No. 98-1152

In The

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, et al.,

Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

BRIEF OF THE STATES OF MINNESOTA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, FLORIDA, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, MISSOURI, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, WYOMING, AND CITY AND COUNTY OF SAN FRANCISCO AS AMICI CURIAE IN SUPPORT OF PETITIONERS

MIKE HATCH
Attorney General
State of Minnesota

JAMES S. ALEXANDER
Assistant Attorney General
Counsel of Record
445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
(651) 282-5724
(Additional Counsel Listed Inside)

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

BRUCE M. BOTEHLO
Attorney General
State of Alaska

JANET NAPOLITANO
Attorney General
State of Arizona

MARK PRYOR
Attorney General
State of Arkansas

BILL LOCKYER
Attorney General
State of California

KEN SALAZAR
Attorney General
State of Colorado

RICHARD BLUMENTHAL
Attorney General
State of Connecticut

ROBERT A. BUTTERWORTH
Attorney General
State of Florida

EARL I. ANZAI
Attorney General
State of Hawaii

ALAN G. LANCE
Attorney General
State of Idaho

JAMES E. RYAN
Attorney General
State of Illinois

JEFFREY A. MODISETT
Attorney General
State of Indiana

THOMAS J. MILLER
Attorney General
State of Iowa

CARLA J. STOVALL
Attorney General
State of Kansas

ANDREW KETTERER
Attorney General
State of Maine

J. JOSEPH CURRAN, JR.
Attorney General
State of Maryland

THOMAS F. REILLY
Attorney General
State of Massachusetts

JENNIFER M. GRANHOLM
Attorney General
State of Michigan

MIKE MOORE
Attorney General
State of Mississippi

JEREMIAH W. NIXON
Attorney General
State of Missouri

JOSEPH P. MAZUREK
Attorney General
State of Montana

FRANKIE SUE DEL PAPA
Attorney General
State of Nevada

PHILIP T. MCLAUGHLIN
Attorney General
State of New Hampshire

JOHN J. FARMER, JR.
Attorney General
State of New Jersey

PATRICIA A. MADRID
Attorney General
State of New Mexico

ELIOT SPITZER
Attorney General
State of New York

HEIDI HEITKAMP
Attorney General
State of North Dakota

BETTY D. MONTGOMERY
Attorney General
State of Ohio

W. A. DREW EDMONDSON
Attorney General
State of Oklahoma

HARDY MYERS
Attorney General
State of Oregon

D. MICHAEL FISHER
Attorney General
State of Pennsylvania

SHELDON WHITEHOUSE
Attorney General
State of Rhode Island

MARK BARNETT
Attorney General
State of South Dakota

JOHN CORNYN
Attorney General
State of Texas

JAN GRAHAM
Attorney General
State of Utah

WILLIAM H. SORRELL
Attorney General
State of Vermont

CHRISTINE O. GREGOIRE
Attorney General
State of Washington

DARRELL V. MCGRAW, JR.
Attorney General
State of West Virginia

JAMES E. DOYLE
Attorney General
State of Wisconsin

GAY WOODHOUSE
Attorney General
State of Wyoming

LOUISE H. RENNE
City Attorney
City and County of
San Francisco

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INTEREST OF THE AMICI STATES

The forty Amici States and the City and County of San Francisco submit this brief in support of the regulations promulgated by the U.S. Food and Drug Administration (FDA) restricting the promotion and sale of tobacco products to minors. The Amici States seek reversal of the Fourth Circuit's decision that the FDA does not have jurisdiction under the Food, Drug and Cosmetic Act (FDCA) to regulate tobacco products.

The question of whether the FDA has jurisdiction to regulate tobacco products under the FDCA is vitally important to the States. This Court has often recognized the States' responsibility to promote the health, safety and welfare of their citizens. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954).

Tobacco products dramatically affect this state interest. Every day, 3,000 American children start using tobacco regularly. Fully one-third of those who continue using tobacco products will suffer from painful, debilitating tobacco-related diseases including lung cancer, oral cancer, throat cancer, bladder cancer, cancer of the esophagus, cancer of the pancreas, heart disease, and chronic obstructive pulmonary disease. Millions of people in this country suffer from these diseases, and die prematurely, because they became addicted to the drug nicotine in the tobacco products they began to use as children. Over 400,000 individuals die each year from tobacco-related diseases – the equivalent of three fully loaded 747s crashing every day, 365 days a year, with no survivors.

The Amici States have made important strides in limiting tobacco use by minors. These States and many local governments have enacted laws designed to prevent young people from using tobacco products. In addition, more than forty state Attorneys General have recently sued the tobacco industry under state laws in their respective state courts. These lawsuits convincingly demonstrated the decades-long conspiracy by the tobacco industry to conceal the deadly and addictive nature of its products. The recent agreements between the States and the nation's five largest tobacco companies settling the States' tobacco litigation achieve important advances in the effort to combat youth smoking. Despite the important achievements of the Amici States, however, tobacco use by young people is on the rise.

The FDA rules at issue here are therefore necessary to complement and supplement the efforts of the States and local governments. These rules – which are directed at the use of tobacco products by young people – cover important ground that the agreements settling the States' tobacco litigation did not and could not address.[1] The FDA's regulations are fully authorized by law and perform a critical role in the comprehensive federal, state and local effort needed to prevent children from using

[1] The terms of the recent settlement between forty-six states, five territories and the District of Columbia and the nation's five largest tobacco companies are contained on the website maintained by the National Association of Attorneys General. *See* <http://www.naag.org/tob2.htm>. Seventeen companies have joined as additional parties to the agreement. The States of Minnesota, Florida, Texas and Mississippi had previously settled their claims against the tobacco companies.

and becoming addicted to the drug nicotine in tobacco products. For the reasons set forth below, those regulations are valid and should be upheld by this Court.

SUMMARY OF ARGUMENT

This Court should reverse the Fourth Circuit's decision, and should hold that the FDA has jurisdiction under the FDCA to regulate tobacco products. This case is of enormous public importance. The regulations at issue address the number one preventable public health problem of our time. The FDA's regulations address matters that cannot be effectively addressed by the States alone. The Fourth Circuit's decision that the FDA lacks the authority to regulate tobacco products as drug delivery devices misconstrues the authority granted to the FDA under the FDCA and impedes the FDA from joining the States in fully addressing this significant public health problem.

The Fourth Circuit's decision misapplies important, well-settled principles of administrative law that require deference to the FDA's judgment and permit the FDA to determine which products fit within the broad statutory framework for regulation of "drugs" and "devices" under the FDCA. The circuit court substituted its judgment for that of the FDA, and essentially ignored the compelling – but until recently secret – evidence from the tobacco industry's own files relied upon by the FDA in asserting jurisdiction over tobacco products.

This evidence overwhelmingly shows, as Judge Hall found in his dissent, "that the companies have known

about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine." Pet. App. 58a (Hall, J., dissenting). Additional evidence the States obtained through their own litigation further exposed the industry's knowledge that its products fall squarely within the FDA's jurisdiction. Again, in the words of Judge Hall's dissent, "the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before." Pet. App. 59a.

Finally, the Fourth Circuit's decision fundamentally misconstrues the relationship between the States and the federal government. The States have enacted laws to prevent young people from using tobacco. The States also have an important role to play in implementing the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act enacted by Congress in 1992. However, the federal government, through the FDA, has a vital role to play in both limiting youth access to tobacco and restricting advertising that appeals to young people. Contrary to the circuit court's conclusion, FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort needed to address this important public health issue.

ARGUMENT

I. The Food And Drug Administration Has Jurisdiction To Regulate Nicotine And Tobacco Products.

The FDA's authority to regulate tobacco products is supported by well-established administrative law that requires deference to agency judgment and permits the FDA to change its position based on new information or for other sound reasons. There is no dispute that Congress has delegated to the FDA the responsibility to determine which specific products are subject to regulation under the FDCA. After an exhaustive and extensive review of a voluminous record, the FDA properly concluded that nicotine-containing tobacco products are drug delivery devices which are subject to regulation. Under long-standing principles of agency law, that conclusion is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

An important part of the current debate about the FDA's jurisdiction over tobacco products centers on the meaning of the term "intent" in the FDCA. The FDCA provides that a drug or device is an article "*intended* to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3) (emphasis added). The industry claims that intent cannot be established absent marketing claims by the industry that its products have a medical or health benefit.[2] Yet nothing in the language of the FDCA

[2] The industry does not dispute that the FDA has jurisdiction over tobacco products marketed with health claims. Pet. App. 80a n.3 ("Plaintiffs do not dispute that FDA has authority to regulate tobacco products marketed as providing

limits the FDA to considering only express marketing claims in determining whether a product is "intended to affect the structure or any function of the body."

The FDA's assertion of jurisdiction over tobacco products is fully consistent with its statutory authority. The FDA has the authority under the FDCA to regulate drugs[3] and devices.[4] And Congress has delegated to the FDA, and not the courts, the responsibility to determine, based on the evidence, which specific products meet the statutory definitions. The FDA properly determined that, irrespective of the industry's marketing claims, tobacco products fall within the statutory standards for both "drug" and "device," and are therefore subject to regulation under the FDCA. The FDA's jurisdictional determination was based on an overwhelming factual record

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medical or other health benefits."). The lower federal courts have long recognized the FDA's jurisdiction to regulate tobacco products marketed as providing a health benefit. *See 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).

[3] The term "drug" is defined to include not only "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

[4] The term "device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body of man or other animals . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

demonstrating that nicotine is a drug, and that the tobacco manufacturers deliberately design and market their products to promote the addictive properties of nicotine. *See, e.g., Jurisdictional Determination*, 61 Fed. Reg. 44,396, 44,854-994 (1996); *Jurisdictional Analysis*, 60 Fed. Reg. 41,453, 41,583-784 (1995). As the FDA explained in the rulemaking record, "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products." 60 Fed. Reg. at 41,464 n.1.

While the administrative record is more than sufficient to support FDA jurisdiction, additional previously secret information discovered in the suits by the Amici States against the tobacco industry unequivocally demonstrates that the industry intends that its products affect the structure and function of the body, and that the industry manipulates and controls the nicotine levels in tobacco products to achieve and maintain addiction. Minnesota's case alone produced over 33 million pages of documents in depositories in Minnesota and England, as well as approximately 40,000 more documents over which the industry had improperly claimed an attorney-client privilege.[5] A recently published article in the Journal of the American Medical Association sets forth many representative tobacco industry documents relating to the

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[5] The tobacco manufacturers and tobacco-related organizations that are parties to the recent national settlement with many of the Amici States have agreed to maintain internet document websites accessible through "<http://www.tobacco-archives.com>" where documents produced in the States' litigation will be accessible to the public.

issues of addiction, cigarette design and nicotine manipulation.[6] The authors conclude, based on their review of thousands of pages of industry documents, that the industry knew for decades of the addictiveness of nicotine and perpetuated that addiction through manipulation of nicotine.[7]

Several of the exhibits in Minnesota's trial against the industry, discussed in the JAMA article, illustrate the industry's true intent:

- A "CONFIDENTIAL" 1969 memo written by W.L. Dunn (known within the industry as "The Nicotine Kid") to Philip Morris research director Dr. Helmut Wakeham:

  > I would be more cautious in using the pharmic-medical model – do we really want to tout cigarette smoke as a drug? *It is, of course, but there are dangerous FDA implications to having such conceptualization go beyond these walls.*[8]

- A "CONFIDENTIAL" Research Planning Memorandum written in 1972 by Claude E. Teague, Jr., assistant director of research at R.J. Reynolds, entitled "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein":

[6] *See* Richard D. Hurt, M.D. & Channing R. Robertson, Ph.D., *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173 (1998) ("Hurt & Robertson").

[7] *Id.* at 1180.

[8] *Id.* at 1176 (emphasis added).

> In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . *Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form.* Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors.[9]

- A 1972 Philip Morris memorandum summarizing the discussion at a conference attended by 25 scientists from England, Canada and the United States:

  > The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . .

[9] *Id.* at 1175 (emphasis added). This document was cited by the FDA in support of its regulation of tobacco products. *See* 60 Fed. Reg. 41,453, 41,617-18 (1995) (quoting from New York Times newspaper report).

> Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.[10]

These documents, and many others like them, unequivocally demonstrate the true intent and understanding of the tobacco industry. The tobacco companies understood a long time ago that "we are in a nicotine rather than a tobacco industry,"[11] and at least one has suggested that it "should learn to look at itself as a drug company rather than as a tobacco company."[12] To suggest that the FDA is without jurisdiction to regulate simply because the industry deliberately failed to publicly acknowledge its true intent would reward the industry for decades of deception and deceit. Such a result would be contrary to public policy. Instead, this Court should broadly construe the FDCA to achieve its purpose of protecting public health. *See United States v. An Article of Drug*, 394 U.S. 784, 798 (1969) ("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. . . . [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent

[10] Hurt & Robertson, *supra* n.6 at 1176; 60 Fed. Reg. 41,453, 41,617 (1995).

[11] Hurt & Robertson, *supra* n.6 at 1176.

[12] *Id.*

with the Act's overriding purpose to protect the public health.").

Regulation of tobacco products is no different than FDA regulation of the many other drugs and devices which are, in the language of the FDCA, "intended to affect the structure or function of the body." While tobacco products may be "different from the run-of-the-mine drugs and devices in the FDA's bailiwick," Pet. App. 74a (Hall, J., dissenting),

> the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert – the FDA – the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, [the Court is] bound to uphold FDA jurisdiction.

Id. at 70a-71a.

The FDA's well-reasoned and extensively documented basis for regulating tobacco products is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). The Fourth Circuit erroneously substituted its own judgment as to whether tobacco products are subject to regulation rather than

upholding the FDA's permissible and well-reasoned construction of the statute. *See Regions Hosp. v. Shalala*, 118 S. Ct. 909, 915 (1998) ("If the agency's reading fills a gap or defines a term in a reasonable way in light of the Legislature's design, we give that reading controlling weight, even if it is not the answer 'the court would have reached if the question initially had arisen in a judicial proceeding.' "), *citing Chevron*, 467 U.S. at 843.

Moreover, that the FDA chose not to regulate tobacco products without express marketing claims sooner does not preclude it from doing so now. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186-87 (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 omitted)). The court in *Action On Smoking And Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980), while upholding the FDA's decision not to exercise jurisdiction over tobacco products at that time, recognized that the agency was free to change its position:

> 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;[13] *accord Banzhaf v. FCC*, 405 F.2d 1082, 1090 n.26 (D.C. Cir. 1968) ("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.").

In addition to being contrary to law, the industry's argument that the FDA should be precluded from regulating nicotine-containing tobacco products because it previously declined to do so rings hollow in view of the industry's history of deception. The change in the FDA's position concerning regulation of the drug nicotine and tobacco products is based in part upon compelling new evidence from the tobacco industry's heretofore secret internal files. If the government had known earlier what the industry knew and conspired to conceal for years – about the addictiveness of nicotine in tobacco products, about the industry's efforts to manipulate levels of nicotine, and about the industry's efforts to target young people – the FDA may well have acted much sooner.

The Amici States urge this Court to reverse the Fourth Circuit's decision precluding the FDA from responding to new evidence to regulate tobacco products because, in the words of Judge Hall's dissent, "the 'cold hard facts' are now in." Pet. App. 64a.

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[13] 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.

II. The Fourth Circuit's Decision Fundamentally Misconstrues The Impact Of State Regulation Of Tobacco Products: The Law Permits, And The Problem Demands, A Comprehensive Federal, State And Local Effort.

This Court should reverse the Fourth Circuit's decision because the lower court misconceives the relationship between the States and the federal government. The Fourth Circuit found that Congress, through the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act of 1992 (ADAMHA amendments), expressed "clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products." Pet. App. 51a. The court concluded that the FDA lacks jurisdiction over tobacco because there is an "inherent conflict" between the FDA's regulations and the primary state regulatory role allegedly established in the ADAMHA amendments. *Id.*

The circuit court's analysis that the FDA's regulations conflict with the ADAMHA amendments is flawed for several reasons. First, as the district court and the dissenting judge at the Fourth Circuit properly observed, the ADAMHA amendments merely establish conditions for the receipt of federal funds; they "do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking." Pet. App. 100a, 69a-70a. The ADAMHA amendments condition future federal substance abuse prevention and treatment block grants on each State 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 each State to submit an annual report to the Secretary of Health and Human Services (HHS) describing the State's efforts to enforce the law, the State's success rate, and the additional enforcement efforts the State will take in the future. 42 U.S.C. § 300x-26(b).

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's regulations 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 ADAMHA amendments and the FDA regulations attack a pervasive national problem from different perspectives:

> While this final rule [implementing the ADAMHA amendments] 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.

Second, the tobacco industry argues here that the "comprehensiveness" of the regulatory scheme enacted by Congress and the role provided for the States under the ADAMHA amendments precludes the FDA from regulating. The industry has made a similar argument for years, more typically when it is asserting that the *States* are precluded from regulating. *See, e.g., Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 80 (1st Cir. 1997) ("In sum, [the tobacco manufacturers] argue that the very comprehensiveness, complexity, and specificity of the federal reporting provisions evince a federal dominance and pervasiveness in ingredient reporting and disclosure that allows no room for supplemental state laws such as the Disclosure Act. Ultimately, we find the manufacturers' arguments unpersuasive."). The industry has also frequently argued in private suits that state regulatory and common law is preempted by specific preemption provisions contained in federal law. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), however, this Court noted the limited nature of the preemption provision in the Public Health Cigarette Smoking Act of 1969 in holding that not all of the state tort claims at issue were preempted.[14] As in these earlier cases, the tobacco industry's

[14] Lower courts have likewise rejected the argument that legislation enacted by Congress precludes additional state regulation of tobacco products. *See, e.g., Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58 (1st Cir. 1997); *Penn Advertising of Baltimore v. Mayor and City Council*, 63 F.3d 1318 (4th Cir. 1995) (Baltimore ordinance prohibiting placement of any sign that advertises cigarettes in a publicly visible location not preempted by federal law), *vacated and remanded on other grounds*, 518 U.S. 1030 (1996), *aff'd on remand*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 520 U.S. 1204 (1997); *see also Banzhaf v. FCC*, 405 F.2d 1082, 1089 (D.C. Cir. 1968) ("Nothing in the [Federal Cigarette Labeling and Advertising Act of 1965] 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").

"comprehensive regulatory scheme" argument also fails here.

Third, there is no reasonable basis to conclude that the FDA regulations leave no room for state regulation of tobacco products. Under 21 U.S.C. § 360k, only state regulations that are different from or in addition to specific FDA requirements are preempted. The FDA has provided numerous examples of state regulations that will not be preempted by its rule, including restrictions on the sale or distribution of tobacco products, restrictions on smoking in public places, penalties on underage smokers and age restrictions on persons who sell tobacco. *See* 61 Fed. Reg. 44,396, 44,549 (1996). This Court has frequently noted the presumption against the preemption of state police power regulations. *See Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Even those state laws that might be preempted could qualify for exemption, thereby further minimizing conflicts. *See* 61 Fed. Reg. 44,396, 44,548-50; 21 U.S.C. § 360k(b). The FDA has stated that its regulations set only a floor for regulation of youth access to tobacco products, and that "[f]ederal cooperation with, and continued reliance upon, innovative and aggressive state and local enforcement efforts is essential." 61 Fed. Reg. at 44,548. Indeed, on November 28, 1997, the FDA published a final rule granting exemptions to Alabama,

Alaska, and Utah, permitting them to enforce their more stringent age requirements. *See* 62 Fed. Reg. 63,271.

Finally, while the States have done a great deal to address the problems of tobacco use, federal food and drug regulation has co-existed with state regulation for years. Although the States unquestionably play an essential role in regulating matters pertaining to public health and safety, the federal government also has a very significant role. *See Medtronic*, 518 U.S. at 475 ("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."). The general design of food and drug regulation allows for complementary state and federal jurisdiction. The circuit courts have recognized this complementary jurisdiction in holding that, while the FDCA is important in setting uniform national standards, the act does not preclude the States from also regulating products subject to FDA authority.[15] This Court has previously rejected arguments that regulation under the FDCA infringes upon the role of the States in regulating matters pertaining to public health and safety. *See United States v. Sullivan*, 332 U.S. 689, 697 (1948) (rejecting claim

[15] *See, e.g., 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) (State law not preempted by the FDCA. "The [FDCA] is not so pervasive as to remove the states entirely from the field of drug regulation.").

that application of FDCA infringes upon powers reserved to the States).

Tobacco use by minors is a pervasive national problem that must be addressed by comprehensive regulation at the federal, state and local level. Unlike the Respondents, the federal government recognizes the need for a comprehensive effort 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 on access and appeal 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. 1492, 1501 (1996).[16] "An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other." Pet. App. 70a (Hall, J., dissenting).

The FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the effort to limit the use of tobacco products by minors. The FDA regulations constitute uniform national standards that the States may build upon. Given the magnitude of

[16] HHS recognizes that local governments also have a role to play: "[T]he Federal statute [ADAMHA] and regulation are minimum requirements to which the States are held. In no way should they be considered as limiting, or requiring States to limit, the powers of local governments to enact or enforce tobacco control laws." 61 Fed. Reg. 1492, 1496 (1996).

the problem, the ADAMHA amendments alone are not enough. The amendments address only the issue of youth *access* to tobacco products. More is needed, including advertising and promotion restrictions, restrictions on retailers, 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, the advances achieved through state litigation against the tobacco industry, 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

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

July 1999

Respectfully submitted,

MIKE HATCH
Attorney General
State of Minnesota

JAMES S. ALEXANDER
Assistant Attorney General
Counsel of Record

445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
(651) 282-5724