

THE FDA V. JOE CAMEL: AN ANALYSIS OF THE FDA'S ATTEMPT TO REGULATE TOBACCO AND TOBACCO PRODUCTS UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT

I. INTRODUCTION

The term "drug" means . . . articles (other than food) intended to affect the structure or any function of the body of man.¹

The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended . . . to affect the structure or any function of the body of man.²

These two provisions from the Federal Food, Drug, and Cosmetic Act (FDCA) define the jurisdiction that Congress has granted the Food and Drug Administration (FDA) to regulate drugs and drug delivery devices. Since the creation of the Food and Drug Administration in 1938, these provisions have not been interpreted by the FDA to include tobacco or tobacco products.

However, on August 9, 1995, David Kessler, Commissioner of Food and Drugs, reversed sixty years of FDA policy and released a Proposed Rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents,"³ seeking to establish regulatory jurisdiction over tobacco and tobacco products. This proposal, citing FDA findings that nicotine is a body-altering drug and that tobacco products are drug delivery devices, declares that the FDA has jurisdiction over tobacco and tobacco products pursuant to the FDCA. Although the FDA has entitled this proposal a child and adolescent protection plan, there is no question that the issue at stake here is the FDA's attempt to establish for itself regulatory jurisdiction over tobacco and tobacco products.

This proposal has sent shockwaves throughout Southern States dependant upon the tobacco industry as well as the halls of Congress. The response has been both swift and extensive. In the two months following Commissioner Kessler's action, five bills were introduced in the Congress challenging the Proposed Rule⁴ and lawsuits seeking declaratory and injunctive relief against Kessler and the FDA have been filed by tobacco companies, advertisers, convenience store operators, and tobacco farmers.

This Note will examine the history of tobacco regulation from the passage of the Pure Food and Drug Act in 1906 through the issuance of the Proposed Rule by the FDA, analyze the Proposed Rule, discuss the challenges, both legislative and legal, to the Proposed Rule, and offer an analysis regarding the battle over the jurisdiction of

1. 21 U.S.C. § 321(g)(2) (1994).

2. 21 U.S.C. § 321(h)(2) (1994).

3. 60 Fed. Reg. 41,314 (1995) (to be codified at 21 C.F.R. §§ 801, 803, 804, and 897).

4. *See* Section IV.

tobacco regulation.

II. THE HISTORY OF TOBACCO REGULATION

The history of Federal involvement in the regulation of tobacco and tobacco products began in 1914 with the pronouncement that tobacco not labelled for medicinal use was not subject to regulation by the predecessor of the FDA. Since then there have been numerous attempts, both legislative and legal, to place tobacco within the jurisdiction of the FDA. All of these attempts have failed due to Congress' clear intent that tobacco not be regulated as a drug or drug delivery device under FDA jurisdiction.

The debate over Federal regulation of tobacco was first addressed in 1914, when the FDA's predecessor (the Bureau of Chemistry in the Department of Agriculture) announced that only tobacco which had been labeled for a medicinal purpose was subject to the scope of the Pure Food and Drugs Act of 1906⁵ and that "tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff, and not for medicinal purposes are not subject to the provisions of the act."⁶ This lack of jurisdiction was addressed in 1929, when legislation was introduced intending to place tobacco within the regulatory jurisdiction of the Bureau of Chemistry, which enforced the nation's drug laws.⁷ Again, noting that the Bureau of Chemistry had no jurisdiction over tobacco which was not labelled as medicinal, Congress did not pass this bill.

The Bureau of Chemistry was replaced as the Federal regulator of drugs in 1938 when the Federal Food, Drug, and Cosmetic Act was enacted, creating the FDA. Under the FDCA, the FDA was granted jurisdiction over any drugs intended to affect the structure or any function of the body,⁸ as well as any device which was intended to deliver such a drug into the body.⁹ At that time, repeating the stance of its predecessor, the FDA announced that it had no jurisdiction under the FDCA over any tobacco product as a drug absent a claim that it was being sold for a medicinal purpose by the manufacturer. This position was reiterated several times between 1940 and 1952.¹⁰

In 1956, a bill was introduced to amend the FDCA to grant FDA regulatory authority over cigarettes.¹¹ This bill did not pass. Similarly, in 1963, bills were introduced in both the House and the Senate to place all smoking products under the authority of the FDA.¹² The sponsor of the House bill acknowledged that the reason for the bill was that "smoking products do not come under the protection of the FDA."¹³ Like all previous attempts, neither of these bills passed.

In 1964, the Surgeon General issued a report which outlined the risks associated with smoking and tobacco use. In response to the report, legislation was again introduced to grant the FDA the authority to regulate tobacco and cigarettes.¹⁴ At this time

5. Pub. L. No. 59-384, 34 Stat. 763 (1906).

6. *Service and Regulatory Announcements*, No. 13 (1914).

7. S. 1468, 71st Cong., 1st Sess. (1929).

8. 21 U.S.C. § 321(g)(2) (1994).

9. 21 U.S.C. § 321(h)(2) (1994).

10. *Action on Smoking and Health (ASH) v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

11. H.R. 11280, 84th Cong., 2nd Sess. (1956).

12. H.R. 5973, 88th Cong., 1st Sess. (1963); S. 1682, 88th Cong., 1st Sess. (1963).

13. 109 Cong. Rec. 10316 (June 6, 1963).

14. H.R. 2248, 89th Cong., 1st Sess. (1965).

officers from both the Department of Health, Education, and Welfare (HEW) and the FDA testified in hearings before the House Committee on Interstate and Foreign Commerce that the FDA had no jurisdiction to regulate tobacco under the FDCA without a claim of medicinal purpose.¹⁵

Ultimately, rather than granting the authority to regulate tobacco to the FDA, Congress enacted the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA)¹⁶ in order to establish a comprehensive Federal program to deal with labeling and advertising with respect to any relationship between smoking and health. In the thirty years since the enactment of the FCLAA, several attempts to place tobacco under the regulatory authority of the FDA have been introduced in Congress. None of these have passed, and the FDA has not legislatively been granted jurisdiction over tobacco and tobacco products.

In 1972 Congressional hearings, FDA Commissioner Charles Edwards reaffirmed that the FDA did not have jurisdiction over tobacco, stating that "the regulation of cigarettes is to be the domain of Congress . . . [and] labeling or banning cigarettes is a step that can be taken only by the Congress. Any such move by the FDA would be inconsistent with the clear congressional intent."¹⁷ At this time, the FDA also rejected a plan by the General Counsel of HEW, Wilmont Hastings, to initiate a test case in order to determine whether the FDA had jurisdiction over cigarettes.¹⁸

In 1976, Congress enacted the Toxic Substances Control Act (TSCA), empowering the EPA to regulate substances that might pose a threat to health.¹⁹ The TSCA's definition of chemical substance included an exception for "tobacco or any tobacco product."²⁰ Also in 1976, following a district court ruling which granted the Consumer Product Safety Commission jurisdiction to consider a petition to regulate cigarettes under the Federal Hazardous Substances Act (FHSA), Congress amended the FHSA to exclude tobacco and tobacco products from its definition of a hazardous substance.²¹ In doing so, Congress stated that:

the clear mandate of Congress is that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, the Cigarette Labeling and Advertising Act of 1969, and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action.²²

Although Congress clearly stated its intent that it alone be the sole Federal regulator of tobacco and tobacco products at these hearings, they were not the end of the debate over expansion of FDA jurisdiction to include tobacco. Between 1977 and 1979, five bills were introduced into Congress (four in the House, one in the Senate) intending to grant jurisdiction to the FDA; all failed.²³

15. *Hearings before the House Comm. On Interstate and Foreign Commerce on H.R. 2248*, 89th Cong., 1st Sess. 193 (1965).

16. 15 U.S.C. §§ 1331-1341 (1994).

17. *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92nd Cong., 2d Sess. (1972) (testimony of FDA Commissioner Charles Edwards).

18. *Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Committee on Commerce*, 92d Cong., 2d Sess. 239, at 245-46 (1972).

19. 15 U.S.C. §§ 2601-2629 (1994).

20. 15 U.S.C. § 2602(2)(B)(iii) (1994).

21. Consumer Product Safety Commission Improvements Act, Pub. L. No. 94-284, 90 Stat. 503 (1976) (codified as amended at 15 U.S.C. § 1261(f)(2) (1994)).

22. S. Rep. No. 251, 94th Cong., 2nd Sess. 43 (1976).

23. H.R. 2419, 95th Cong., 1st Sess. (1977); H.R. 3879, 95th Cong., 1st Sess. (1977); H.R. 7168,

Through 1976, all major attempts to place tobacco within the regulatory reach of the FDA had come from Congress itself. Private initiative to do so was first attempted in 1977, when a citizen's watchdog group, Action on Smoking and Health (ASH), along with thirteen other organizations, filed a petition with the FDA requesting that it assert jurisdiction over tobacco. When the Commissioner of Food and Drugs, Donald Kennedy, rejected the petition, ASH filed suit in order to challenge that decision.²⁴ The chief issue in this case was ASH's contention that tobacco manufacturers were selling cigarettes with the sole intention of delivering a body altering drug (nicotine), therefore placing them within the regulatory jurisdiction of the FDA. The Circuit Court, affirmed the lower court's holding that ASH did not, and could not, establish the near exclusivity of consumer use of cigarettes with the intent to affect the structure or any function of the body of man. In holding that tobacco did not fall within the regulatory jurisdiction of the FDA, the Circuit Court stated that any expansion of the FDCA is the job of Congress.

However, ASH was not alone in being concerned with the hazards of tobacco use. In fact, research and medical studies which have been released in the last two decades have left no doubt about the dangers of tobacco and tobacco products use. These dangers include increased rates of cancer, heart attacks, and birth defects among users. In response to these studies, as well as public awareness of these dangers, efforts to place tobacco within the jurisdictional authority of the FDA have been stepped up in recent years.

Since *ASH*, tobacco regulation has been addressed by Congress almost annually; however, there has been nothing to indicate any change in Congress' approach towards FDA regulation of tobacco and tobacco products. In 1984, the House Committee on Energy and Commerce stated that "Federal laws that protect the public from hazardous food, drugs, and consumer products do not apply to cigarettes."²⁵ This declaration once again reaffirmed Congress' stance that tobacco and tobacco products do not fall within the regulatory reach of the FDA.

In 1986, Congress, addressing the separate regulatory need for smokeless tobacco products, enacted the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA).²⁶ The CSTHEA was enacted in order to provide a Federal regulatory scheme in order to regulate the manufacture, packaging, and distribution of smokeless tobacco products. Significantly, the CSTHEA does not grant any regulatory jurisdiction to the FDA regarding smokeless tobacco products.

Following the enactment of the CSTHEA, efforts attempting to place tobacco and tobacco products within the purview of the FDA continued. In 1987, 1989, 1992, and 1993, bills were introduced to create new regulatory categories for tobacco and tobacco products.²⁷ These categories would have placed tobacco and tobacco products under

95th Cong., 1st Sess. (1977); S. 3317, 95 Cong., 2d Sess. (1978); H.R. 279, 96th Cong., 1st Sess. (1979).

24. *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

25. H.R. Rep. No. 805, 98th Cong., 2d Sess. 12 (1984).

26. 15 U.S.C. §§ 4401-4408 (1994) (see below, Section II, part A for a full discussion of the provisions of the CSTHEA).

27. H.R. 3294, 100th Cong., 1st Sess. (1987); H.R. 1494 and S. 769, 101st Cong., 1st Sess. (1989); H.R. 4350 and S. 2298, 103d Cong., 1st Sess. (1992); H.R. 2147 and S.672, 104th Cong., 1st Sess. (1993).

the regulatory umbrella of the FDA. None of these bills were enacted.

As shown by the FDA's consistent refusal since 1938 to regulate nicotine as a drug, as well as Congress' clear intent that it not be allowed to do so, the release of Commissioner Kessler's Proposed Rule to expand FDA jurisdiction to include regulation of tobacco and tobacco products is both a complete reversal of its longstanding policy regarding such regulation and a unilateral move to grant itself jurisdiction where Congress has not seen fit to do so.

III. PRESENT GOVERNMENT REGULATION

Consistent with the provisions of the Federal Cigarette Labelling Act and Comprehensive Smokeless Tobacco Health Education Act, Congress has created a comprehensive program to regulate the manufacture, packaging, and distribution of tobacco and tobacco products. However, the Federal government is not the sole regulator of tobacco. There are also regulations regarding tobacco and tobacco products in place in all fifty states. The following is an analysis of the present position of government regulation of tobacco and tobacco products.

A. Federal Regulation

As evidenced by numerous concessions of anti-tobacco forces, clear Congressional legislative intent, and several findings by Congressional committees, Congress has reserved for itself the right to regulate tobacco and tobacco products. The bulk of this regulation exists in two statutes: the Federal Cigarette Labeling and Advertising Act (FCLAA),²⁸ and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA).²⁹

The FCLAA was enacted in 1965 in order to establish a "comprehensive federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health."³⁰ Among its provisions which regulate the manufacture, packaging, and distribution of cigarettes, the FCLAA grants the Federal Trade Commission (FTC) the authority to administer the implementation and administration of the programs by which all packs of cigarettes sold or distributed, as well as all advertisements for cigarettes, within the United States must carry one of four Congressionally mandated warning labels.³¹ The Act also grants the Department of Health and Human Services (HHS) the authority to review lists of ingredients added to tobacco in cigarettes and to report to Congress on any perceived health effects of those added ingredients.³² Finally, the Secretary of HHS is authorized to transmit an annual report to Congress concerning current information about the health consequences of smoking and recommendations for legislation.³³

In 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act, in order to establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products.³⁴

28. 15 U.S.C. §§ 1331-1341 (1994).

29. 15 U.S.C. §§ 4401-4408 (1994).

30. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 2, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. § 1331 (1994)).

31. 15 U.S.C. §§ 1333(a)(1), 1333(c) (1994).

32. 15 U.S.C. § 1335(a) (1994).

33. 15 U.S.C. § 1337(a) (1994).

34. Pub. L. No. 99-252, § 2, 100 Stat. 30 (1986) (codified at 15 U.S.C. § 4401(a)(1) (1994)).

Among its provisions regulating smokeless tobacco products, the CSTHEA grants the Secretary of HHS the authority to develop and distribute educational programs, materials and public service announcements concerning the dangers of smokeless tobacco, including making grants available to the states to assist in the distribution of such information.³⁵ The Act also prohibits the manufacture, packaging, or distribution of any smokeless tobacco product without one of four warning labels,³⁶ and requires all manufacturers, packagers, and importers of smokeless tobacco to provide the Secretary of HHS a list of all ingredients used in the manufacture of that product, as well as the quantity of nicotine contained in that product.³⁷

Further, the Act requires the Secretary of HHS to report biennially to Congress a summary of health research on smokeless tobacco, as well as information regarding any ingredients used in the manufacture of smokeless tobacco which poses a health risk, and any recommendations for legislation and administrative action.³⁸ Finally, the Act requires the FTC to report biennially to the Congress the state of sales, advertising, and marketing practices associated with smokeless tobacco, with any recommendations for legislation and administrative action.

There are several other agencies within the federal government which have regulatory interests in tobacco and tobacco products. Among the agencies which have minor regulatory interests are the Bureau of Alcohol, Tobacco and Firearms,³⁹ the Secretary of Health and Human Services,⁴⁰ the Department of Agriculture,⁴¹ and the Internal Revenue Service.⁴²

Together, the regulations contained in the FCLAA, the CSTHEA, as well as the minor regulatory interests of other governmental agencies, provide an extensive regulatory scheme which Congress has implemented and now uses to regulate tobacco and tobacco products.

B. State Regulation

The federal government is not the only regulator of tobacco and tobacco products. There is currently regulation of these products in all fifty states. Major areas that have been regulated by state governments include restrictions on tobacco and tobacco products use by minors,⁴³ licensing requirements,⁴⁴ and restrictions on vending ma-

35. 15 U.S.C. § 4401 (1994).

36. 15 U.S.C. § 4402(a) (1994).

37. 15 U.S.C. § 4403 (1994).

38. 15 U.S.C. §§ 4403(b), 4407(a) (1994).

39. ATF has authority to collect excise taxes on tobacco products, to regulate manufacture of tobacco products, and to qualify and regulate manufacture of tobacco products. 27 C.F.R. § 270.1 (1994).

40. The Secretary has authority to transmit to Congress every three years a report describing current research findings made with respect to the addictive property of tobacco and to recommend legislation and administrative action deemed appropriate. 42 U.S.C. § 290aa-2 (1988).

41. The Department of Agriculture has the authority to set production quotas and price levels for tobacco leaf. Agricultural Adjustment Act of 1938, 7 U.S.C. § 1281 (1994).

42. The IRS has the authority to implement tax collection for the sale of cigarettes, Internal Revenue Code, 26 U.S.C. § 5701(b) (1994).

43. These regulations include a minimum age of purchase (19 in 3 states, 18 in 47 states), the prohibition of the purchase or use by minors of tobacco or tobacco products (in 32 states), and the prohibition of possession of tobacco or tobacco products by minors (in 17 states). The Tobacco Institute, *State Tobacco Sales Restriction Laws* (September, 1995) (unpublished material on file with Jour-

chine and loose cigarette sales.⁴⁵ Thus, several areas of regulation covered by the FDA's Proposed Rule have been addressed by state governments for years.

C. Summary of Present Government Regulation of Tobacco

As required by the FCLAA, and reflective of Congress' clearly expressed intent that it be the sole federal regulator of tobacco and tobacco products, a comprehensive federal program has been implemented by Congress to regulate tobacco and tobacco products. This program includes regulation by the FDCA, FCLAA, CSTHEA, as well as several other Government Agencies. Further, this federal program has been supplemented by further regulation in all fifty states. Taken together, these federal and state schemes adequately regulate the manufacture, packaging, marketing, distribution, and sales of tobacco and tobacco products. Further, these schemes can be expanded, allowing further regulatory measures to be enacted without creating new regulatory categories or the requiring the expansion of any enabling legislation, thereby drastically reducing the need for the FDA's Proposed Rule.

IV. THE FDA'S PROPOSED RULE

On August 9, 1995, FDA Commissioner David Kessler, released a Proposed Rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents."⁴⁶ The regulatory objectives of the Proposed Rule are as follows:

[To] reduce the many avenues of easy access to tobacco products available to children and teenagers, and to make it harder for young people to buy these products, . . . reduce the powerful and alluring imagery used in tobacco advertising and promotion that tends to encourage impressionable young people to initiate tobacco use, . . . enhance the positive image of a smoke-free generation, . . . and educate people about the specific and relevant health risks associated with tobacco use and to disseminate information about quitting.⁴⁷

Upon issuing this Proposed Rule, Commissioner Kessler also released an analysis of agency jurisdiction over tobacco and tobacco products. This section will analyze both the FDA's claim of jurisdiction and the Proposed Rule itself, highlighting its important regulatory elements.

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44. These regulations include the requirement of a retailer license (in 35 states), requirement that a license, law or sign be posted (in 35 states), provisions for unannounced inspections by state officials (in 19 states), and allowance for the suspension or revocation of a retailer license for violations of state regulatory codes (in 16 states). *Id.*

45. These regulations include mandating retailer supervision of vending machines (in 17 states), restrictions regarding the location of vending machines (in 17 states), as well as the prohibition of loose sales of cigarettes (in 19 states). *Id.*

46. 60 Fed. Reg. 41,314 (1995) (to be codified at 21 C.F.R. pts. 801, 803, 804, and 897) (proposed August 11, 1995).

47. U.S. Food and Drug Administration, DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Nicotine In Cigarettes and Smokeless Tobacco Products is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act*, 60 Fed. Reg. 41,454, 41,787 (1995).

A. The Jurisdictional Claim

Along with the release of the Proposed Rule, the FDA issued an analysis of its jurisdiction over tobacco and tobacco products: *Nicotine In Cigarettes and Smokeless Tobacco Products Is a Drug and These Products Are Nicotine Delivery Devices Under The Federal Food, Drug, and Cosmetic Act*.⁴⁸ Citing extensive investigation and analysis, the FDA concluded that cigarettes and smokeless tobacco products “affect the structure or any function of the body” because they have pharmacological effects and lead to addiction,⁴⁹ and that tobacco manufacturers “intend” that their products have addictive and significant pharmacological effects.⁵⁰ Based upon those findings, the FDA has concluded that nicotine-containing cigarettes and smokeless tobacco products are drug delivery systems that are appropriately regulated as devices.⁵¹

B. The Regulations that Make up The Rule

The FDA’s Proposed Rule includes three major regulatory components designed to reduce tobacco and tobacco use by minors. The first consists of regulations that would govern the advertising and promotion of tobacco and tobacco products, the labeling of tobacco packaging, and the retail sales of tobacco and tobacco products. The second outlines the duties and responsibilities of manufacturers, distributors, marketers, and retailers of tobacco and tobacco products. Finally, penalties and sanctions to be assessed against violators are detailed.

The proposed regulations regarding advertising and promotion of tobacco and tobacco products include restrictions on outdoor advertising,⁵² other forms of advertising,⁵³ restrictions on the use of logos and brand names,⁵⁴ a requirement that all cigarette advertisements include the phrase “cigarettes—a nicotine delivery device,”⁵⁵ prohibition of brand-name sponsorships,⁵⁶ the distribution of free product samples,⁵⁷ and all advertising in any media not specifically enumerated within the Proposed Rule.⁵⁸ The Proposed Rule also grants the FDA broad authority to pursue false or misleading cigarette advertising.⁵⁹

48. *Id.* at 41,545.

49. *Id.* at 41,467.

50. *Id.* at 41,471.

51. *Id.* at 41,455.

52. The proposal bans all outdoor advertising within 1,000 feet of any playground, elementary school or secondary school, including signs on retail stores. *Proposed Regulations, supra* note 47, at 41,374 (897.30(b)).

53. The proposal limits all other advertising to black text on a white background except for advertising in certain adult periodicals and requires all cigarette advertising to carry a second warning statement in addition to the Surgeon General’s warning already required. *Id.* at 41,374 (897.32(a)), (897.32(c)).

54. The Proposed Rule limits logos and brand names on race cars, driver uniforms, etc, to a black on white format, and bans both the use of tobacco brand names on any non-tobacco product and the use on tobacco products of brand names associated with non-tobacco products except those in use by Jan. 1, 1995. *Id.* at 41,374 (897.30(a)(2)), (897.34(a)), (897.32), (897.16(a)).

55. *Id.* at 41,374 (897.32(b)).

56. The Proposed Rule would allow only corporate sponsorships, so long as the tobacco company was extant on Jan.1, 1995. *Id.* at 41,374 (897.34(c)).

57. The proposal would ban such distribution either through the mail or in person. *Id.* at 41,374 (897.16(d)).

58. *Id.* at 41,374 (897.30(a)).

59. This includes omissions, lack of balance, and lack of substantial evidence. *Id.* at 41,375

Proposed regulations regarding the labeling of tobacco and tobacco products include a requirement that each package display the word "cigarettes" under the brand name in letters at least half as large as those used in the brand name,⁶⁰ and a ban on all cigarette labeling in any media not specifically enumerated in the proposed rule.⁶¹ In addition, several provisions in the Proposed Rule regulate the sale and distribution of tobacco and tobacco products. These proposed regulations include bans on vending machine sales,⁶² self-service displays,⁶³ sale and distribution by mail,⁶⁴ sales other than from unopened packages,⁶⁵ and sale of packages containing fewer than 20 cigarettes.⁶⁶

The Proposed Rule also provides that every person who furthers the marketing of cigarettes or smokeless tobacco products will be deemed a distributor—including presumably, advertising agencies, publishers, and outdoor companies.⁶⁷ Every distributor is responsible for ensuring that the cigarettes or smokeless tobacco products it manufactures, labels, advertises, packages, distributes or sells comply with the Proposed Rule.⁶⁸

The Proposed Rule would also require tobacco manufacturers to fund a \$150,000,000 per-year national public education campaign to discourage underage tobacco use,⁶⁹ remove from retail outlets all self service displays, advertising, labeling and other manufacturer-owned items that do not comply with the Proposed Rule,⁷⁰ and conduct visual inspections within the normal course of business in order to ensure that retailers are complying with the Proposed Rule.⁷¹ Further, it would require that every retailer ensure that all sales are direct, face to face transactions.⁷²

Together, these provisions would regulate the packaging, marketing, distribution, and sales of tobacco and tobacco products. They also call for an annual payment by tobacco manufacturing companies of \$150,000,000 to fund an educational program designed to discourage underage tobacco use. In addition, the Proposed Rule contains several provisions outlining penalties and sanctions to be imposed for violations of these regulations. Failure to comply with any of the restrictions or requirements in the FDA proposal would result in the misbranding of the cigarette brand(s) involved, a prohibited act under the FDCA.⁷³ Such prohibited acts may be enjoined by court act and punished as misdemeanors without a *mens rea* requirement.⁷⁴ Further, misbranded articles (cigarettes or labeling) may be seized and condemned by the federal govern-

(897.36).

60. *Id.* at 41,374 (897.24).

61. *Id.* at 41,374 (897.30(a)).

62. *Id.* at 41,374 (897.16(c)).

63. *Id.*

64. *Id.*

65. *Id.* at 41,373 (897.14(c)).

66. *Id.* at 41,374 (897.16(b)).

67. *Id.* at 41,373 (897.3(c)).

68. *Id.* at 41,373 (897.10).

69. *Id.* at 41,374 (897.29).

70. *Id.* at 41,373 (897.12(a)).

71. *Id.*

72. *Id.* at 41,373 (897.14).

73. 21 U.S.C. §§ 321(a)-(c), (k), 502(a),(q), 709.

74. Intentional acts and second offenses of the same offense are punishable as felonies. 21 U.S.C. § 304(a) (1994).

ment.⁷⁵

Civil penalties may be assessed by the FDA for violations of the device provisions of the FDCA in the amount of \$15,000 per violation and up to \$1,000,000 for all violations joined in a single proceeding. Also, based upon the criteria for restricted devices, an argument could be constructed that failure to comply with the FDA-imposed restrictions subjects the noncomplying product or labeling to the notification, replacement-refund, or recall provisions applicable to devices.⁷⁶

C. Summary of the FDA's Proposed Rule to Regulate Tobacco and Tobacco Products

The FDA has based its claim that it has jurisdiction over tobacco and tobacco products upon findings that nicotine is a drug within the definition of the FDCA and that the tobacco industry intends to distribute nicotine in order to affect the structure or function of the body. From these findings, the FDA concluded that tobacco and tobacco products are drug delivery devices within the definition of the FDCA.

The proposed regulations that make up the Proposed Rule cover the marketing, packaging, advertising, sales, and distribution of tobacco and tobacco products. However, the Proposed Rule is problematic in that several of its regulations are already in place as preexisting federal or state regulations. Further, several of the provisions are of dubious constitutionality. Although several of these regulations are already in place within the regulatory schemes provided by Congress and the state governments, these proposed regulations would be contained within the Code of Federal Regulations. Moreover, the Proposed Rule does not call for the repeal of any provisions of the FDCA, FCLAA, or CSTHEA, and, thus, would create a second federal regulatory scheme for the regulation of tobacco and tobacco products.

Several other provisions of the Proposed Rule are problematic in that they invoke constitutional questioning. Packaging and marketing regulations called for by the proposal both compel and restrict language used in marketing and advertising of tobacco and tobacco products. These include the requirement of a second warning on all tobacco packaging and advertising, a prohibition of the use of tobacco product logos and brand names on non-tobacco products, a prohibition of brand name sponsorships, and a ban on advertising in several media forms.

Other such regulations include a ban on several varieties of tobacco sales methods which are not face-to-face, the declaration that any person involved in tobacco marketing is deemed a distributor of tobacco and tobacco products, and requirement of an annual \$150,000,000 payment to fund an anti-tobacco educational program. Because of the overlapping nature of several of the proposed regulations, as well as the questionable constitutionality of several others, the Proposed Rule was challenged immediately in both the Halls of Congress and the tobacco states of the South.

75. 21 U.S.C. § 304(a) (1994).

76. 21 U.S.C. § 518 (1994).

V. CHALLENGES TO FDA REGULATION

Following the announcement of the Proposed Rule by Commissioner Kessler, several challenges to the FDA plan were quickly initiated. These challenges came in two forms. First, Congressional legislation was introduced in order to pre-empt, or outright prohibit, the FDA regulations. In addition, lawsuits were filed by the five largest tobacco manufacturers in the United States, several groups of tobacco farmers, advertisers, and convenience store owners against the FDA and Commissioner Kessler, seeking an injunction against the enactment of the proposed rule.

A. House Bills

The first legislative response to the Proposed Rule was from Rep. David B. Funderburk of North Carolina on September 6, 1995. Funderburk's bill, entitled the Motor Sports Protection Act,⁷⁷ prohibits any regulation of tobacco or tobacco product advertising or use at any NASCAR event, or other sporting event, by the Secretary of HHS or any other Federal official under the FDCA, FCLAA, or CSTHEA. The bill has been co-sponsored by fifty representatives (14 democrats, 36 Republicans)⁷⁸ and has been referred to the House Commerce Committee.

One day later, on September 7, 1995, a second bill, the Tobacco Farmer Protection Act,⁷⁹ was introduced onto the House floor by Rep. L.F. Payne (D-VA). This bill, co-sponsored by twenty-two representatives (11 democrats, 11 Republicans),⁸⁰ prohibits the Secretary of Health and Human services from regulating the sale or use of tobacco products under the FDCA, FCLAA, or CSTHEA.⁸¹ Payne's bill repeals any regulations issued by the Secretary of HHS enacted prior to passage of the bill and declares that the Secretary of HHS has no authority to regulate the sale or use of tobacco or tobacco products.

On September 28, 1995, Rep. Scotty Baesler (D-KY) introduced the Youth Smoking Prevention Act of 1995⁸² which has since gained three co-sponsors.⁸³ This bill is pre-emptive in nature, implementing federal regulation over tobacco, while denying the FDA any jurisdiction over tobacco and tobacco products. The Youth Smoking Prevention Act has regulations regarding the sale and distribution of tobacco and tobacco products to minors⁸⁴ and the sale and distribution of tobacco and tobacco

77. H.R. 2265, 104th Cong., 1st Sess. (1995).

78. Bass (R-NH), Beasler (D-KY), Ballenger (R-NC), Barr (R-GA), Boehner (R-OH), Browder (D-AL), Bryant (R-TN), Bunning (R-KY), Burr (R-NC), Burton (R-IN), Callahan (R-AL), Chambliss (R-GA), Chrysler (R-MD), Clayton (D-NC), Coble (R-NY), Collins (R-GA), Cramer (D-AL), DeLay (R-TX), Goodlatte (R-VA), Gordon (D-TN), Graham (R-SC), Hefner (D-NC), Hancock (R-MO), Heineman (R-NC), Hilleary (R-TN), Hostettler (R-NC), Jones (R-NC), Kingston (R-GA), Lewis (R-KY), McIntosh (R-IN), Mica (R-FL), Myrick (R-NC), Norwood (R-GA), Parker (D-MS), Payne, Jr. (D-VA), Peterson (D-FL), Quillen (R-TN), Roberts (R-KY), Rogers (R-KY), Rose (D-NC), Scarborough (R-FL), Scott (D-VA), Sisisky (D-VA), Stump (R-AZ), Souder (R-IN), Tanner (D-TN), Taylor (R-NC), Ward (D-KY), Watts (R-OK), and Zeliff (R-NH). *Id.*

79. Although the bill has been referred to as the Tobacco Farmer Protection Act, this has not been officially adopted as the short title. *Id.*

80. Ballenger (R-NC), Beasler (D-KY), Boucher (D-VA), Bunning (R-KY), Chambliss (R-GA), Clyburn (D-SC), Clement (D-TN), Coble (R-NC), Funderburk (R-NC), Gordon (D-TN), Hefner (D-NC), Jones (R-NC), Peterson (D-FL), Rogers (R-KY), Rose (D-NC), Scott (D-VA), Spratt (D-SC), Taylor (R-NC), and Ward (D-KY). *Id.*

81. H.R. 2238(1)(a), 104th Cong., 1st Sess. (1995).

82. H.R. 2414, 104th Cong., 1st Sess. (1995).

83. Hamilton (D-IN), Ward (D-KY), and Rose (D-NC). *Id.*

84. The bill prohibits the sale of tobacco or tobacco products to minors, prohibits minors from

products generally.⁸⁵ It also has several licensing requirements⁸⁶ and regulations regarding the advertising of tobacco and tobacco products.⁸⁷ Finally, it requires the Secretary of HHS to make an annual report to Congress on the actions taken by states pursuant to the bill.

Although the legislation introduced by Reps. Funderburk and Payne intends merely to prohibit enforcement of the Proposed Rule released by Commissioner Kessler, while Rep. Baesler's bill intends to enact a regulatory scheme similar to the FDA's proposal, all three express the same purpose: the prohibition of FDA regulation of tobacco and tobacco products. In fact, Both Rep. Payne and Rep. Baesler have included provisions in their bills which expressly deny the FDA any jurisdictional authority over tobacco and tobacco products.

B. Senate Bills

The first response to Commissioner Kessler's announcement from the Senate came on September 16, 1995, when Senator Wendell Ford (D-KY) introduced the Tobacco Products Control Act of 1995.⁸⁸ Much like Rep. Baesler's House bill, the Tobacco Products Control Act seeks to regulate tobacco through Congress, while denying any jurisdictional authority to the FDA. Senator Ford's bill, which has no co-sponsors and has been referred to the Senate Commerce Committee, seeks to establish limits on advertising and to provide for increased enforcement of existing state regulations on advertising for tobacco and tobacco products.⁸⁹ It also includes provisions which would prohibit vending machine sales⁹⁰ and distribution of tobacco or tobacco products without charge.⁹¹

On September 29, 1995, Senator Jesse Helms (R-NC) introduced The Motorsports Protection Act,⁹² attacking the Proposed Rule. This bill, which has three

buying tobacco or tobacco products or presenting false identification for the purpose of buying tobacco or tobacco products, prohibits the distribution of free samples of tobacco or tobacco products to minors, and prohibits the distribution of tobacco or tobacco products through the mail to minors. *Id.* at § 3.

85. The bill prohibits sales of cigarettes in packs of less than twenty, vending machine sales unless the vending machine is in plain view and under direct supervision and control of the retailer, and requires that all sales of tobacco and tobacco products be face to face sales. *Id.*

86. The bill requires retailers of tobacco or tobacco products to be licensed with their state and requires states to conduct random unannounced inspections. *Id.*

87. The bill prohibits any billboard advertising within the line of sight of a school or playground, and prohibits brand names or logos from being placed on any non-tobacco product marketed specifically to minors, including toys and video games. *Id.*

88. S. 1262, 104th Cong., 1st Sess. (1995).

89. Ford's bill amends the FCLAA to prohibit billboard advertising within 500 feet of schools unless the billboard is adjacent to an interstate and faces away from the school, or is attached to buildings which sell tobacco or tobacco products, prohibits advertising in magazines which have 15% or more minor readership, prohibits payments made to motion pictures for the placement of tobacco or tobacco products as a prop in any motion picture produced for viewing by the general public, and prohibits the use of brand names or logos in any video game or family amusement center. *Id.* at § 2.

90. Unless the vending machine is located at a private club, bar or bar area of a food service establishment, place of employment where the workforce is not significantly made up of minors, or allowable by state law. *Id.* at § 4.

91. Unless the tobacco or tobacco product is distributed through coupons allowed by section 7 of the FCLAA, where individuals can demonstrate they are at least 18, in locations that can be separately segregated to deny access to minors, or where state law permits. *Id.*

92. S. 1295, 104th Cong., 1st Sess. (1995).

co-sponsors,⁹³ denies the FDA any authority to regulate, in any manner, tobacco or tobacco products.⁹⁴ It also prohibits the regulation of any use or promotion of tobacco or tobacco product by any NASCAR participant or agent. This prohibition applies to any enforcement by the FDA under the FDCA, FCLAA, CSTHEA, as well as any Executive order issued by the President.⁹⁵

Both pieces of legislation introduced by Senators Ford and Helms have provisions which expressly deny any jurisdiction over tobacco and tobacco products to the FDA and have been referred to the Senate Commerce Committee. However, these are two fundamentally different bills. While Senator Helms' bill intends merely to prohibit enforcement of any FDA regulation of tobacco and tobacco products, Senator Ford's bill is an attempt to preemptively enact a regulatory scheme similar to the FDA plan.

C. The Courts

On September 7, 1995, five major tobacco companies filed suit against the FDA and Commissioner Kessler in the United States District Court for the Middle District of North Carolina seeking to enjoin the FDA from implementing its Proposed Rule.⁹⁶ This suit, *Coyne Beahm, Inc., et al. v. FDA, et al.*,⁹⁷ attacks the FDA's Proposed Rule on two fronts. First, it claims that the FDA is denied any jurisdiction over tobacco and tobacco products by its enabling legislation, the FDCA, the Administrative Procedure Act, the FCLAA, and the CSTHEA. Second, it challenges the Constitutionality of several of the regulations which comprise the Proposed Rule.

In their complaint, the tobacco companies claim that any attempt by the FDA to expand its jurisdiction to include tobacco and tobacco products violates the FDA's enabling legislation. Specifically, the complaint alleges that the FDA's proposal to regulate nicotine as a drug, and tobacco and tobacco products as drug delivery devices, violates Congress' clearly expressed intent that it be the sole federal regulator of tobacco and tobacco products.⁹⁸ It further alleges that the FDA is precluded from such regulatory jurisdiction by the FDCA, FCLAA, and the CSTHEA.⁹⁹ The tobacco companies also contend that the FDA's assertion of jurisdiction relies upon materials not in the public record and thereby deprives them of their fundamental right to private and meaningful comment, which violates both the Administrative Procedure Act and the Fifth Amendment.¹⁰⁰

The cigarette companies have also attacked the constitutionality of several of the regulations not contained within the existing federal or state regulatory schemes.¹⁰¹ The companies contend that several of these proposed regulations violate Articles I and II of the Constitution. The suit claims that the requirement that the tobacco companies fund a mandated \$150,000,000 per year anti-smoking educational campaign is an exer-

93. Faircloth (R-NC), Warner (R-VA), and Thompson (R-TN). *Id.*

94. S. 1295, 104th Cong., 1st Sess., § 3 (1995).

95. *Id.* at § 1.

96. Similar suits have since been filed by tobacco farmers, advertisers, and convenience store operators.

97. Plaintiffs' First Amended Complaint at 94, *Coyne Beahm, Inc., et al. v. FDA, et al.*, No. 2:95CV00591 (M.D.N.C. filed Sept. 7, 1995).

98. *Id.* at 94.

99. *Id.* at 69-77. For an analysis of the legislative history and Congress' intent regarding the regulation of tobacco and tobacco product, see discussion *supra* section II.

100. *Id.* at 82.

101. For a discussion of these controversial provisions see *supra*, section 3, part C.

cise of executive power not authorized by Article II of the Constitution or by valid act of Congress.¹⁰² In addition, the suit asserts that this requirement violates the separation of powers prescribed in the Constitution:¹⁰³ it constitutes a tax not enacted by Congress in violation of Article I, §§ 7, 8.¹⁰⁴

The tobacco companies also claim that the Proposed Rule would violate the provision of Article I, § 9, which mandates only Congress to appropriate money.¹⁰⁵ Further, the complaint contends that the regulations violate Article II's provision against conscripting private persons for law enforcement, and Article I, § 8, cl. 3 by exceeding the Federal government's power under the Commerce Clause by establishing a national minimum sales age.¹⁰⁶ Finally the complaint alleges that the FDA's plan violates the First,¹⁰⁷ Fourth,¹⁰⁸ Fifth,¹⁰⁹ Eighth,¹¹⁰ Ninth,¹¹¹ and Tenth Amendments to the Constitution.¹¹²

On October 4, 1995, the tobacco companies filed a Motion for Summary Judgment,¹¹³ asking the District Court to enjoin any regulatory action by the FDA. At the same time, the FDA filed a Motion to Dismiss,¹¹⁴ seeking to have the tobacco companies' suit dismissed on the grounds that there is no case or controversy until final regulatory action is taken. At this time, it is probable that the District Court will deny both of these motions and schedule the suit to be heard on its merits sometime in early 1996.

D. Summary

At this time, it appears that none of the legislative challenges to Commissioner Kessler and the FDA will be successful. All of the bills that have been introduced in the House have been referred to the Commerce Committee, where Committee Chairman Thomas Bliley (R-VA) likely will not allow any tobacco legislation to get through

102. *Id.* at 109(a).

103. *Id.*

104. *Id.* at 109(b).

105. *Id.* at 109(c).

106. *Id.* at 110, 111.

107. These violations include both compelling and restricting the tobacco companies' speech in connection with cigarettes, restricting the tobacco's use of certain trademarks and copyrights without statutory authority, and requiring burdensome reporting procedures to the FDA. *Id.* at 113-14, 119.

108. The Fourth Amendment is violated by the proposal's requiring burdensome reporting procedures to the FDA. *Id.* at 119.

109. These violations include requiring the tobacco companies to fund an educational fund, prohibiting the tobacco companies from using certain trademarks or copyrights without statutory authority, and holding cigarette manufacturers liable for the acts of others over whom they have no legal or practical authority or control through vicarious liability. *Id.* at 114, 115(a), 116.

110. The Eighth Amendment is violated by the Proposed Rule's plan to hold cigarette manufacturers liable for the acts of others over whom they have no legal or practical authority or control through vicarious liability. *Id.* at 116.

111. The Ninth Amendment would be violated by the FDA's assumption of rights and powers reserved to Congress. *Id.* at 118.

112. These violations include a requirement that tobacco companies fund an educational program, which cannot be granted by Congress in that it is not within the powers granted to Congress by the Constitution, and violates rights and powers reserved to Congress. *Id.* at 115(b), 118.

113. Plaintiffs' Motion for Summary Judgment, *Coyne Beahm, et al. v. FDA, et al.* Case No. 2:95CV00591 (M.D.N.C. filed Oct. 4, 1995).

114. Defendants' Motion to Dismiss, *Coyne Beahm, et al. v. FDA, et al.*, Case No. 2:95CV00591 (M.D.N.C. filed Oct. 6, 1995).

the committee to the House floor due to the controversial nature of tobacco regulation. This will effectively kill any chance of House legislative opposition to the Proposed Rule.

On the Senate side, it seems unlikely that either the Helms or the Ford bill will make it out of the Senate Commerce Committee. There has been no action taken on Senator Ford's bill, which has been met with stern disapproval from several Southern Republican Senators, including Helms. These Southern Senators will not support any further regulation of tobacco and tobacco products, neither from the FDA nor from Congress. To date, the only action that has been taken on the Helms bill has been its placement on the Senate Calendar for discussion.

Therefore, it appears that the fate of the FDA's Proposed Rule will be decided in the Courtroom. As mentioned above, the court is likely to dismiss both the FDA's motion to dismiss and the tobacco companies' motion for summary judgment, placing the trial on the merits sometime early in 1996. It is also likely that the other court cases will proceed on roughly the same schedule.

In considering these cases, the courts will apply the test set out by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*.¹¹⁵ In *Chevron*, the Supreme Court held that lower courts must weigh the typical deference given to regulatory agencies in attempting to expand or define their own jurisdiction against the typical deference given to clear congressional intent in restricting the jurisdiction of regulatory agencies. The issue in the present case will likely center on the clarity of Congress' intent.

It is clear that many attempts to legislatively grant such jurisdiction to the FDA have been rejected. Although such an argument from silence is likely to be problematic in court, as the failure of these bills may have resulted from any number of factors completely independent from the issue of tobacco regulation, it seems probable that a court would find clear Congressional intent from this history. The comments made by Representatives, Senators, and other governmental officials at Congressional hearings will also be considered. Although these factors are not dispositive of Congressional intent, they are likely to be considered strong indicators of such. Taken together, the combination of legislative history and testimony before Congressional hearing suggest that the district court will rule that Congress, and Congress alone, be the sole Federal regulator of tobacco and tobacco products.

VI. ANALYSIS AND CONCLUSION

This Note has examined the legislative history of the FDA's enabling legislation, the FDCA, as well as other legislation which Congress has enacted in order to regulate tobacco and tobacco products, the FCLAA and CSTHEA. This note then concludes that Congress has shown clear intent that it, and it alone, be the sole regulator of tobacco and tobacco products. It has also analyzed the FDA's Proposed Rule, concluding that it is problematic in two ways. First, it would create a second, overlapping, federal scheme for the regulation of tobacco and tobacco products. Secondly, several of the proposal's regulations are of dubious constitutionality.

This Note has also examined the legislative and legal challenges to the FDA

115. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., et al.*, 467 U.S. 837 (1984).

proposal, concluding that any legislative attempt to preempt or prohibit the Proposed Rule is unlikely to make it through Congress and that the fate of the Proposed Rule will likely rest in the hands of the Courts.

Based upon the Supreme Court's decision in *Chevron*, the key issue in any regulatory jurisdiction case is going to be the clarity of Congressional intent in restricting such regulatory jurisdiction. Although there is no definitive statement of such intent regarding FDA regulation of tobacco and tobacco products, it seems clear that Congress has repeatedly shown such intent throughout the last seventy years.

In addressing this issue, courts are likely to examine the history of Congressional regulation of tobacco and tobacco products as well as statements made at Congressional Committee hearings, noting that Congress has consistently denied any regulatory authority over tobacco and tobacco products to the FDA. Based upon these factors, the courts are likely to rule that Congress has shown clear intent that it alone be the sole Federal regulator of tobacco and tobacco products, and deny such regulatory jurisdiction to the FDA.

Barring a settlement between the FDA and tobacco manufacturers, final resolution of this issue is unlikely to come from the courts any time soon. There is little doubt that these cases will be appealed and that complete adjudication will take several years. A more direct resolution to the issue would be a definitive Congressional statement concerning the regulatory jurisdiction of the FDA over tobacco and tobacco products. If such a statement were to come from Congress, it would likely come in the form of an FDA reform bill out of the House Commerce Committee, denying such jurisdiction to the FDA. However, given Congress' reluctance to directly address the issue of tobacco regulation, such a bill would have a small chance of making its way through the legislative maze of Congress, leaving the courts as the likely arbiter of this very sensitive and complex issue.

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