int'l Dev., 887 F.2d 275, 297 (D.C. Cir. 1989) (citation omitted).

As the Supreme Court has made clear, the use of trade names has only the most peripheral connection to the values underlying the commercial speech doctrine. In Friedman v. Rogers, 440 U.S. 1, 99 S. Ct. 887, 59 L. Ed. 2d. 100 (1979), the Supreme Court sustained the constitutionality of a state statute that prohibited the use of trade names by optometrists. In so doing, the Court explained that "[a] trade name is . . . a significantly different form of commercial speech from that considered in Virginia Pharmacy and Bates," for it "has no intrinsic meaning." 440 U.S. at 11-12, 99 S. Ct. at 895. As a result, restrictions on the use of trade names "ha[ve] only the most incidental effect on the content of . . . commercial speech . . . ." Id. at 15-16, 99 S. Ct. at 897. Restricting the use of trade names "does not prohibit or limit the type of informational advertising held to be protected in Virginia Pharmacy and Bates, [so that] the factual information associated with trade names may be conveyed freely and explicitly to the public." Id. at 16, 99 S. Ct. at 897.

Like the statute upheld in Friedman, the restriction in section 897.16(a) has "only the most incidental effect on the content" of commercial speech by tobacco manufacturers. Here, as in Friedman, "the factual information associated with trade names may be conveyed freely and explicitly to the public." 440 U.S. at 16, 99 S. Ct. at 897. Indeed, FDA's restriction is considerably narrower than the one in Friedman, because it merely prohibits the use of a relatively small number of brand names in order to prevent "exploit[ation of] the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people," 61 Fed. Reg. 44444, while leaving manufacturers free to use any other brand names that they choose. Although plaintiffs assert that section 897.16(a) is

"unnecessarily restrictive" (Third Brief at 42), they fail to suggest a workable alternative that would be materially less restrictive.

6. Notice Requirement (§ 897.30(a)(2))

Plaintiffs challenge the constitutionality of section 897.30(a)(2), which requires manufacturers, distributors, and retailers to give written notice to FDA 30 days prior to using new advertising media (i.e., media other than those listed in section 897.30(a)(1)). The notice "shall describe the medium and discuss the extent to which the advertising . . . may be seen by persons younger than 18." Id. Contrary to plaintiffs' apparent belief, manufacturers are not required to engage in face-to-face "discussions" with FDA; instead, the regulation contemplates nothing more than the filing of a written notice providing the specified information. The object of the notice requirement is to "giv[e] the agency an opportunity to review the problems presented by a new media and to design new regulations or adapt current ones." 61 Fed. Reg. 44501.

Plaintiffs' challenge to the notice requirement, like their challenge to the brand name requirement, does not appear to be ripe for adjudication under Article III.[59/] But even if it were ripe, it would be without merit. Section 897.30(a)(2) does not impose any restriction on the use of new media for tobacco advertising. In particular, it does not require manufacturers, distributors, or retailers to obtain permission or approval from FDA before using

internet?

[59/] Plaintiffs do not allege that they are planning to advertise in new media, much less that the use of such media is imminent or likely in the foreseeable future. As a result, it can hardly be said that the effects of section 897.30(a)(2) "have been 'felt in a concrete way by the challenging parties,'" Reno, 509 U.S. at 57, 113 S. Ct. at 2495, or that a future application of the regulation to the plaintiffs is "'reasonably certain,'" DKT Memorial Fund, 887 F.2d at 297.

new media. See 61 Fed. Reg. 44502 ("Th[e] notification is for discussion purposes only, and is not in any way intended to imply, or create a need for, prior approval"); 61 Fed. Reg. 44501 (provision "will not prohibit the tobacco industry from advertising in new media"). Instead, the regulation simply requires that FDA be notified 30 days before the use of a new medium begins.

Plaintiffs claim that the notice requirement is an unconstitutional prior restraint. Third Brief at 43. However, because section 897.30(a)(2) does not require agency approval or permission for the use of new advertising media, it is not a prior restraint in the First Amendment sense. See Texans Against Censorship, Inc. v. State Bar of Texas, 888 F. Supp. 1328, 1366 (E.D. Tex. 1995), aff'd mem., No. 95-40376 (5th Cir. Oct. 9, 1996). Moreover, even if it were a prior restraint, the fact that the notice requirement is confined to commercial speech means that ordinary prior restraint rules do not apply. See Central Hudson, 447 U.S. at 571 n.13, 100 S. Ct. at 2354; Virginia State Board of Pharmacy, 425 U.S. at 771 n.24, 96 S. Ct. at 1830; Telco Communications, Inc. v. Carbaugh, 885 F.2d 1225, 1234 (4th Cir. 1989), cert. denied, 495 U.S. 904 (1990); Kleiner v. First National Bank of Atlanta, 751 F.2d 1193, 1204 (11th Cir. 1985). "[B]ecause traditional prior restraint principles do not fully apply to commercial speech, a State may require 'a system of previewing advertising campaigns to insure that they will not defeat' state restrictions." Zauderer, 471 U.S. at 668 n.13, 105 S. Ct. at 2291 (Brennan, J., concurring in relevant part and dissenting in part). Indeed, the Supreme Court has specifically approved the use of preview and notice requirements in the commercial speech context. See Shapero, 486 U.S. at 476, 108 S. Ct. at 1923 (plurality opinion) (state may require lawyers "to file any

solicitation letter with a state agency" in order to "giv[e] the State ample opportunity to supervise mailings and penalize actual abuses"); Central Hudson, 447 U.S. at 571 n.13, 100 S. Ct. at 2354.

7. Self-Service Displays (§ 897.16(c))

Section 897.16(c) generally requires retailers to engage in "direct, face-to-face" sales of tobacco products, prohibiting (with certain exceptions) the use of vending machines, self-service displays, and other "impersonal" modes of sale. The convenience store plaintiffs claim that this regulation, which is directed solely at the means by which tobacco products are sold, is actually an impermissible regulation of commercial speech, because certain prohibited modes of sale, such as self-service displays, function not only to deliver the product but also to advertise it.

This claim is wholly without merit. Self-service displays and other "impersonal" sales mechanisms are restricted under section 897.16(c) because they are one of the primary means by which children obtain cigarettes. The effect of this regulation on the supposed commercial "message" (if any) conveyed by self-service displays is incidental to the underlying prohibition on the sales device itself. Central Hudson and its progeny are directed at the regulation of commercial speech; they have no bearing on the Government's power to regulate the underlying commercial activity. Moreover, even if Central Hudson were applicable, the convenience store plaintiffs do not identify any respect in which the restriction on self-service displays is overbroad.

CONCLUSION

For the foregoing reasons, the Court should deny plaintiffs' motions for summary judgment and enter judgment in favor of defendants finding (1) that FDA has the authority

under the FDCA to regulate cigarettes and smokeless tobacco, and (2) that FDA's regulation of advertising and other promotion of cigarettes and smokeless tobacco is consistent with the First Amendment.

Respectfully submitted,

FRANK W. HUNGER
Assistant Attorney General
Civil Division

WALTER C. HOLTON, JR.
United States Attorney

GEORGE J. PHILLIPS
Counselor to the
Assistant Attorney General
Civil Division

EUGENE M. THIROLF
Director
Office of Consumer Litigation

OF COUNSEL:

MARGARET JANE PORTER
Chief Counsel

KAREN E. SCHIFTER
PATRICIA J. KAEDING
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

GERALD C. KELL
N.C. State Bar No. 5698
DEBORAH M. AUTOR
GREGORY T. EVERTS
DOUGLAS N. LETTER
SCOTT R. McINTOSH
Department of Justice
Washington, D.C. 20530
(202) 514-1586

Comp Time - official statements

Total Pages: 7

LRM ID: MDH21

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Friday, February 28, 1997

URGENT

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Melinda D. Haskins
PHONE: (202)395-3923 FAX: (202)395-6148
SUBJECT: Proposed Report on HR1 Working Families Flexibility Act of 1997
DEADLINE: Noon Monday, March 3, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The House Education and Workforce Committee is scheduled to mark up H.R. 1, the Ballenger (R-NC) comp time bill, on Wednesday, March 5th. The attached letter, expressing the Department of Labor's views on H.R. 1, will be transmitted to the Committee before the bill's mark up.

Note the Department of Labor letter on H.R. 1 is similar to one on S. 4 that it transmitted on February 26th to the Senate Labor and Human Resources Committee. (See attachment) The Department would like to send this letter to the Committee on Monday, March 3rd. Your expeditious review is most appreciated.

DISTRIBUTION LIST

AGENCIES:
25-COMMERCE - Michael A. Levitt - (202) 482-3151
61-JUSTICE - Andrew Fois - (202) 514-2141
76-National Economic Council - Sonyia Matthews - (202) 45/6-2174
92-Office of Personnel Management - James N. Woodruff - (202) 606-1424
107-Small Business Administration - Mary Kristine Swedin - (202) 205-6700

EOP:
John A. Koskinen
Nancy A. Min
Kenneth S. Apfel
John Podesta
John L. Hilley

Larry R. Matlack
Barry White
Janet Himler
Douglas D. McCormick
Tracey E. Thornton
Pauline M. Abernathy
Lisa M. Kountoupes
Alice E. Shuffield
Bruce N. Reed
Elena Kagan
James C. Murr
Janet R. Forsgren
Cynthia M. Smith

LRM ID: MDH21 **SUBJECT:** Proposed Report on HR1 Working Families Flexibility Act of 1997

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Melinda D. Haskins Phone: 395-3923 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this reponse sheet**

DRAFT

The Honorable William F. Goodling
Chairman
Committee on Education and the Workforce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Goodling:

We understand that your Committee will consider H.R. 1, the "Working Families Flexibility Act of 1997," on Wednesday, March 5. I am writing to emphasize the Administration's strong opposition to H.R. 1, and to urge your Committee not to order the bill reported.

The Administration believes strongly that any legislation to authorize compensatory time -- "comp time," or paid time-off -- under the Fair Labor Standards Act (FLSA) should be linked to expansion of the Family and Medical Leave Act (FMLA), as the President proposed during the last Congress. The FMLA provides important benefits to working families and has proved effective in meeting the needs of both families and businesses. And, unlike comp time, which would be optional, family and medical leave is a right that covered employers may not deny to eligible employees. Expanding FMLA to give working families the flexibility they need for greater involvement in the education of their children and elder care will go a long way toward achieving the stated goals of H.R. 1. The bill before your Committee does not include FMLA expansion, and it should.

Any comp time legislation must effectively and satisfactorily address three fundamental principles: real choice for employees; real protection against employer abuse; and preservation of basic worker rights including the 40-hour workweek.

Real choice for employees must include the right to choose whether to earn comp time or overtime premium pay; the right to take comp time when needed for FMLA purposes; the right to choose to use comp time for any purpose with two weeks notice unless its use would cause substantial injury to the employer; and the right to "cash out" accrued comp time for pay on 15 days notice, as well as a prohibition against giving employers the unilateral right to cash out an employee's accrued comp time at their discretion. Real protection against employer abuse must include a number of protections that are entirely absent from H.R. 1, such as the exclusion of vulnerable workers and

part-time, seasonal and temporary workers, including garment and construction workers; special protections in cases where the employer goes bankrupt or out-of-business; prohibitions against employers' substituting comp time for paid vacation or sick leave benefits, or penalizing employees who choose overtime premium pay instead of comp time; damages that allow an employee to obtain adequate relief if denied the use of comp time or denied overtime assignments; and strong effective provisions for enforcement. Preservation of worker rights requires preserving the 40-hour workweek and the right to receive premium pay for overtime work.

DRAFT

President Clinton will veto any bill that does not meet these fundamental principles. While the President has called for and strongly supports enactment of responsible comp time legislation, he will not sign any bill -- including H.R. 1 -- that diminishes employees' rights to receive time-and-a-half overtime premium pay when they work more than a 40-hour workweek. Workers -- not employers -- must be able to decide how best to meet the current needs of their families.

The Office of Management and Budget advises that there is no objection to the submission of this report.

Sincerely,

DRAFT

CYNTHIA A. METZLER
Acting Secretary of Labor

Attachment

U.S. DEPARTMENT OF LABOR

SECRETARY OF LABOR
WASHINGTON, D.C.

FEB 26 ....

The Honorable James M. Jeffords
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Chairman Jeffords:

We understand that your Committee will consider S. 4, the "Family Friendly Workplace Act," on Wednesday, February 26. I am writing to emphasize the Administration's strong opposition to S. 4, and to urge your Committee not to order the bill reported.

The Administration believes strongly that any legislation to authorize compensatory time -- "comp time," or paid time-off -- under the Fair Labor Standards Act (FLSA) should be linked to expansion of the Family and Medical Leave Act (FMLA), as the President proposed during the last Congress. The FMLA provides important benefits to working families and has proved effective in meeting the needs of both families and businesses. And, unlike comp time which would be optional, family and medical leave is a right that covered employers may not deny to eligible employees. Expanding FMLA to give working families the flexibility they need for greater involvement in the education of their children and elder care will go a long way toward achieving the stated goals of S.4. The bill before your Committee does not include FMLA expansion, and it should.

Any comp time legislation must effectively and satisfactorily address three fundamental principles: real choice for employees; real protection against employer abuse; and preservation of basic worker rights, including the 40-hour workweek.

Real choice for employees must include the right to choose whether to earn comp time or overtime premium pay; the right to take comp time when needed for FMLA purposes; the right to choose to use comp time for any purpose with two weeks notice unless its use would cause substantial injury to the employer; and the right to "cash out" accrued comp time for pay on 15 days notice, as well as a prohibition against giving employers the unilateral right to cash out an employee's accrued comp time at their discretion. Real protection against employer abuse must include a number of protections that are entirely absent

from S.4, such as the exclusion of vulnerable workers; special protections in cases where the employer goes bankrupt or out-of-business; prohibitions against employers' substituting comp time for paid vacation or sick leave benefits, or penalizing employees who choose overtime premium pay instead of comp time; damages that allow an employee to obtain adequate relief if denied the use of comp time or denied overtime assignments; and strong effective provisions for enforcement. Preservation of worker rights requires preserving the 40-hour workweek, the right to receive premium pay for overtime work, and the cardinal FLSA principle that overtime is earned whenever an employer knows or has reason to know that overtime is being worked. Several provisions of S. 4., including the 80-hour biweekly work program and the flexible credit hour program, could effectively eliminate these rights.

President Clinton will veto any bill that does not meet these fundamental principles. While the President has called for and strongly supports enactment of responsible comp time legislation, he will not sign any bill -- including S. 4 -- that obliterates the principle of time-and-a-half for overtime or that destroys the 40-hour workweek. Workers -- not employers -- must be able to decide how best to meet the current needs of their family.

The Office of Management and Budget advises that there is no objection to the submission of this report.

Sincerely,

CYNTHIA A. METZLER
Acting Secretary of Labor

Tobacco - litigatic

provide a broad range of child protection services to children and families at risk. Demonstrations have already been approved for DE, IL, NC and OR. This waiver was announced at your adoption event on February 14.

- **NY Medicaid Waiver:** The Health Care Financing Administration (HCFA) is currently completing negotiations with NY on the design of the state's Medicaid 1115 proposal. HCFA is also examining a proposal to provide transitional assistance to voluntary and public hospitals for retraining staff and increasing their development of outpatient clinic services.

- **Graduate Medical Education:** On February 17, the HCFA Administrator will announce a major Medicare demonstration on graduate medical education. HCFA will provide incentive payments totaling $400 million over six years to qualified teaching hospitals in NY that will reduce the number of residents they train, helping hospitals to transfer these residents' patient care duties to other health care professionals. The demonstration could save as much as $300 million.

- **Tobacco Litigation:** On February 10, the Federal District Court in Greensboro, NC, heard oral arguments in the four NC lawsuits challenging FDA's regulations restricting the sale and distribution of tobacco products to protect children and adolescents. U.S. District Judge William Osteen announced that he would issue a decision in five to ten weeks. He also indicated that provisions of the tobacco regulations due to become effective on February 28 that prohibiting retailers from selling tobacco products to persons under the age of 18 and requiring them to check the ID of customers under the age of 27 to verify their age would not be stayed.

- **Medical Utility of Marijuana:** On February 19-20, NIH will sponsor a scientific workshop on the medical utility of marijuana. The review group's conclusions will assist the NIH Director in considering actions NIH could take to fund research on the therapeutic potential of marijuana for patients with specific illnesses.

- **State Regulation of Tobacco:** In a *Federal Register* notice, FDA will propose to act on applications of AL, AK, UT and WA to continue to regulate tobacco products. The action that FDA is proposing will allow state statutes to remain in effect and not be preempted by the Federal tobacco regulations. FDA will also announce an opportunity for a hearing on the proposals. Under the Federal Food, Drug and Cosmetic Act, FDA requirements for medical devices preempt state and local requirements that differ from federal requirements. FDA can grant exemptions if the requirement is: (1) more stringent than an FDA requirement, or (2) required by compelling local conditions and not in violation of an FDA requirement.

FA-tobacco