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

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

v.

UNITED STATES FOOD & DRUG ADMINISTRATION AND DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS,
Defendants,

Case No. 2:95CV00591

and

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

v.

DAVID KESSLER, M.D. COMMISSIONER OF FOOD AND DRUGS, AND UNITED STATES FOOD & DRUG ADMINISTRATION,
Defendants.

Case No. 2:95CV00593

and

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

v.

UNITED STATES FOOD & DRUG ADMINISTRATION AND DAVID KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS,
Defendants.

Case No. 6:95CV00665

and

NATIONAL ASSOCIATION OF CONVENIENCE STORES, AND ACME RETAIL, INC.,
Plaintiffs,

v.

DAVID KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, AND UNITED STATES FOOD & DRUG ADMINISTRATION,
Defendants.

Case No. 2:95CV00706

November 27, 1996

AMICUS CURIAE MEMORANDUM OF THE STATE OF MINNESOTA AND OTHER INTERESTED STATES

STATEMENT OF THE MATTER BEFORE THE COURT

On August 28, 1996, the United States Food and Drug Administration (FDA) issued its final regulations on cigarettes and smokeless tobacco under the Federal Food, Drug and Cosmetic Act (FDCA). 61 Fed.Reg. 44,396 *et seq*. (1996). Plaintiffs in these four consolidated cases have brought motions for summary judgment, arguing that the FDA does not have jurisdiction to regulate tobacco products, and seeking

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a permanent injunction enjoining the implementation of the FDA's tobacco regulations. Plaintiffs' motions should be denied. The FDA's regulations are fully consistent with applicable law, and are an essential step in a comprehensive federal, state and local effort to curb the illegal use of tobacco by minors.

STATEMENT OF FACTS

On August 11, 1995, the FDA published proposed regulations restricting the sale and distribution of tobacco products to protect children. 60 Fed.Reg. 41,314 *et seq*. (1995). During the public comment period which followed, the FDA received over 700,000 public comments. This extensive public interest reflects the importance of the regulations at issue here. Although the FDA declined to exercise general jurisdiction over cigarettes in the late 1970's, dramatic new evidence has since come to light on the issue of the intended use of cigarettes and smokeless tobacco. "Before 1980, no major public health organization had determined that nicotine was an addictive drug. Between 1980 and 1994, however, every leading scientific deliberative panel and organization with expertise in addiction concluded that nicotine is addictive or dependence-producing." 61 Fed.Reg. 45,228 (1996). Important evidence has also been developed indicating that smokers use tobacco products primarily for their pharmacological effects, and that tobacco companies intend their products to be used for this purpose *Id*. at 45,223-237.

The current data on smoking among minors is sobering. Recent data indicates that the average age when people first try smoking is 14.5 years of age, and that the average age when people become daily smokers is 17.7 years of age. Department of Health and Human Services, Office on Smoking and Health, "Preventing Tobacco Use Among Young People: A Report of the Surgeon General," at 65 and 67 (1994). "Nearly all first use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco." *Id*. at 5. Approximately three million youths smoke, and an additional one million adolescent males use smokeless tobacco. *Id*. Seventy-five percent of all adult smokers report that they became addicted to tobacco before they were 18 years old. *Id*. at 65. Both the Surgeon General and the Institute of Medicine have concluded that effective, enforced restrictions on youth access to tobacco products are important tools in reducing tobacco use by minors. *Id*. at 254, 275.

However, access restrictions alone are not enough. Many studies have shown that young people are aware of, respond favorably to, and are influenced by cigarette advertising. 61 Fed.Reg. 45,245 (1996). *See* Institute of Medicine, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," at 123-24 (1994). This is not surprising, since the tobacco industry spent over $4.6 billion in 1991 alone advertising and promoting tobacco products. Federal Trade Commission Report to Congress for 1991 Pursuant To Federal Cigarette Labeling and Advertising Act. One study found that 30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking. 61 Fed.Reg. at 45,246 (1996). Moreover, tobacco companies have increasingly marketed their products through the promotion of concerts and sporting events. The sponsorship of these events makes tobacco highly visible to youth and strengthens the association between cigarettes and athletic ability, artistic expression, entertainment, glamour, and individuality. While the voluminous record underlying the FDA's recent regulations will not be reviewed in detail here, the compelling data contained therein underscores the need for a comprehensive approach to address the issue of tobacco use by minors, including the FDA regulations at issue in this case.

QUESTION PRESENTED

Does the United States Food and Drug Administration have jurisdiction to adopt regulations concerning cigarettes and smokeless tobacco?

ARGUMENT

I.

THE FOOD AND DRUG ADMINISTRATION HAS JURISDICTION TO REGULATE CIGARETTES AND SMOKELESS TOBACCO

Our federal and state governments both have an essential role to play in regulating matters relating to public health and safety. Courts have long recognized the primacy of the states in regulating to preserve public health and safety. "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are 'primarily, and historically, . . . matters of local concern,' the 'states traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.'" *Medtronic, Inc. v. Lohr*, __ U.S. __, 116 Sup.Ct. 2240, 2245, 135 L.Ed.2d 700 (1996) (citations omitted); *see also Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 720, 105 S.Ct. 2371, 2378, 85 L.Ed. 714 (1985) ("Given the presumption that state and local regulation related to matters of health and safety can normally coexist with

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federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety."); *Barsky v. Board of Regents*, 347 U.S. 442, 449, 74 S.Ct. 650, 654, 98 L.Ed. 829 (1954) ("[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health and safety of everyone there. It is a vital part of a state's police power.").

Virtually all states have passed laws regulating various aspects of food and drugs. As of 1993, 46 states had a basic law covering drugs, devices and cosmetics, 36 states had laws governing new drugs, and 38 states had laws governing cosmetics and medical devices. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *State Law Data 1993*, at II-11 (1993). The FDA and the Association of Food and Drug Officials have worked together over the years to develop model ordinances and codes in the food and drug area in order to encourage uniformity among local, state and national authorities having food and drug protection responsibilities. *Id.* at 1. Many of these model ordinances and codes have been adopted in various jurisdictions around the country. Together with the FDCA and the regulations adopted by the FDA, these state and local laws provide significant additional protections to the American public.

However, the central role played by the states in our federal system does not preclude the Federal Government from also playing a role. "Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people." *Medtronic*, 116 Sup.Ct. at 2246. Congressional action with respect to food and drugs is a prime example of the legitimate exercise of federal authority over a subject involving the public health and safety. "Congress' first significant enactment in the field of public health was the Food and Drug Act of 1906, a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug." *Id.* at 2246. Several decades later, Congress enacted the Federal Food, Drug and Cosmetic Act of 1938 (FDCA). 52 Stat. 1049. The Medical Device Amendments of 1976 were later passed by Congress in response to the mounting consumer and regulatory concern about injuries caused by the introduction of a vast array of new medical equipment "from bedpans to brainscans." 90 Stat. 539; *Medtronic*, 116 S.Ct. at 2246. Given the Supreme Court precedent, the history of Congressional action, and the history of actions taken by the FDA and other agencies in implementing the laws enacted by Congress, it is apparent that the federal government also plays an essential role in the protection of public health and safety.

Although it has been argued that the FDA regulations on cigarettes and smokeless tobacco infringe upon the primary role of the states in regulating on matters concerning public health and safety, the general design of food and drug regulation provides for concurrent state and federal jurisdiction[1] Courts have frequently held that while the Food, Drug and Cosmetic Act is important in setting uniform national standards, the act does not preclude the states from also regulating food and drugs. *See, e.g.*, *Hill v. Searle Laboratories*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (FDCA does not preempt Florida statute concerning the fitting and selling of hearing aids. "Because the federal requirements did not regulate every aspect of this area, the state had the implied reservation of power to fill out the scheme."); *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978)(New York Generic Drug Act not preempted by the FDCA. "The [FDCA] is not so pervasive as to remove the states entirely from the field of drug regulation."); *Kociemba v. J.D. Searle & Co.*, 680 F.Supp. 1293, 1299 (D.Minn. 1988) (citing the "widely held view that FDA regulation of prescription drugs establishes *minimum* standards, both as to design and warning.").

The FDA's authority to regulate tobacco products is not only authorized by law, but is a critically important part of the traditional federal and state concurrent regulation of matters affecting the public health and safety. The FDA regulations constitute uniform minimum standards which the states, consistent with their own respective authority,

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[1] Concurrent state and federal regulation of food and drugs is consistent with other regulatory models. For example, section 5 of the Federal Trade Commission Act, prohibiting unfair or deceptive trade practices, has been interpreted historically as coexisting with state laws regulating false advertising and deceptive business practices. *See e.g., American Financial Services v. FTC*, 767 F.2d 957, 989-91 (D.C. Cir. 1985), *cert. denied* 475 U.S. 1011, 106 S.Ct. 1185, 89 L.Ed.2d 301 (1986); *Motor Vehicle Mfrs. Ass'n v. Abrams*, 899 F.2d 1315 (2d Cir 1990) (N.Y. "lemon" law procedures involving automobile defects not preempted by FTC regulations), *cert. denied* 499 U.S. 912, 111 S.Ct. 1122, 113 L.Ed.2d 230 (1991). Similarly, state antitrust laws have generally not been held to be preempted by the federal Sherman Act. *California v. ARC America Corp.*, 490 U.S. 93, 103, 109 S.Ct. 1661, 1665, 102 L.Ed.2d 29 91989) (finding state antitrust laws to be within an area "traditionally regulated by the states..[O]n several occasions, the Court has recognized that the federal antitrust laws do not preempt state law.").

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may build upon. The FDA agrees that its regulations set uniform minimum standards, and stresses the need for a cooperative approach at various levels of government:

> Federal cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential. FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgment that more stringent State or local requirements are inappropriate.

61 Fed. Reg. 44,548 (1996). Uniform minimum standards are important because the regulatory efforts of one state will be frustrated if minors can easily travel into a bordering state which is much more lenient in its approach to regulating tobacco products.

The FDA regulations also directly complement state efforts in other respects. For example, section 1334(b) of the Cigarette Act provides that "[n]o . . . prohibition based on smoking and health shall be imposed *under State law* with respect to the advertising or promotion of any cigarettes." 15 U.S.C. § 1334(b)(emphasis added). Given the explicit preemption of certain state laws concerning cigarette advertising, the advertising restrictions contained in the FDA rule play an important role in supplementing the states' efforts to limit the illegal use of cigarettes by minors. Advertisements that encourage teen smoking undermine state laws and polices. Laws prohibiting minors from purchasing tobacco products will be much less effective if children are continually bombarded by advertising and promotional items designed to entice them into life long, and life shortening, smoking addiction. Moreover, it is difficult to effectively combat billion dollar national advertising campaigns on a state by state basis.

The FDA rule provision restricting tobacco sponsorship of sporting and entertainment events also complements state regulatory efforts. Such sponsorship has been effectively used by the tobacco manufacturers to avoid the federal ban on broadcast advertising, and to advertise tobacco products on the types of televised events which particularly appeal to teenagers and young adults. The FDA rule provision prohibiting the sale or distribution of non-tobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic will also complement state efforts. Studies have shown that promotional items such as tee shirts, hats and other sporting goods have great appeal among young people. When worn by young people, these items can become "walking billboards," which can come into schools and other places where tobacco advertising is generally prohibited. In short, the FDA's regulations are consistent with the model of concurrent federal and state jurisdiction over food and drug regulation, and are an important complement to state efforts to combat the illegal use of tobacco products by minors.

II.

THE FOOD AND DRUG ADMINISTRATION'S REGULATION OF TOBACCO IS CONSISTENT WITH CURRENT LAW

A. Congress Has Not Enacted A Comprehensive Regulatory Scheme That Precludes Further Regulation Of Tobacco

One of the central arguments being advanced by the plaintiffs here is that Congress has enacted a comprehensive regulatory scheme governing tobacco which, in essence, occupies the field and prevents additional regulation of tobacco products by the FDA and presumably by state and local governments. This argument has been rejected by courts for several decades. Although not explicitly labeled as such, plaintiffs are essentially making a preemption argument.[2]

If the field is comprehensively regulated, as plaintiffs assert, then no further regulation at the state or local level would be permitted. However, despite the consistent attacks of the tobacco and advertising industries, courts have not concluded that Congress has enacted a comprehensive legislative scheme which precludes further state and federal efforts to regulate tobacco products. In addition, as discussed below, courts have narrowly construed preemption provisions in federal tobacco legislation, and have been reluctant to hold that either state common law tort claims or state regulation of tobacco is preempted by federal law.

In *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842, 90 S.Ct. 50, 24 L.Ed. 93 (1969), for example, plaintiffs challenged a ruling of the Federal Communications Commission (FCC) requiring radio and television stations which carry cigarette advertising to devote broadcast time to presenting the

[2] Federal-state preemption law does not directly govern the issue of the FDA's jurisdiction to regulate tobacco products. Nevertheless, principles from federal-state preemption law are instructive, and serve to establish that the FDA's tobacco regulations are fully consistent with existing law.

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case against smoking. The court held that the FCC's action was not precluded by the Federal Cigarette Labeling and Advertising Act of 1965, refusing to accept plaintiffs' argument that Congress had enacted a comprehensive program which precluded the FCC regulations at issue[3] The Court stated:

> [T]here are positive indications that Congress's 'comprehensive program' was directed at the relatively narrow specific issue of 'cigarette labeling and 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.

Id. at 1089[4] As the FDA notes, "[e]nactment of legislation giving other agencies authority over particular aspects of cigarettes means only that Congress has decided to take those particular actions; it does not imply that Congress has determined that other Federal regulation is prohibited." 61 Fed.Reg. 44,546-547 (1996).

Cognizant of the essential role played by the states in regulating matters concerning public health and safety, courts have also been reluctant to preempt state law relating to tobacco. In the decades since *Banzhaf*, the tobacco and advertising industries have argued that state regulatory and common law is preempted by the preemption provision contained in the Public Health Cigarette Smoking Act of 1969 (hereinafter "the Cigarette Act"). 15 U.S.C. §§ 1331-1340. This provision states:

> § 1334 Preemption
>
> . . .
>
> (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 Act.

15 U.S.C. § 1334(b). This explicit preemption provision was recently interpreted in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). In *Cipollone*, the Court held that certain state law causes of action are not preempted by section 1334(b). 505 U.S. at 531-32, 112 S.Ct. at 2525. The Court started its consideration of the preemption issue "'with the assumption that the historic police powers of the states [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." 505 U.S. at 517, 112 S.Ct. at 2617, *citing Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947). The Court considered each of plaintiff's claims, focusing its preemption analysis on the express language of section 5(b):

> The appropriate inquiry is not whether a claim challenges the 'propriety' of advertising and promotion, but whether the claim would require the imposition under state law of a requirement or prohibition based on smoking and health with respect to advertising or promotion.

Id. 505 U.S. at 526, 112 S.Ct. at 2622. The Court held that some of plaintiff's claims were preempted, but others were not. *Id.* 505 U.S. at 532, 112 S.Ct. at 2625. In the course of its analysis, the Court recognized that the Cigarette Act does not prelude the states from exercising their police powers to regulate tobacco products:

> The 'pre-emption of regulation or prohibition with respect to cigarette advertising is narrowly phrased to preempt only State action based on smoking and health. It would in no way affect the power of any State . . . with respect to the taxation or other sale of cigarettes to minors, or the prohibition of smoking in public buildings, or similar police regulations.'

Cipollone, 505 U.S. at 530 n. 26, 112 S.Ct. at 2624 n.26, *citing* S.Rep. No. 91-566 at 12 (1969).

Courts since *Cipollone* have upheld state regulation of tobacco products. In *Mangini v. R.J. Reynolds Tobacco Co.*, 7 Cal. 4th 1057, 875 P.2d 73, 31 Cal.Rptr.2d 358 (Cal. 1994), *cert. denied* 115 S.Ct. 577, 130 L.Ed.2d 493 (1994), for example, plaintiff sued R.J.

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[3] Specifically, plaintiffs argued that the FCC's action was precluded by language in the Cigarette Labeling and Advertising Act providing that "no statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Federal Cigarette Labeling and Advertising Act of 1965, §5(b), 15 U.S.C. §1334(b) (Supp. 1966).

[4] The holding in *Banzhaf* was recently cited with approval by the Supreme Court. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 519, 112 S.Ct. 2608, 2618-19, 120 L.Ed.2d 407 (1992).

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Reynolds Tobacco Co., as a result of the company's Old Joe Camel advertising campaign.[5] The issue considered by the California Supreme Court was whether attempts in California to regulate or prohibit advertisement of cigarettes to minors were preempted by federal law, specifically section 5(b) of the Cigarette Act. The court determined that plaintiff's cause of action was not preempted:

> As noted previously, it is unlawful in California to sell cigarettes to minors or for minors to buy them. Advertising aimed at such unlawful conduct would assist vendors in violating the law. The predicate duty is to not engage in unfair competition by advertising illegal conduct or encouraging others to violate the law. In *Cipollone*, the predicate duty -- not to deceive -- was not "based on smoking and health," this one is similarly not. "Thus, we conclude that the phrase 'based on smoking and health' fairly but narrowly construed does not encompass the more general duty not to "unfairly assist or advertise illegal conduct." This action is therefore not preempted.

Id. at 80, *citing Cipollone* (citations omitted).

More recently, in *Penn Adv. of Baltimore v. Mayor and City Council*, 63 F.3d 1318 (4th Cir. 1995)[6], the court upheld Baltimore city Ordinance 307, which prohibited the placement of any sign that "advertises cigarettes in a publicly visible location," i.e. on "outdoor billboards, sides of building[s], and free standing signboards."[7] *Id.* at 1321. The court disagreed that the city ordinance was preempted by section 5(b) of the Cigarette Act. The court followed the Supreme Court's analysis in *Cipollone*, and determined that the ordinance was not a "prohibition based on smoking and health . . . imposed under state law with respect to . . . advertising or promotion." *Id.* at 1324, *citing* 15 U.S.C. § 1334(b); *but c.f. Vango Media, Inc. v. City of New York*, 34 F.3d 68, 73-74 (2d Cir. 1994) (holding that the Cigarette Act preempts an ordinance requiring city-licensed facilities to display one message addressing the dangers of smoking for every four tobacco advertisements displayed)[8]

As the above discussion illustrates, courts have *not* viewed Congressional action over a period of several decades regulating various aspects of the sale of tobacco products as adopting a comprehensive legislative scheme which occupies the field and precludes further regulation of tobacco at the federal, state and local level. While occasionally striking down regulations which directly conflict with specific provisions of federal law, courts have specifically preserved and protected state common law and state regulatory law directed at curbing tobacco use. Moreover, specific preemption provisions contained in federal tobacco legislation have been construed narrowly as courts have been careful to preserve "the assumption that the historic police powers of the States [are] not to be superseded . . . unless that [was] the clear and manifest purpose of Congress." *Cipollone*, 505 U.S. at 517, 112 S.Ct. at 2617.

Significantly, Congressional action giving certain federal agencies specific roles to play in regulating tobacco products has not been construed by the courts as precluding action by other federal agencies within their respective spheres of authority. *See Banzhaf v. F.C.C.*, 405 F.2d at 1089. In fact, courts have upheld the FDA's assertion of jurisdiction over specific brands of cigarettes on several occasions, concluding in each case that the cigarettes at issue were drugs within the meaning of the Food, Drug and Cosmetic Act. *United States v. 354 Bulk Cartons, Etc.*, 178 F.Supp. 847 (D.N.J. 1959)(Trim cigarettes are drugs within the meaning of the FDCA); *United States v. 46 Cartons, Etc.*, 113 F.Supp. 336 (D.N.J. 1953)(Fairfax cigarettes are drugs within the meaning of the FDCA). Although the FDA previously declined to exercise more general jurisdiction over tobacco products, the court in *Action On Smoking And Health v. Harris*, 655 F.2d 236 (D.C.Cir. 1980) left open the possibility that the agency could chose to do so in the

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[5] The suit alleged that R.J. Reynolds had undertaken an extensive advertising campaign designed to attract teenage smokers. The result of the campaign was that the number of teenage smokers who chose Camel cigarettes rose from 0.5% in 1988 to between 25 and 33% in 1992. During this same time period, illegal Camel sales to teenage smokers rose from $6 million to $476 million.

[6] *Penn Advertising* was recently reaffirmed by the Fourth Circuit Court of Appeals on remand from the United States Supreme Court. *Penn Adv. of Baltimore v. Mayor and City Council*, No. 94-2141 (4th Cir. Nov. 13, 1996).

[7] The ordinance provided that: "[n]o person may place any sign, poster, placard, device, graphic display, or other form of advertising that advertises in a publicly visible location. In this section, 'publicly visible location' includes outdoor billboards, sides of building[s], and free standing billboards." *Penn Advertising*, 63 F.3d at 1321 n.1.

[8] The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. §§ 4401-08) reflects the continuing efforts of Congress to enact narrowly tailored preemption provisions which do not preempt all state law. *See Cipollone*, 505 U.S. at 519, 112 S.Ct. at 2618 ("in the Comprehensive Smokeless Tobacco Health Education Act of 1986, Congress expressly pre-empted state or local imposition of a 'statement relating to the use of smokeless tobacco products and health' but, at the same time, preserved state-law damages actions based on those products.").

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future:

> 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.

Id. at 242 n. 10,[9] *accord Banzhaf*, 405 F.2d at 1090 ("Nor do we think the FCC's 1964 disclaimer of intent to deal with the cigarette problem deprives it of authority it would otherwise have had to do so now.").

B. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act Of 1992 Does Not Preclude The Regulation Of Tobacco By The FDA

Plaintiffs, as well as the three states which have filed amicus briefs supportive of the plaintiffs, argue that the relatively recent enactment of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992[10] (ADAMHA amendments) by Congress is further evidence of a comprehensive regulatory scheme which precludes the FDA regulations at issue here. Plaintiffs also argue that the FDA's regulations impinge upon the states' proper regulatory role under the ADAMHA amendments. These arguments miss the mark. The ADAMHA amendments condition future federal substance abuse prevention and treatment block grants on states having in effect a law prohibiting the sale or distribution of tobacco products to individuals under the age of 18. 42 U.S.C. § 300x-26(a)(1). The amendments further condition such grants on each state having a program to annually conduct random, unannounced inspections to ensure compliance with the law. The amendments require states to submit an annual report to the Secretary of Health and Human Services (HHS) describing the efforts taken by each state to enforce the law, the success rate which has been achieved, and the additional enforcement efforts to be taken by the state in the future. 42 U.S.C. § 300x-26(b).

It is difficult to discern why the FDA regulations in any way infringe upon regulatory efforts by the states under the ADAMHA amendments. There is no preemption provision in the FDA regulations. Nor is there any reason for inferring that "the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that [the FDA] 'left no room' for supplementary state regulation." *Hillsborough*, 471 U.S. at 714, 105 S.Ct. at 2375, *citing Sante Fe Elevator Corp*., 331 U.S. at 230, 67 S.Ct. at 1152. In fact, the only reasonable inference is to the contrary. Congress enacted narrowly tailored legislation requiring only that states have laws precluding the sale and distribution of tobacco products to minors, and that states have a program in place to enforce such laws, as a condition of receiving future federal block grants. There is no reasonable basis for arguing that the FDA regulations infringe upon the ability of the states to regulate for the public health and safety under the ADAMHA amendments. So long as state regulations directed at tobacco use by minors do not actually conflict with the FDA regulations, or other provisions of federal law, such regulations will not be preempted. *Hillsborough*, 471 U.S. at 714, 105 S.Ct. at 2375 ("Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law.").

It is even more difficult to discern why limited Congressional action directed explicitly at the states in any way limits the adoption by the FDA of the regulations at issue. The regulations adopted by the FDA and the ADAMHA amendments have an entirely different focus. The ADAMHA amendments are targeted at the states. The FDA regulations, on the other hand, are targeted at the tobacco industry and retailers. The FDA is not precluded from regulating within its sphere of authority simply because Congress has also given the states a direct role to play in regulating the illegal use of tobacco by minors. The FDA regulations are simply another example of concurrent federal and state regulation in the food and drug area, which, in turn, is consistent with the concurrent role of the federal government and the states in regulating to protect public health and safety.

State and local governments have long played an important role in regulating tobacco products, and the FDA's regulations do not preclude such regulatory efforts in the future. Toward the end of minimizing the health hazards of cigarette smoking, most states have enacted one or more measures to restrict cigarette smoking. These include restrictions on smoking in public or private places, restrictions on cigarette sales to minors, restrictions on distribution of cigarette samples, restrictions on sales of cigarettes in vending

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[9] The court in *Harris* was also careful to note that it was expressing "no opinion on the question of FDA jurisdiction over cigarettes or cigarette filters as `medical devices.'" *Harris*, 655 F.2d at 237 n. 4. As this court is aware, this is part of the basis upon which the FDA is currently asserting jurisdiction over tobacco products.

[10] The amendments are codified at 42 U.S.C. § 300x-26. Earlier this year, the Department of Health and Human Services issued a final rule implementing the ADAMHA amendments. 61 Fed.Reg. 1492 *et seq*. (1996).

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machines and licensing requirements. *See* Tobacco-Free America Legislative Clearinghouse, *State Legislated Actions on Tobacco Issues* (1990); *see also* Minnesota Department of Health, *The Minnesota Tobacco-Use Prevention Initiative: 1987-88*, at 3 (1989)("Preventing the death, disease, economic loss and disability that smoking exacts each year is a top public health priority in Minnesota."). The FDA regulations do not preclude the states from exercising their police powers to regulate tobacco products in the future.

Tobacco use by minors is a pervasive national problem which must be combated by comprehensive regulation at the local, state and federal level. Contrary to plaintiffs' assertions, the FDA regulations and the ADAMHA amendments and accompanying regulations are consistent and complementary regulatory efforts. The Department of Health and Human Services recognizes this:

> The final rule being issued today will complement and be consistent with any rule that FDA promulgates . . . While this final rule is directed to the States and the FDA proposal focuses on the tobacco industry and retailers, they are both designed to help address the serious public health problem caused by young people's use of and addiction to nicotine-containing tobacco products. By approaching this public health problem from different perspectives, these actions together would help achieve the President's goal of reducing the number of young people who use tobacco products.

61 Fed.Reg. 1492 (1996). Unlike the plaintiffs, the federal government recognizes the need for comprehensive efforts at the federal, state and local level to combat tobacco use by minors:

> The outcome, however, will depend on the nature and extent of the enforcement actions taken by the States [implementing the ADAMHA amendments] and, if the FDA proposed restrictions . . . were made final, the synergistic effect such efforts would have when combined with such additional control measures, and with any supplemental tobacco control measures the States may adopt.

61 Fed.Reg. 1501 (1996).[11]

Perhaps most importantly, given the magnitude of the problem, the ADAMHA amendments alone are not enough. The ADAMHA amendments only address the issue of youth *access* to tobacco products. More is needed, including advertising and promotion restrictions, and additional educational efforts directed at children. The FDA regulations are an important step in the right direction. When combined with the ADAMHA amendments and other federal laws, current laws at the state and local level, and additional efforts to be undertaken in the future, the FDA's regulations will help limit the number of American youth who become addicted to nicotine. Millions of individuals will benefit, both now and in the future.

CONCLUSION

Plaintiffs' motions for summary judgment should be denied. The FDA's regulations on cigarettes and smokeless tobacco are fully consistent with the Food, Drug and Cosmetic Act, and will play an important part in continuing federal, state and local efforts to address illegal tobacco use by minors.

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[11] HHS recognizes that local governments also have a role to play: "[T]he Federal statute and regulation are minimum requirements to which the States are held. In no way should they be considered as limiting, or requiring State to limit, the powers of local governments to enact or enforce tobacco control laws." 61 Fed.Reg. 1487 (1996).

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