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Tobacco Symposium

The FDA's Decision to Regulate Tobacco Products*

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Since the Surgeon General's Report of 1964, this country has officially recognized that tobacco use is a serious health problem.¹ The numbers themselves are staggering. Approximately fifty million Americans smoke cigarettes,² three million of whom are children.³ Recent studies show that between seventy-seven and ninety-two percent of smokers are addicted to the nicotine in tobacco.⁴ Each year, more than 400,000 Ameri-

* This article is based on a speech given at Pace University School of Law in April 1997.

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1. See generally Pub. Health Serv., U.S. Dep't of Health, Educ., Welfare, Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service, U.S. Department of Health, Education, and Welfare, Public Health Service, 1964.

2. See 61 Fed. Reg. 44396, 44398 (1996).

3. See *id.*

4. See *id.* at 44812.

cans die from tobacco related diseases;⁵ more than from AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires combined.⁶

Tobacco use is not like an infectious disease where the cure depends on developing a drug or vaccine. Instead, anyone can eliminate, or at least greatly reduce, their risk of disease from tobacco products simply by not smoking cigarettes or using smokeless tobacco products.

Yet reducing tobacco use has been as great a challenge as any public health problem this country has ever addressed. Unlike other diseases, the challenge is not scientific; it is political. For years, the tobacco companies had the votes on Capitol Hill to block any proposed legislation, and no comprehensive tobacco legislation was enacted.⁷

I worked on Capitol Hill during the early 1990s, which included the first six months after the Food and Drug Administration announced its tobacco investigation. I then moved to the FDA in November 1994, becoming Deputy Commissioner for Policy, where my responsibilities included tobacco regulation.

In the early 1990s, I worked for the House Subcommittee on Health and Environment, chaired by California Congressman Henry Waxman, a staunch tobacco opponent. During those years, Congressman Waxman and others introduced legislation to regulate the sale and promotion of tobacco products. Hearings were held, but all attempts at comprehensive tobacco legislation failed.

In February 1994, an agency that had not been actively involved in the tobacco issue presented a new opportunity for tobacco regulation. In responding to a petition by a tobacco control group, Dr. David Kessler, then Commissioner of Food and Drugs, announced that the FDA would investigate whether the nicotine in tobacco products was a drug that could be regu-

5. *See id.* at 44398.

6. *See id.*

7. However, the industry agreed to the enactment of several significant laws, including the FEDERAL CIGARETTE LABELING AND ADVERTISING ACT, which requires warning statements on cigarettes and smokeless tobacco products. 15 U.S.C. § 1331 (1982) *et seq.* *See also* COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT, 15 U.S.C. § 4401 (1986) *et seq.*

lated by the FDA.⁸ That was an historic decision because it provided an opportunity for taking decisive action on tobacco without requiring action by Congress. Regulations issued by federal agencies have the force of law, yet do not have to be approved by Congress. If an administrative agency has jurisdiction, it can issue regulations to implement that jurisdiction.

The significance of this letter was not lost on anyone who was following the issue. Congressman Waxman immediately scheduled hearings, which included dramatic testimony from the chief executive officers of the tobacco companies. These executives raised their right hands, swore to tell the truth, and then, one by one, denied that nicotine was addictive.

These hearings also included appearances by FDA Commissioner Kessler.⁹ At the first hearing, Commissioner Kessler described the results of the first stage of the FDA's investigation into the tobacco industry; describing what the companies knew and how they used that information to make cigarettes and smokeless tobacco products.

As Dr. Kessler explained, the first clue that the tobacco industry was highly focused on controlling nicotine levels came from a search of the industry's patents. These patents revealed that, beginning in the early 1960s, the tobacco companies conducted extensive research on controlling the precise amount of nicotine delivered by a cigarette.¹⁰

Perhaps the most interesting of these patents was one concerning the addition of an organic acid to tobacco to mask the harsh flavor of nicotine. The stated purpose was to increase the amount of nicotine in a cigarette through the use of high nicotine tobaccos, without creating an unacceptably harsh tasting cigarette. These patents contradicted the industry's claim that nicotine was used solely for its taste. Here was research being conducted on how to increase nicotine levels, despite its taste. However, the patents did not demonstrate that the companies were actually controlling the nicotine levels in commercial prod-

8. Letter from David A. Kessler, Commissioner of Food and Drugs, Food and Drug Administration, to Scott Ballin, Chairman, Coalition on Smoking or Health (February 25, 1994).

9. See *Regulation of Tobacco Products (Part 1)*, *supra* note **.

10. See *id.*

ucts. They only demonstrated that research had been conducted.¹¹

Some of the early evidence on the actual conduct of tobacco companies came from the Federal Trade Commission. The FTC is responsible for implementing the law requiring the warnings that one sees on cigarette packages and advertising.¹² It also collects, on a yearly basis, data on nicotine and tar levels of all domestic cigarettes. During the 1970s and 80s, in response to reports that "tar" was the troublesome ingredient in cigarettes, the tobacco companies designed so-called "low tar" cigarettes. Since both tar and nicotine are in tobacco smoke, nicotine levels should have been reduced in an amount equivalent to the tar reduction, which is what the companies always claimed happened. Yet, when the FDA analyzed the FTC data from the 1980s, it showed that the nicotine content for all marketed cigarettes on a sales-weighted basis began to rise in 1982, while sales-weighted tar levels continued to drop.¹³ This evidence was very significant because it suggested that in fact the companies were attempting to keep nicotine levels from being reduced below a certain level.¹⁴

During the investigation, the FDA discovered that the industry could control the level of nicotine in cigarettes in a number of ways. One method was blending leaves from different positions on the stalks of tobacco plants.¹⁵ By blending different stalk positions from different tobacco varieties over several crop years, the companies had literally dozens and dozens of nicotine combinations from which to choose.

The agency found that one company went even further. The FDA received a tip that the Brown & Williamson Tobacco Company had created a new tobacco variety that contained twice the usual amount of nicotine. The new tobacco was called "Y-1." With luck and persistent digging, FDA investigators discovered that the patent had been put to use.¹⁶

11. See *Regulation of Tobacco Products (Part 3)*, *supra* note **.

12. See FEDERAL CIGARETTE LABELING AND ADVERTISING ACT, 15 U.S.C. 1331 (1982).

13. See *Regulation of Tobacco Products (Part 1)*, *supra* note **.

14. See 61 Fed. Reg. 44369, 44916 (1996).

15. See 60 Fed. Reg. 41704-7 (1995); 61 Fed. Reg. 44982-3 (1996).

16. See *Regulation of Tobacco Products (Part 3)*, *supra* note **.

One of the three people named on the patent was a scientist from a small genetic engineering firm in New Jersey. The scientist told the agency that the New Jersey company had been hired to genetically engineer the Y-1 plant so it would not produce pollen or seeds; therefore, it could not be stolen from the field by competitors. She also said that she had shipped several pounds of Y-1 seeds to Brazil, where Brown and Williamson had patented the plant, and that she had actually seen Y-1 growing in the fields.

The FDA sent an investigator to check U.S. Customs records for evidence that Y-1 had been brought back into the U.S. It was a long shot, but the investigator persisted and informed the agency that he had found two invoices showing that in September 1992, Brown and Williamson had shipped over 500,000 pounds of "your order project Y-1" into the U.S.¹⁷

When confronted with evidence about Y-1, Brown and Williamson executives acknowledged that they had as much as four million pounds of this high nicotine tobacco, and that it had already been used commercially.¹⁸ More importantly, they admitted that Y-1 was intended as a "blending tool" to lower the tar yield in certain products, while maintaining the nicotine level, although they said it was never used for that purpose.¹⁹

The agency also uncovered hundreds of studies conducted by the tobacco companies — some public, some private — on nicotine's effect on the brain and central nervous system.²⁰ They identified the specific receptors in the brain upon which nicotine acts,²¹ and examined nicotine's effects on human behavior and mood.²² They measured how fast nicotine is adsorbed into the bloodstream²³ and the brain, and how much nicotine is necessary to "satisfy" smokers.²⁴

One of the most interesting studies conducted by a tobacco company was performed by Dr. Victor DeNoble, a research scientist who ran a laboratory at Philip Morris between 1980 and

17. *See id.* at 19.

18. *See id.* at 20.

19. *See* 61 Fed. Reg. 44369, 44938 (1996).

20. *See id.* at 44854-44915.

21. *See id.* at 44896.

22. *See id.* at 44901.

23. *See id.* at 44906.

24. *See* 61 Fed. Reg. 44396, 44870 (1996).

1984. Phillip Morris was trying to create a safer cigarette that would have the same effects on the brain as those with nicotine, but would not have the unhealthy effects on the heart.²⁵ In order to develop this product, the company had to have a complete understanding of nicotine's effects on the brain, including its addictive qualities.²⁶

In his work, Dr. DeNoble demonstrated for the first time that rats will self-administer nicotine, one of the hallmarks of addictive substances.²⁷ The Journal *Phopharmacology* accepted Dr. DeNoble's paper describing these findings for publication, but Philip Morris subsequently forced DeNoble to withdraw the manuscript. Years later, Philip Morris shut down Dr. DeNoble's lab.²⁸ Dr. DeNoble agreed to testify before Congress, and his testimony gave the FDA and Congress important evidence that Philip Morris *knew* of nicotine's pharmacological properties.

Even more impressive was the investigation's discovery of internal tobacco industry documents that showed company officials knew nicotine was a powerful drug which had addictive properties.²⁹ For example, according to the general counsel of Brown and Williamson in 1963, "[w]e are then, in the business of selling nicotine, an addictive drug."³⁰ A draft of remarks in 1969 by Philip Morris' Vice President for Research and Development to the Board of Directors states, "[w]e are of the conviction . . . that the ultimate explanation for the perpetuated cigaret[te] habit resides in the pharmacological effect of smoke upon the body of a smoker"³¹ In 1972, an R.J. Reynolds official perceived the tobacco industry as "a specialized, highly ritualized and stylized segment of the pharmaceutical industry."³²

When that phase of the investigation was over, the FDA had to decide whether nicotine products met the definition of a drug under the Federal Food, Drug and Cosmetic Act³³. In or-

25. *See id.* at 44859.

26. *See id.* at 44860.

27. *See id.* at 44861.

28. *Regulation of Tobacco Products (Part 2)*, *supra* note **.

29. *See* 61 Fed. Reg. 44369, 44854 (1996).

30. *See id.* at 44884.

31. *See id.* at 44856.

32. *See id.* at 44867.

33. *See* 21 U.S.C. § 301 (1972).

der for the agency to find that nicotine is a drug, it had to determine that nicotine affects “the structure and function of the human body,” and that the tobacco manufacturers “intended” that nicotine have this effect.³⁴

It was clear from the evidence collected and numerous studies that nicotine affects the structure and function of the body. Every major medical organization, including the U.S. Surgeon General, the American Medical Association, and the World Health Organization has found that the scientific evidence overwhelmingly shows that nicotine is addictive.³⁵ The companies themselves had carefully documented the effects of nicotine on the brain.³⁶ That alone is enough to meet this requirement.³⁷

On the issue of intent, it was also clear from the evidence, the industry’s research on nicotine, and the statements of corporate officials, that the manufacturers knew nicotine had drug-like effects.³⁸ In addition, the agency found that it would be foreseeable to a reasonable manufacturer that consumers would use the product for its drug-like effects.³⁹ These facts are sufficient to establish intent.⁴⁰

The same findings apply to smokeless tobacco. The evidence shows that smokeless tobacco companies understood the pharmacological effects of nicotine,⁴¹ designed their products to deliver the optimum dose of nicotine to their customers,⁴² and aimed their products at youthful users. For example, the country’s largest smokeless tobacco manufacturer, U.S. Tobacco, developed a marketing strategy that started new users on brands with relatively low levels of nicotine and progressively moved them up to higher nicotine doses that new users could not toler-

34. *Id.* at § 321 (g)(1)(C).

35. *See* 61 Fed. Reg. 44396, 44702-02 (1996).

36. *See id.* at 44854.

37. *See id.*

38. *See id.*

39. *See id.* at 44692.

40. *See* 61 Fed. Reg. 44396, 44847 (1996).

41. *See id.* at 45100.

42. *See id.* at 45108.

ate.⁴³ The evidence led the FDA to assert jurisdiction over cigarettes and smokeless tobacco.⁴⁴

Once it established that it had jurisdiction, the FDA had to decide what action to take. This was a difficult issue. Even though tobacco products are deadly, the agency had to take into account the nearly forty million Americans already addicted to the nicotine in tobacco products. The agency concluded that a ban could create a black market, similar to that which resulted from Prohibition in the 1930s. Thus, it was unclear whether a ban would actually reduce tobacco use.⁴⁵ Consequently, after careful consideration of the issue, the agency decided that a ban was not the best public health option.

After studying the issue, the FDA focused on two key elements: children and addiction. In the past, the debate had always been about getting adults to stop smoking. Because nicotine is addictive, this has been only partially successful. In terms of public health, it appeared that prevention would be a much more effective approach.

When the agency looked at the age at which tobacco use commonly begins, the answer was clear: childhood and adolescence. Eighty-two percent of all regular smokers begin as teenagers and more than half are already addicted by the time they reach adulthood.⁴⁶ If an individual can avoid tobacco use during adolescence, the chance that he or she will ever begin is very small.

The FDA investigation also showed that the tobacco companies fully understood that it is children, not adults, who begin using tobacco. The evidence strongly suggested that tobacco companies used that knowledge to target teenagers in their advertising and promotional campaigns.⁴⁷

Like the evidence on jurisdiction, some of the most compelling evidence came from tobacco company executives themselves. For example, one R.J. Reynolds official wrote in 1984 about the importance of adolescents to the survival of the industry: "Young smokers have been the critical factor in the growth

43. *See id.* at 45120.

44. *See id.* at 44619.

45. *See* 61 Fed. Reg. 44396, 44398 (1996).

46. *See id.*

47. *See id.* at 44476.

and decline of every major brand and company over the last 50 years.”⁴⁸ Another RJR official put it even more clearly in 1973, when he said, “[r]ealistically, if our company is to survive and prosper over the long-term, we must get our share of the youth market.” He added, “[e]vidence is now available [that] indicate[s] that the 14-18 year old age group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained over the long term.”⁴⁹

This industry focus on children appears to have been successful. Some 3,000 children and adolescents begin to smoke each day.⁵⁰ That's more than 1,000,000 new young smokers per year. Of those 3,000 who begin to smoke, 1,000 will quit and 1,000 will get lucky; but every day 1,000 children who start smoking will die prematurely.⁵¹ The FDA realized that if it could reduce the number of children who start smoking by fifty percent, it could save 500 lives per day — almost 200,000 lives per year. This would be comparable to eliminating all deaths from automobile accidents for four consecutive years.⁵²

The FDA's investigation allowed it to see the roots of the problem and to develop a strategy that could gain broad support: keep cigarettes and other tobacco products out of the hands of children. This approach has a strong appeal that transcends politics. Smokers, and even tobacco companies, agree that children should not smoke. Every state has a law prohibiting the sale of tobacco products to children.

To keep children from using tobacco products, the FDA had to address two issues: adolescent access to tobacco products and the appeal of these products created by annual multi-billion dollar advertising budgets. The agency had to limit both the supply of tobacco to children and the demand for these products. It would not be enough merely to limit access; if the demand

48. See *id.* at 44841, n. 129; O.Phelps and J. Hodges, *Suit: Kids were Focus of Reynolds Strategy*, STAR TRIBUNE, July 11, 1996, at 1A.

49. See 61 Fed. Reg. 44396, 44481.

50. See *id.* at 44422.

51. See *id.* at 44399.

52. See “Motor Vehicle Occupants and Nonoccupants Killed and Injured, 1985-1995,” Traffic Safety Facts 1995— Overview, U.S. Department of Transportation, National Highway Traffic Safety Administration, National Center for Statistics and Analysis, 1995.

among adolescents remained high, they would find a way to get tobacco products.

The access provisions in the rule are straightforward. After the rule goes into effect, it will generally be illegal to sell cigarettes except in a face-to-face transaction where the buyer demonstrates that he or she is eighteen or older. That means no vending machines (except in bars and other places not accessible to kids).⁵³ It means no free samples.⁵⁴ It means that cigarettes must be placed beyond reach — behind the counter or in locked cabinets.⁵⁵

Regulating advertising, although more difficult, is essential. One effect of advertising is to make tobacco products socially acceptable — to associate them with fun, sex and sports. These advertisements are very effective in appealing to children. The three most heavily advertise brands: Marlboro, Camel and Newport, are smoked by eighty-six percent of young smokers.⁵⁶ By contrast, thirty-nine percent of adults choose one of the “generic” brands which are advertised less, and are less expensive.⁵⁷

R.J. Reynolds claims that it did not intend for its “Joe Camel” character to appeal to kids. Yet, one study found that thirty percent of three year olds and ninety-one percent of six year olds could identify Joe Camel as a symbol for smoking.⁵⁸ During the five years following the launch of the Joe Camel campaign, Camel’s market share among minors climbed from below four percent to between thirteen and sixteen percent, while its market share among adults remained stagnant.⁵⁹

Under the rule, most tobacco advertising will no longer contain the colorful images that young people have come to associate with these products. Most tobacco ads will be restricted to a black and white text-only format. There are a few exceptions to this requirement, including advertisements in publications read

53. See 61 Fed. Reg. 44396, 44448 (1996).

54. See *id.* at 44460.

55. See *id.* at 44453.

56. See *id.* at 44482.

57. See *id.*

58. See 60 Fed. Reg. 41314, 41333 (1995).

59. See *id.*

primarily by adults, and in places totally inaccessible to young people.⁶⁰

Furthermore, billboards and other outdoor advertising within 1,000 feet of schools and playgrounds are totally prohibited.⁶¹ Tobacco companies will also no longer be permitted to sell or distribute promotional items such as t-shirts, caps, and sporting goods that carry the brand names and logos of tobacco products.⁶² These items are so popular with children, according to a Gallup survey, that nearly half of adolescents who smoke, and over one quarter who do not, own at least one of them.⁶³

At the same time, the rule will prohibit tobacco companies from linking sporting, racing, and other events to tobacco products.⁶⁴ For instance, the Winston Cup auto race would no longer be sponsored by the cigarette brand name Winston. Instead, it would be presented in the name of the company, R.J. Reynolds, not in the name of a product to which adolescents are becoming addicted.

There is one more dimension of the tobacco initiative that the FDA announced it intended to pursue: education.⁶⁵ Most children and teenagers already know that tobacco is dangerous, but few believe that the risks apply to them. The FDA has stated it will initiate a process which could require tobacco companies to support a televised educational campaign to educate young people about the health risks of tobacco.⁶⁶ These types of messages proved effective in the late 1960s when broadcasters were required to air them to counter the cigarette advertising then permitted on television.⁶⁷

The final rule was published in August 1996, and the first provisions of the FDA's regulation of tobacco age and identification requirements went into effect in February 1997. The rest

60. See 61 Fed. Reg. 44396, 44465 (1996).

61. See *id.*

62. See *id.* at 44466.

63. See *id.* at 44525.

64. See *id.* at 44466.

65. See 61 Fed. Reg. 44396, 44538 (1996).

66. The agency has considered utilizing section 518(a) of the FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. § 360h (1982), if the evidentiary standard is met, to require the cigarette and smokeless tobacco manufacturers to notify customers and potential customers, including children, of the dangers of tobacco use. See 61 Fed. Reg. 44396, 44538 (1996).

67. See *id.*

of the access provisions, and all of the advertising and promotion provisions, were scheduled to go into effect in August 1997. The sponsorship provisions were scheduled to become effective in August 1998.

The cigarette and smokeless tobacco industries, advertising trade groups, and convenience store operators immediately filed a lawsuit against the FDA in U.S. District Court in Greensboro, North Carolina, challenging the validity of the FDA's regulation⁶⁸. They sought summary judgment, claiming as a matter of law that: (1) Congress had withheld from the FDA the authority to regulate cigarettes and smokeless tobacco; (2) the Act does not authorize the FDA to regulate these products as drugs and delivery devices; and (3) the restrictions imposed by the FDA on advertising violate the First Amendment⁶⁹.

On April 25, 1997, Judge Osteen ruled that the FDA had jurisdiction to regulate cigarettes and smokeless tobacco as drug delivery systems under the combination product and restricted device provisions of the Act.⁷⁰ He declined to rule on the plaintiff's constitutional claim, finding instead that the advertising provisions were invalid on statutory grounds⁷¹. The tobacco companies and advertisers have appealed to the U.S. Court of Appeals for the Fourth Circuit. Oral Argument was held on August 11, 1997.

Two months after Judge Osteen's decision, the tobacco industry entered into a tentative settlement with a number of states' Attorneys General to resolve lawsuits that the states had brought against the tobacco companies, seeking reimbursement for expenses incurred under the federal Medicaid program. The settlement would provide, by legislation, consent agreements, and contracts, that: the tobacco industry submit to modified FDA jurisdiction; agree to be bound by the FDA's access and advertising restrictions; and pay \$368.5 billion over 25 years to states, injured plaintiffs, federal programs, including \$500 million per year for public education about the hazards of tobacco. Opinions vary on the sufficiency and wisdom of the settlement, but only three and a half years ago, when Commissioner Kess-

68. *See* Coyne Beahm v. FDA, 966 F.Supp 1374 (M.D.N.C. 1997).

69. *See id.*

70. *See id.*

71. *See id.*

ler sent his letter responding to a citizen's petition, it was unimaginable that this country would have made so much progress in adopting meaningful steps to reduce tobacco use.