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 *AMICUS CURIAE* AMERICAN CANCER SOCIETY, INC. IN SUPPORT OF PETITIONERS

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PRELIMINARY STATEMENT

This brief is submitted by the American Cancer Society ("ACS") as *amicus curiae*[1] urging reversal of a decision by the United States Court of Appeals for the Fourth Circuit that invalidated the regulation of tobacco products by the Food and Drug Administration ("FDA")[2] under the Food, Drug, and Cosmetic Act ("FDCA").[3]

INTEREST OF ACS

ACS is a non-profit public health organization with a membership of over 2.3 million volunteers throughout the country, including over 50,000 physicians. ACS is committed to one goal — the control and elimination of cancer through advocacy, education, research and service.

Research conducted and supported by ACS since the 1950s has played a pivotal role in identifying the use of tobacco products as a major cause of cancer. It is now undisputed that tobacco use greatly increases one's risk of developing cancer of the lungs, mouth, throat, larynx, bladder and other organs.[4] Indeed, about 87% of lung cancer deaths and 30% of all cancer

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1. All parties have consented to the filing of this brief by letters filed with the Clerk. Counsel for ACS authored this brief in whole, and no person or entity, other than ACS, made a monetary contribution to its preparation or submission.

2. 61 Fed. Reg. 44,396 (1996).

3. 21 U.S.C. § 301, *et seq.*

4. American Cancer Society, *Prevention and Risk Factors*, at 1 (June 1999).

deaths are attributable to the use of tobacco products.[5] In total, more than 400,000 people die prematurely each year from diseases attributable to tobacco use.[6]

ACS has been in the forefront of educating the public about the risks of tobacco use, focusing particularly on the nation's youth. ACS has repeatedly urged the FDA to assert jurisdiction over tobacco products and strongly endorsed the FDA's rule-making proceedings in this case. Because of the importance of tobacco control to ACS' mission, ACS sought and obtained permission to file this *amicus* brief to place before the Court the views of members of the public and health professionals committed to the eradication of cancer.

SUMMARY OF ARGUMENT

The number one health problem in the nation today is tobacco use. Adolescents have again begun smoking in greater numbers than since the 1960s — in part in response to alluring advertising and promotion by the tobacco industry. A dramatic increase in promotion in the last decade includes the use of brand name products that appeal to adolescents, sponsorship of sporting events, and payments to celebrities and film stars to glamorize smoking. These sophisticated marketing techniques far outstrip existing regulatory checks on the industry.

Statistical data readily demonstrate the magnitude of the problem. Over a recent eight-year period, tobacco use by youths

5. American Cancer Society, *Cancer Risk Report – 1998.*

6. Centers for Disease Control, *Cigarette Smoking — Attributable Mortality and Years of Potential Life Lost — United States, 1990*, MORBIDITY AND MORTALITY WEEKLY REPORT, Aug. 27, 1993, at 645-49.

increased by 30%.[7] More than 3 million American children and teenagers now smoke cigarettes, and every 30 seconds a child in the United States becomes a regular smoker.[8] In addition, some 1 million male high school students use smokeless tobacco[9] — a practice which has become particularly popular as a result of advertising focusing on flavored brands and youth-oriented themes.[10] In percentage terms, nearly half of male high school students and more than a third of female students use some form of tobacco.[11]

Moreover, adolescents have begun to use tobacco at very early ages and find it difficult to stop. The average teen smoker starts at 13 and becomes a regular smoker by age 14.5.[12] Although some 70% of adolescents regret their decision to

7. Centers for Disease Control, *Incidence of Initiation of Cigarette Smoking — United States, 1965-1996*, MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 9, 1998, at 837-40.

8. Centers for Disease Control, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, at 58 (1994).

9. 61 Fed. Reg. at 44,398.

10. Centers for Disease Control, *Smokeless Tobacco Brand Preference and Brand Switching Among U.S. Adolescents and Young Adults* (1995).

11. Centers for Disease Control, *Tobacco Use Among High School Students — United States, 1997*, MORBIDITY AND MORTALITY WEEKLY REPORT, Apr. 3, 1998, at 229-33.

12. Robert Wood Johnson Foundation Survey, *Results of a National Household Survey to Assess Public Attitudes About Policy Alternatives for Limiting Minors' Access to Tobacco Products* (Dec. 1994).

use tobacco,[13] less than one in seven has successfully quit.[14] ACS and other health organizations thus recognize that tobacco use by youth is a pediatric disease.

The reason why youths cannot readily stop the use of tobacco lies in the addictive properties of the drug nicotine — a fact which has become public knowledge only in recent years as a result of painstaking scientific research demonstrating that nicotine is similar to amphetamines, cocaine and morphine in causing compulsive drug-seeking behavior.[15] Indeed, there is a higher percentage of addiction among tobacco users than among users of cocaine or heroin.[16] Bolstering the scientific consensus on nicotine are recently unmasked tobacco industry deliberations, demonstrating the industry's long-standing knowledge of nicotine's effects.[17]

Responding to the alarming increase in tobacco use among youth and the scientific consensus on the addictive effects of nicotine, the FDA acted in 1996 to regulate tobacco products as "drugs" and "devices" under the FDCA, seeking as a first step to restrict the advertising and sale of tobacco products to

13. The George H. Gallup Int'l Institute, *Teenage Attitudes and Behavior Concerning Tobacco*, at 54 (Sept. 1992).

14. Centers for Disease Control, *Selected Cigarette Smoking Initiation and Quitting Behaviors Among High School Students — United States, 1997*, MORBIDITY AND MORTALITY WEEKLY REPORT, May 22, 1998, at 386-89.

15. 61 Fed. Reg. at 44,700.

16. *Id.* at 44,812-13.

17. *Id.* at 44,856, *et seq.*

minors.[18] The FDA's initiative was firmly grounded in the law and holds out the promise of protecting the health of the coming generation of Americans.

ARGUMENT

I.

CONGRESS VESTED BROAD REMEDIAL AUTHORITY IN THE FDA.

The Food and Drug Act of 1906 vested the FDA with limited jurisdiction over "drugs" as narrowly defined in medical practice.[19] In 1938 Congress enacted the FDCA to expand the FDA's jurisdiction to include "devices" that are "intended to affect the structure or any function of the body."[20] Congress said that this legislation was "essential if the consumer is to be protected against a multiplicity of abuses not subject to" preexisting law.[21] In explaining the principles of construction applicable to the FDCA, this Court stated in 1943:

> By the Act of 1938, Congress extended the range of . . . control over illicit and noxious articles . . . . The purposes of this legislation . . . touch phases of the lives and health of people which . . . are largely beyond self-protection. Regard for these

18. *Id.* at 44,616, *et seq.*

19. *See United States v. Bacto-Unidisk*, 394 U.S. 784, 793-94 (1969).

20. *Id.* at 794-98.

21. S. Rep. No. 646, 74th Cong. 1st Sess., at 1 (1935).

> purposes should infuse construction of the legislation if it is to be treated as a working instrument of government . . . .[22]

More than two decades later, this Court echoed these words in the leading decision construing the FDCA:

> remedial 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 . . . .[23]

In so ruling, this Court emphasized that in extending the reach of the original statute, "Congress fully intended that the Act's coverage be as broad as its literal language indicates — and . . . broader than any strict medical definition might otherwise allow."[24]

Although the FDCA as enacted in 1938 covered "devices," the statute did not provide for comprehensive regulatory control.[25] In 1976 Congress filled this gap by passing the Medical Device Amendments of 1976, which vested authority in the FDA to impose restrictions on the sale of devices based on the risk posed to the public.[26] Despite this amendment, the statute proved inadequate because of technical requirements

22. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

23. *Bacto-Unidisk*, 394 U.S. at 798.

24. *Id.*

25. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-77 (1996).

26. *Id.*; *see* 21 U.S.C. § 360c(a)(1).

for classifying a product as either a "drug" or a "device."[27] In 1990 Congress responded by enacting the Safe Medical Devices Act of 1990, which added new powers for FDA regulation of "combination"[28] products consisting of components of both drugs[29] and devices.[30]

From the statutory history of the FDCA and this Court's decisions construing the statute, three fundamental principles emerge. First, the progressive expansion of the FDA's powers makes plain that "the Act's coverage be as broad as its literal language indicates"[31] — that the FDCA "be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[32] Thus, for example, in determining

27. *See* S. Rep. 101-513, 101st Cong., 2d Sess., at 30 (1990).

28. 21 U.S.C. § 353(g)(1).

29. 21 U.S.C. § 321(g)(1)(C) defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man . . . ."

30. 21 U.S.C. § 321(h)(3) defines "device" to include:

> an instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

31. *Bacto-Unidisk*, 394 U.S. at 798.

32. *Id.*

whether a drug or device is "intended to affect the structure or any function of the body" within the meaning of the FDCA,[33] it is imperative to "pierce all of a manufacturer's subjective claims of intent and even his misleading[ ] . . . labels"[34] by determining objective intent[35] and the actual use of products by consumers.[36] Were the FDA "bound by the manufacturer's subjective claims of intent,"[37] artful promotion of a toxic drug would shackle the FDA in achieving the statute's remedial purposes.

Second, as this Court has recognized, the FDA is particularly well-equipped to administer the FDCA by reason of the agency's " 'specialization, . . . insight gained through experience and . . . flexible procedure.' "[38] This Court has directed that "substantial weight [be given] to the agency's view of the statute."[39] In short,

33. *See* notes 29 & 30, *supra.*

34. *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975).

35. *Id. See also* 21 C.F.R. §§ 201.128, 801.4 (FDA regulations define "intended use" in terms of the "objective intent of the persons legally responsible for . . . labeling . . . .").

36. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess., at 14 (1976) (legislative history of Medical Device Amendments of 1976); S. Rep. No. 361, 74th Cong., 1st Sess., at 4 (1935) (legislative history of FDCA).

37. *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).

38. *Weinberger v. Bentex Pharm.*, 412 U.S. 645, 654 (1973) (quoting *Far Eastern Conference v. United States*, 342 U.S. 570, 574-75 (1952)).

39. *Medtronic, Inc.*, 518 U.S. at 496.

> It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that . . . regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment.[40]

Finally, in applying its " 'insight gained through experience' ", the FDA must necessarily respond to advances in scientific learning and new realities. As this Court has repeatedly noted, " '[regulatory] agencies do not establish rules of conduct to last forever' " and "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.' "[41] Without the power to adapt to change, regulation would be "stereotyped" and the public interest disserved.[42]

40. *Bacto-Unidisk*, 394 U.S. at 791-92. *See also Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984) (" 'The power of an administrative agency . . . necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.' " (quoting *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)).

41. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (quoting *American Trucking Ass'ns, Inc. v. Atchison, Topeka and Santa Fe Ry. Co.*, 387 U.S. 397, 416 (1967), & *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968)). *See also Rust v. Sullivan*, 500 U.S. 173, 186 (1991) ("[a]n agency is not required to 'establish rules of conduct to last forever . . . .' ").

42. *See NBC v. United States*, 319 U.S. 190, 219-20 (1943).

II.

THE FDA PROPERLY ASSERTED JURISDICTION OVER TOBACCO PRODUCTS TO PROTECT AMERICA'S YOUTH FROM AN ADDICTIVE DRUG.

A. Lacking Knowledge Of The Addictive Properties Of Nicotine, The Government Initially Relied On Disclosure Of Health Risks To Stem Tobacco Use.

This Court has noted that "physicians ha[ve] suspected a link between smoking and illness for centuries . . . ."[43] By the early 1960s the volume of scientific evidence prompted the U.S. Surgeon General to convene an advisory committee on the subject.[44] In 1964 the committee's landmark study concluded that " '[c]igarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.' "[45] At that time the scientific community at large did not understand what was well known by the tobacco industry — that addiction to nicotine in tobacco is the major reason for continued smoking. Only in the 1990s has the medical community realized that nicotine is as addictive as other drugs, such as amphetamines, cocaine and morphine.

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43. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992).

44. *Id.*

45. *Id.* (quoting U.S. Dep't of Health, Education and Welfare, U.S. Surgeon General's Advisory Committee, Smoking and Health 33 (1964)).

Unaware that tobacco products are, in essence, drug delivery devices for nicotine, the FDA declined jurisdiction under the FDCA in the 1960s[46] — a position entirely consistent with judicial precedent, *FTC v. Liggett & Myers Tobacco Co.*,[47] which had held that cigarettes merely "soothe the troubled mind of modern man" and do not constitute "drugs" "intended to affect the structure or any function of the body . . . ."[48]

Federal policy initially focused on the limited goal of educating the public about the potential dangers of cigarette smoking to health. Having previously regulated cigarette advertising under the Federal Trade Commission Act, the Federal Trade Commission in 1964 proposed regulations requiring a clear and prominent disclosure on all cigarette packages and advertising that "cigarette smoking is dangerous to health and may cause death from cancer and other diseases."[49] States likewise acted to regulate advertising.[50] In mid-1965, after extensive deliberations, Congress enacted the Federal Cigarette Labeling and Advertising Act mandating that cigarette packages carry the warning: "CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO

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46. *See, e.g.*, Hearings Before the House Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess., at 56 (1964).

47. 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953) (construing provision of Federal Trade Commission Act comparable to the FDCA).

48. *Id.* at 574, 577.

49. *Cipollone*, 505 U.S. at 513.

50. *Id.*

YOUR HEALTH."[51] Congress imposed no restrictions on advertising at the time.[52]

In 1969 the FTC reinstituted its 1964 proceedings to address restrictions on cigarette advertising.[53] Another initiative came from the Federal Communications Commission, which proposed a prohibition of cigarette advertising on broadcast media.[54] In this context, Congress enacted the Public Health Cigarette Smoking Act of 1969, which amended the 1965 legislation to require a more stringent warning that cigarette smoking is "dangerous", as well as imposing a complete prohibition of cigarette advertising on television and radio.[55]

In the 1970s the FDA was petitioned by public citizens' groups to regulate cigarettes under the FDCA. Still in the dark about the addictive properties of nicotine, the FDA declined jurisdiction. On review to the Court of Appeals the petitioners challenged what they characterized as no more than "blind adherence" by the FDA to the court's decision in *FTC v. Liggett & Myers Tobacco Co.*[56] In dismissing the challenge, the Court of Appeals concluded that the FDA "would not be performing [its] statutory duty" if it were "to ignore clearly relevant judicial

51. Pub. L. 89-92, 79 Stat. 282 (1965), as amended, 15 U.S.C. §§ 1331-1340.

52. *Cipollone*, 505 U.S. at 514.

53. *Id.* at 514-15.

54. *Id.*

55. Pub. L. 91-222, 84 Stat. 87 (1970), as amended, 15 U.S.C. §§ 1331-1340.

56. *See* note 47, *supra*.

decisions."[57] The FDA's position clearly reflected the state of scientific knowledge at the time.

B. A Scientific Consensus On The Addictive Properties Of Nicotine As A Drug Impelled The FDA To Regulate Tobacco Products.

1. *The Research*

In studies conducted on animals in the early 1980s scientists first discovered that nicotine causes repeated, compulsive use of the drug — a distinguishing characteristic of addictive drugs.[58] In 1983 scientists demonstrated that nicotine was addictive in humans.[59] In the mid-1980s scientists discovered that nicotine produces withdrawal syndromes.[60] In the early 1990s studies demonstrated that "[n]icotine, like other addictive drugs (*e.g.*, cocaine, amphetamine, and morphine), produces its addictive effects by actions increasing dopamine concentrations within the mesolimbic system of the brain."[61] Nicotine exposure was also shown to cause an increase in the number of nicotinic receptors in the central nervous system,

57. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 242 (D.C. Cir. 1980). The decision by the Court of Appeals is also supported by this Court's subsequent holding in *Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985), in which the Court held unreviewable under the Administrative Procedure Act a determination by the FDA to refrain from taking enforcement action under the FDCA.

58. 61 Fed. Reg. at 45,229.

59. *Id.* at 45,230.

60. *Id.* at 45,231.

61. *Id.*

associated with the development of nicotine tolerance.[62] In the early 1990s, nicotine was shown to produce effects on the brain associated with changes in mood and alertness.[63] Finally, by the mid-1990s, it was apparent that nicotine replacement therapies were effective in assisting smokers to quit, thereby providing additional evidence that nicotine is the ingredient in tobacco products that causes addiction.[64]

In short, by 1995 when the FDA commenced the rule-making proceedings at issue in this case, "[e]very expert organization that ha[d] commented on whether nicotine is addictive ha[d] concluded that it is"[65] — including the U.S. Surgeon General, the Royal Society of Canada, the World Health Organization, the American Medical Association and the U.K. Medical Research Council.[66]

2. *Industry Deliberations*

This scientific consensus, reached only after meticulous research in the 1980s and 1990s, confirmed what the tobacco industry already knew. Deliberations only recently unmasked to public view revealed that the tobacco industry had long recognized that nicotine is a powerful drug.

As early as 1962, a consultant to British American Tobacco stated in an internal document that " 'nicotine is a very

62. *Id.* at 45,232.

63. *Id.* at 45,231.

64. *Id.* at 45,232.

65. *Id.* at 44,703.

66. *Id.* at 44,702-03.

remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect . . . .' "[67] A 1963 report commissioned by British American Tobacco likewise acknowledged that a denial of nicotine intake to chronic smokers produces a " 'crav[ing] for renewed drug intake . . . .' "[68]

In 1972 an R.J. Reynolds executive explained that " 'the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry . . . based upon design, manufacture and sale of attractive dosage forms of nicotine . . . .' "[69] Perhaps most graphically, a Philip Morris scientist in 1972 characterized the cigarette in these terms:

> "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 . . . .
>
> Think of a puff of smoke as the vehicle of nicotine . . . .

67. C. Ellis, *The Smoking and Health Problem*, at 15-16 (1962) (quoted in 61 Fed. Reg. at 44,882).

68. C. Haselbach *et al.*, *A Tentative Hypothesis on Nicotine Addiction*, at 2 (1963) (quoted in 61 Fed. Reg. at 44,884).

69. C. Teague, *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, at 2 (1972) (quoted in 61 Fed. Reg. at 44,869).

> Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."[70]

Philip Morris scientists subsequently acknowledged that cigarettes serve as " 'a narcotic, tranquilizer, or sedative' "[71] and that " '[n]icotine is a powerful pharmacological agent with multiple sites of action . . . known to have effects on the central and peripheral nervous system . . . .' "[72]

It has become apparent in recent years that the tobacco companies' research on the effects of nicotine rivals that of traditional pharmaceutical companies. As the FDA found:

> Before marketing a prescription drug, a pharmaceutical company studies the pharmacokinetics of the drug (how it is absorbed into the body, metabolized, and excreted), the pharmacodynamics of the drug (what specific effects the drug has on the body's chemistry and metabolism as it makes its way through the body), and the clinical effects of the drug (whether the drug is effective in producing the desired therapeutic or physiological effects). The cigarette manufacturers have conducted or funded the same studies for nicotine. As a result, the cigarette

70. W. Dunn, *Motives and Incentives in Cigarette Smoking*, at 5-6 (1972) (quoted in 61 Fed. Reg. at 44,856).

71. A. Udow, *Why People Start to Smoke* (1976) (quoted in 61 Fed. Reg. at 44,857).

72. J. Charles, *Nicotine Receptor Program* (1980) (quoted in 61 Fed. Reg. at 44,857-58).

> manufacturers' understanding of the pharmacological effects and uses of nicotine are closely analogous to — if not more extensive and sophisticated than — the understanding any pharmaceutical company has of traditional drug products.[73]

Indeed, R.J. Reynolds recently announced a new venture to compete head-to-head with pharmaceutical companies.[74] Capitalizing on its knowledge of nicotine, R.J. Reynolds hopes to develop nicotine-based drugs to treat Alzheimer's, Parkinson's and other diseases.[75]

In designing and manufacturing cigarettes, the tobacco industry has developed what Philip Morris concedes to be " 'complex computer models to help determine nicotine and tar deliveries . . . allow[ing] blend ingredients, filter and paper components, and numerous other variables to be considered simultaneously. . . .' "[76] The industry establishes parameters for nicotine at the tobacco growing stage.[77] In making purchasing decisions, the industry inspects leaf characteristics to determine nicotine content — the higher stalk tobacco leaves contain more nicotine than lower stalk leaves on the same plant.[78] The industry uses leaf blending as a primary means to

73. 61 Fed. Reg. at 44,911-12.

74. S.L. Hwang, *R.J. Reynolds Hopes to Spin Nicotine Into Drugs*, WALL STREET JOURNAL, June 28, 1999, at B1.

75. *Id.*

76. 61 Fed. Reg. at 44,980.

77. *Id.* at 44,981.

78. *Id.* at 44,982.

control nicotine levels. Leaf blending produces consistency and uniformity to negate variations in nicotine associated with genetics and soil and climatic conditions.[79] The industry likewise controls nicotine content through inputs during manufacturing, such as reconstituted tobacco and ammonia compounds.[80] During the process, quality control checks are used to determine the exact amount of nicotine in the product.[81] In particular, ammonia added to reconstituted tobacco can increase the level of "free" nicotine in the cigarette, constituting in the words of a cigarette manufacturer, " 'the soul of Marlboro.' "[82] In sum,

> cigarette manufacturers carefully control and manipulate the nicotine delivery of their commercially marketed cigarettes to provide smokers with a pharmacologically active dose of nicotine. Among other practices, the manufacturers use high-nicotine blends that increase nicotine deliveries . . . ; rely on filtration and ventilation technologies that selectively remove more tar than nicotine; add ammonia compounds that increase the delivery of "free" nicotine; and carefully control the nicotine level in all cigarettes . . . . An inevitable consequence of these practices is to keep consumers smoking by sustaining their addiction.[83]

79. *Id.* at 44,983-84.

80. *Id.* at 44,984-86.

81. *Id.* at 44,985.

82. *Id.* at 44,986.

83. *Id.* at 44,993-94.

3. *The FDA's Conclusions*

On the basis of the scientific consensus on nicotine and the tobacco industry's own concessions, the FDA commenced rule-making proceedings to address whether tobacco products should be subject to jurisdiction under the FDCA. The evidence before the FDA compelled two fundamental findings of fact. First, nicotine, like amphetamines, cocaine and morphine, "substantially alters the structure and function of the brain and other systems of the body."[84] When cigarette smoke is inhaled, nicotine enters the mouth, passes into the lungs, is absorbed into the bloodstream and diffuses into the brain — all within approximately 11 seconds.[85] In the brain, nicotine binds to unique receptors on the surfaces of brain cells, causing "the number of nicotinic receptors . . . to increase and significantly alter[ing] the brain's normal electrical and metabolic activity . . . ."[86] Nicotine can produce both sedating and stimulating effects, depending on dose and circumstances.[87]

Second, "nicotine causes and sustains addiction" by directly affecting the so-called mesolimbic system of the brain that signals pleasure and reward and modulates emotions.[88] Upon stimulation by an addictive substance, the mesolimbic system responds by rewarding repeated consumption of the

84. *Id.* at 44,698.

85. *Id.* at 44,698-99.

86. *Id.* at 44,699-700.

87. *Id.*

88. *Id.* at 44,700.

substance.[89] Nicotine, like amphetamines, cocaine and morphine, causes compulsive drug-seeking behavior associated with drug addiction.[90] Research demonstrates, for example, that from 77% to 92% of smokers are addicted and that tobacco users show a higher percentage of addiction than users of other drugs, such as cocaine and heroin.[91]

From these findings of fact, the FDA reached three inevitable legal conclusions. First, because "nicotine's addictive and other pharmacological effects and uses are so widely recognized . . . they must be considered foreseeable to a reasonable tobacco manufacturer."[92] Accordingly, nicotine is "intended to affect the structure or any function of the body of man" and hence is a "drug" for purposes of the FDCA.[93] Similarly, the administrative record made plain that cigarettes contain "device" components (*e.g.*, the blend, filter and ventilation system) that are designed to release tobacco smoke delivering a controlled amount of nicotine to the brain.[94] Finally, the "drug" (nicotine) and the "device" (the cigarette) comprise a "combination" product subject to FDA jurisdiction under the FDCA.[95]

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89. *Id.*

90. *Id.*

91. *Id.* at 44,812-13.

92. *Id.* at 45,233.

93. *Id.* at 45,207, *et seq.*

94. *Id.* at 45,208, *et seq.*

95. *Id.* Similar conclusions apply with respect to smokeless tobacco. Processed tobacco in smokeless products delivers nicotine (Cont'd)

Although subjecting tobacco products to regulation, the FDA deferred consideration of discrete questions more properly addressed during a classification proceeding — such as the imposition of controls that would result in a "reasonable assurance of safety and effectiveness" for the use of tobacco products:

> It would not be appropriate for FDA to make a final determination at this time as to whether the application of all appropriate regulatory controls identified in a classification proceeding would result in a reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco for any users. This determination must await completion of the classification process and of any regulatory steps identified in the classification process . . . .[96]

(Cont'd)
to the cheek and gum tissue for absorption; porous pouches also used in smokeless products hold processed tobacco in the mouth, controlling the absorption of nicotine. *Id.* at 45,213-14. Accordingly, smokeless tobacco products are "combination" products containing device components that deliver nicotine to the body. *Id.*

96. *Id.* at 44,412; s*ee also* 21 U.S.C. § 360c. The FDA's determination is made by "weighing 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) — a standard "predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury" because "[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits derived." H.R. Rep. No. 853, 94th Cong., 2d Sess., at 16-17 (1976).

4. *Focus on Youth*

In deciding upon appropriate regulatory steps at this time, the FDA was particularly swayed by evidence that nicotine addiction is a "pediatric disease." The evidence before the FDA demonstrated that despite a decline in smoking in most segments of the adult population, the incidence of tobacco use among youth had increased significantly to more than 4 million persons.[97] Moreover, the evidence left no doubt that an overwhelming proportion of adolescents regret their decision to smoke, two-thirds saying they want to stop but find it difficult to do so.[98] If left unchecked, this nicotine addiction will continue into adulthood, as evidenced by the fact that more than 80% of adults who ever smoked had their first cigarette before the age of 18, and more than half of these adults had already become regular smokers by that age.[99] The FDA found obvious implications for public health:

> the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking. Approximately one out of every three young people who become regular smokers each day will die prematurely as a result . . . .
>
> As long as children and adolescents become addicted to cigarette and smokeless tobacco use . . . there is little chance that society will be able [to] reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because . . . anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.[100]

97. 61 Fed. Reg. at 44,398.

98. *Id.*

99. *Id.*

To discharge its obligations under the FDCA, the FDA carefully tailored regulations to target adolescent smoking. Among other things, the regulations prohibit the sale of tobacco products to persons under the age of 18 and require retailers to verify the age of purchasers.[101] In addition, the regulations limit young people's access to tobacco by prohibiting free samples and the sale of products through vending machines and self-service displays except where adolescents are not present.[102] Finally, the regulations limit advertising to which children are exposed to black-and-white, text-only format, prohibit outdoor advertising within 1,000 feet of playgrounds and schools and prohibit sponsorship of sporting and other events by use of a brand name of a tobacco product.[103]

The FDA's determination that tobacco products are subject to regulation under the FDCA was not only a "permissible"[104] construction of the statute but indeed compelled by the scientific evidence amassed during the administrative proceedings and by the tobacco industry's recently-discovered

100. *Id.* at 44,399.

101. *Id.* at 44,616, *et seq.*

102. *Id.*

103. *Id.*

104. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. at 843.

internal documents. The FDA's assertion of jurisdiction is not, as the tobacco industry has contended, a "change of position" designed to override Congressional will but rather a reasoned response to a new scientific consensus. In attempting to curb nicotine addiction at its source — by reducing adolescent smoking — the FDA has fulfilled its responsibility under the FDCA to protect "the lives and health of people which . . . are largely beyond self-protection."[105]

105. *Dotterweich*, 320 U.S. at 280.

CONCLUSION

For all the foregoing reasons, the decision of the Court of Appeals should be reversed.

Respectfully submitted,

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