



9-1-1995

Is It Curtains for Joe Camel - A Critical Analysis of the 1995 FDA Proposed Rule to Restrict Tobacco Advertising, Promotion and Sales to Protect Children and Adolescents

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Recommended Citation

Charles J. Harder, *Is It Curtains for Joe Camel - A Critical Analysis of the 1995 FDA Proposed Rule to Restrict Tobacco Advertising, Promotion and Sales to Protect Children and Adolescents*, 16 Loy. L.A. Ent. L. Rev. 399 (1995).

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COMMENTS

IS IT CURTAINS FOR JOE CAMEL? A CRITICAL ANALYSIS OF THE 1995 FDA PROPOSED RULE TO RESTRICT TOBACCO ADVERTISING, PROMOTION AND SALES TO PROTECT CHILDREN AND ADOLESCENTS

I. INTRODUCTION

According to medical studies conducted by the United States Department of Health and Human Services, cigarettes and other tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illnesses, heart disease and other health problems related to smoking or the use of smokeless tobacco products.¹ Cigarettes kill more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.²

Of the forty-six million Americans who currently smoke cigarettes³ and the five million who use smokeless tobacco products (including chewing tobacco and snuff),⁴ over three million smokers and one million smokeless tobacco users are under eighteen years of age.⁵ This is the case even though all states prohibit the sale of tobacco products to persons under

1. DEP'T OF HEALTH AND HUMAN SERVICES, *Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990*, 42 MORBIDITY AND MORTALITY WKLY. RPT. 645 (1993) [hereinafter DHHS, *Cigarette Smoking—Attributable Mortality*].

2. INSTITUTE OF MEDICINE, *GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS 3* (Barbara S. Lynch & Richard J. Bonnie eds., 1994). Collectively, AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires cause nearly 251,000 deaths per year. *Id.*

3. DEP'T OF HEALTH AND HUMAN SERVICES, *Cigarette Smoking Among Adults—United States, 1993*, 43 MORBIDITY AND MORTALITY WKLY. RPT. 925 (1994) [hereinafter DHHS, *Cigarette Smoking Among Adults*].

4. DEP'T OF HEALTH AND HUMAN SERVICES, *Use of Smokeless Tobacco Among Adults—United States, 1991*, 42 MORBIDITY AND MORTALITY WKLY. RPT. 263 (1993) [hereinafter DHHS, *Use of Smokeless Tobacco*].

5. DEP'T OF HEALTH AND HUMAN SERVICES, *PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 58* (1994) [hereinafter SGR 1994].

the age of eighteen, and a few states prohibit cigarette sales to persons under nineteen or twenty-one.⁶

In the last ten years, while most adults decreased their use of cigarettes, smoking by American teenagers and younger children failed to decline.⁷ This fact is even more significant when one considers that anyone who does not begin smoking by childhood or adolescence is unlikely to ever begin.⁸ Eighty-eight percent of smoking adults have their first cigarette before age eighteen, and seventy-one percent have already become daily smokers by that age.⁹ Moreover, the earlier a person begins to smoke, the more likely that person is to become a heavy smoker in later years.¹⁰

In an effort to reduce by half the number of underage smokers, the United States Food and Drug Administration ("FDA") proposed a rule on August 10, 1995, to implement the following measures:

(1) prohibit, by federal law, all sales of tobacco products to persons under eighteen years of age and require all vendors of tobacco products to verify, by photographic identification, the age of all young buyers;

(2) ban all cigarette vending machines, self-service displays, mail order sales, free samples, and the sale of cigarettes in quantities of fewer than twenty;

(3) ban all outdoor advertisements within 1000 feet of a school, restrict all other outdoor and in-store advertisements to black and white text only, and restrict all advertisements in magazines and other publications, in which fifteen percent or more of the readership is persons under the age of eighteen, to black and white text only;

(4) prohibit a sponsored event (such as a sporting event) from being identified with a cigarette or smokeless tobacco product brand name (such as Marlboro or Camel) or any other brand-identifying characteristic (such as the "Marlboro Man" or "Joe Camel")—only the tobacco company name (such as Philip Morris or R.J. Reynolds) could be used as the official sponsor;

6. REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS TO PROTECT CHILDREN AND ADOLESCENTS, 60 Fed. Reg. 41,314, 41,315 (1995) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807) (proposed Aug. 11, 1995) (citing COALITION ON SMOKING AND HEALTH, STATE LEGISLATED ACTIONS ON TOBACCO ISSUES, App. G (1993)).

7. INSTITUTE OF MEDICINE, *supra* note 2, at 8.

8. SGR 1994, *supra* note 5, at 5.

9. *Id.* at 67.

10. Emanuela Taioli & Ernst L. Wynder, *Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood*, 325 NEW ENG. J. MED. 968, 969 (1991).

(5) prohibit the manufacturing or sale of any non-tobacco product (such as a T-shirt, cap, or sporting good) displaying the brand name of a cigarette or smokeless tobacco product—though the tobacco company name could be displayed on such merchandise; and

(6) require all tobacco manufacturers to contribute to a \$150 million national educational campaign fund to purchase anti-smoking advertisements directed at people under eighteen.¹¹

The FDA has asserted jurisdiction over the issue by declaring that nicotine is a “drug” and tobacco products are drug delivery “devices” under their respective definitions in the Federal Food, Drug and Cosmetic Act (“FDCA”)¹² and, as such, cigarettes and smokeless tobacco products that contain nicotine are subject to regulation by the FDA.¹³ There are presently four pending lawsuits challenging the legality of the FDA action: *Coyne Beahm, Inc. v. FDA*,¹⁴ *American Advertising Federation v. Kessler*,¹⁵ *United States Tobacco Co. v. FDA*,¹⁶ and *National Association of Convenience Stores v. FDA*.¹⁷ These actions were filed in the United States District Court, Middle District of North Carolina and have been assigned to United States District Judge William L. Osteen, Sr.

This Comment will analyze the major legal issues concerning the FDA’s proposed rule. Additionally, it will argue that the proposal is both constitutionally and jurisdictionally sound, with the exception of the proposed national educational campaign fund. Part II will provide an overview of federal efforts to restrict the promotion of tobacco. Part III

11. 60 Fed. Reg. 41,326-28 (1995).

12. 21 U.S.C. § 321(g)(1)-(h)(3) (1994).

13. 60 Fed. Reg. 41,465-66 (1995).

14. The full title of this action is: *Coyne Beahm, Inc., Brown & Williamson Tobacco Corp., Liggett Group Inc., Lorillard Tobacco Co., Philip Morris Inc., and R.J. Reynolds Tobacco Co. v. United States FDA and David A. Kessler, M.D., Comm’r of FDA*. (Civil Action File Number 2:95CV00591) (amended complaint filed Sept. 7, 1995).

15. The full title of this action is: *American Advertising Fed’n; American Ass’n of Advertising Agencies, Inc.; Association of Nat’l Advertisers, Inc.; Magazine Publishers of Am.; Outdoor Advertising Ass’n of Am.; Point of Purchase Advertising Inst. v. David A. Kessler, M.D., Comm’r, FDA; United States FDA; and Donna Shalala, Secretary, U.S. Dep’t. of Health and Human Services* (Civil Action File Number 2:95CV00593) (amended complaint filed Sept. 27, 1995).

16. The full title of this action is *United States Tobacco Co.; Brown & Williamson Tobacco Corp.; Conwood Co., L.P.; National Tobacco Co., L.P.; The Pinkerton Tobacco Co.; Swisher Int’l, Inc.; Central Carolina Grocers, Inc.; Davenport, J.T., Inc.; N.C. Tobacco Distrib. Comm., Inc. v. United States FDA; David A. Kessler, M.D., Comm’r of FDA* (Civil Action File Number 2:95CV00665) (complaint filed Sept. 19, 1995).

17. The full title of this action is *National Ass’n of Convenience Stores, ACME Retail, Inc. v. David A. Kessler, M.D., Comm’r, FDA, United States FDA* (Civil Action File Number 2:95CV00706) (complaint filed Oct. 4, 1995).

will discuss the problem of tobacco use by young people. Part IV will outline the specific provisions in the FDA's proposed rule. Parts V and VI will discuss the constitutional and jurisdictional issues, respectively. Part VII will analyze the legality of the educational campaign fund. Finally, Part VIII will give background on Judge Osteen's relevant history on tobacco-related issues and litigation.

II. THE HISTORY OF FEDERAL RESTRICTIONS ON TOBACCO PROMOTION

A. *Current Federal Law*

Ever since tobacco was found to have adverse affects on human health, Congress has enacted legislation to restrict the promotion of tobacco products.¹⁸ In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act ("the Cigarette Act") which required cigarette packages and advertisements to feature the warning label: "CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH."¹⁹ The Cigarette Act has subsequently been amended to feature a variety of other, sterner warning messages.²⁰ The Cigarette Act also requires the Secretary of Health and Human Services ("Secretary") to establish a program to research the effects of smoking on human health, develop materials for informing the public of such effects, and biennially report to Congress regarding federal activities undertaken pursuant to the Cigarette Act.²¹

In 1970, Congress amended the Cigarette Act by adopting the Public Health Cigarette Smoking Act,²² making it "unlawful to advertise

18. The statutes discussed herein are not an entire catalogue of all federal law relating to tobacco regulation but merely those federal laws that relate directly to the subject matter of the 1995 FDA proposed rule.

19. 15 U.S.C. §§ 1331-41 (1994).

20. 15 U.S.C. section 1333 requires one of the following messages to be printed on all cigarette packages and advertisements:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Id. § 1333.

21. *Id.* § 1341.

22. *Id.* § 1335.

cigarettes . . . on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission."²³ This amendment effectively banned all television and radio advertisements for cigarettes as of January 1, 1971.

In 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act²⁴ ("the Smokeless Act") which established a federal program to regulate the promotion and sale of smokeless tobacco. The Smokeless Act requires warning labels to be placed on all packages and advertisements of smokeless tobacco products,²⁵ and bans advertisements for smokeless tobacco products from all electronic media, including television and radio, within the jurisdiction of the Federal Communications Commission ("FCC").²⁶ The Smokeless Act also directs the Secretary to develop and carry out educational programs regarding the dangers to human health from the use of smokeless tobacco²⁷ and to make such programs available to states, local governments, school systems, and the media.²⁸ The Smokeless Act further directs the Secretary to conduct and support research on the effect of smokeless tobacco on human health and collect, analyze, and disseminate that information.²⁹

B. *Recent Unsuccessful Federal Legislation*

In recent years, legislation has been introduced in Congress to create additional restrictions on cigarette and smokeless tobacco promotion. In 1987, Congress considered bills H.R. 1272³⁰ and H.R. 1532³¹ which

23. In *Capital Broadcasting Co. v. Mitchell*, six radio stations brought suit against the U.S. Attorney General seeking a permanent injunction against the 1970 Act, alleging that it violated their rights under the First Amendment. 333 F. Supp. 582 (D.D.C. 1971), *aff'd mem.*, 405 U.S. 1000 (1972). The U.S. District Court for the District of Columbia upheld the statute on the grounds that "product advertising is less vigorously protected than other forms of speech" and that Congress, pursuant to its powers to regulate interstate commerce, "has the power to prohibit the advertising of cigarettes in any media." *Id.* at 584.

24. 15 U.S.C. §§ 4401-08 (1994).

25. One of the following three labels must be placed on all smokeless tobacco packages and advertisements (other than outdoor billboard advertising):

WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

WARNING: THIS PRODUCT MAY CAUSE DISEASE AND TOOTH LOSS

WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

Id. § 4402(a)(1)-(2).

26. *Id.* § 4402(f).

27. *Id.* § 4401(a)(1)(A).

28. *Id.* § 4401(a)(1)(B).

29. 15 U.S.C. § 4401(a)(1)(C)-(D) (1994).

30. H.R. 1272, 100th Cong., 1st Sess. (1987).

31. H.R. 1532, 100th Cong., 1st Sess. (1987).

would have banned all tobacco advertising, sports sponsorships by tobacco companies, and the distribution of tobacco samples. Two years later, H.R. 1250³² and H.R. 1493³³ were introduced to impose a “tombstone” format (black and white text only) on most tobacco advertisements, ban tobacco brand name sponsorship, and ban the marketing of non-tobacco products featuring brand names. In 1990, Congress considered H.R. 5041,³⁴ that would have imposed a “tombstone” format on most tobacco advertisements, prohibited tobacco advertisements within 1000 feet of schools, banned sports sponsorships under tobacco brand names, and prohibited free distribution of tobacco samples. More recently, in 1993, H.R. 2147³⁵ was introduced to give the FDA jurisdiction over tobacco products and require FDA regulation of tobacco advertising, including a sports sponsorship ban. That same year, Congress considered H.R. 3614,³⁶ which would have imposed restrictions on tobacco brand name sports sponsorships and prohibited the free distribution of tobacco samples. However, none of the above bills received the necessary committee votes to be heard by the full House of Representatives and thus never became law.

III. THE PROBLEM: TOBACCO CONSUMPTION BY YOUNG PEOPLE

A. *The Effects of Tobacco Advertisements on Tobacco Consumption by Young People*

According to FDA statistics, “each year the cigarette industry loses about 1.7 million customers in the United States; about 400,000 die from diseases caused by their smoking and another 1.3 million quit smoking.”³⁷ One of the industry’s primary sources for replacement smokers is young people. One major study reported that *each day* 3000 young people become regular smokers.³⁸

32. H.R. 1250, 101st Cong., 1st Sess. (1989).

33. H.R. 1493, 101st Cong., 1st Sess. (1989).

34. H.R. 5041, 101st Cong., 2d Sess. (1990).

35. H.R. 2147, 103d Cong., 1st Sess. (1993).

36. H.R. 3614, 103d Cong., 1st Sess. (1993).

37. 60 Fed. Reg. 41,317 (1995) (citing INSTITUTE OF MEDICINE, *supra* note 2, at 115; DHHS, *Cigarette Smoking—Attributable Mortality*, *supra* note 1, at 645; John P. Pierce et al., *Trends in Cigarette Smoking in the United States, Projections to the Year 2000*, 261 JAMA 61, 65 (1989)).

38. Pierce, *supra* note 37, at 64.

According to the FDA, the primary reason why so many young people begin to smoke is the inundation of pro-tobacco messages from advertisements and other promotional activities. Tobacco products are among the most heavily advertised products in the United States. In 1993, the tobacco industry spent \$6.2 billion on cigarette and smokeless tobacco advertising, promotion and marketing.³⁹ According to the FDA:

Tobacco product brand names, logos, and advertising messages are pervasive, appearing on billboards, on buses and trains, in magazines and newspapers, and on clothing and other goods. These ubiquitous images and messages convey to young people that tobacco use is desirable, socially acceptable, safe, healthy, and prevalent in society. One study found that 30 percent of 3 years olds [sic] and 91 percent of six year olds associate the "Joe Camel" cartoon figure with cigarettes. Studies also show that most young people buy the most heavily advertised cigarette brands, whereas many adults buy generic or "value category" cigarette brands, which have little or no image advertising.⁴⁰

According to the United States Surgeon General, seventy-one percent of all regular adult smokers began smoking daily by age eighteen; the average age of becoming a daily smoker is less than eighteen years.⁴¹ Also, those who started smoking by early adolescence are more likely to be heavy smokers than those who began smoking as adults.⁴² The FDA finds these statistics unacceptable because: (1) all states currently prohibit sales of tobacco products to persons under the age of eighteen;⁴³ (2) nicotine contained in cigarettes and smokeless tobacco products is a highly addictive drug which causes the user to continually use the product over

39. 60 Fed. Reg. 41,315 (1995) (citing FEDERAL TRADE COMMISSION, REPORT TO CONGRESS FOR 1993, PURSUANT TO THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT, at table 3D (1995); FEDERAL TRADE COMMISSION, REPORT TO CONGRESS, PURSUANT TO THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986, at table 4D (1995)).

40. 60 Fed. Reg. 41,315 (1995). See also John P. Pierce et al., *Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California*, 266 JAMA 3154 (1991); Paul M. Fischer et al., *Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991); DEP'T OF HEALTH AND HUMAN SERVICES, *Changes in Cigarette Brand Preferences of Adolescent Smokers—United States, 1989-1993*, 42 MORBIDITY AND MORTALITY WKLY. REP. 577, 579 (1994).

41. SGR 1994, *supra* note 5, at 67 (the average age is 17.7 years).

42. Taioli & Wynder, *supra* note 10, at 968-69.

43. 60 Fed. Reg. 41,315 (1995).

time;⁴⁴ and (3) long-term use of tobacco products causes major health problems and often leads to premature death.⁴⁵

*B. Health Problems Related to Long-Term
Tobacco Consumption*

The FDA cites several studies which link long-term smoking to major health problems including cancer, respiratory illnesses, and heart disease, among many others. Cigarette smoking contributes to the risk of heart attacks, chest pain, and even sudden death.⁴⁶ Overall, smokers have a seventy percent greater death rate from coronary heart disease than nonsmokers.⁴⁷ Smoking caused approximately 180,000 deaths from cardiovascular disease in 1990.⁴⁸ One study estimates that thirty to forty percent of all coronary heart disease deaths are attributable to smoking.⁴⁹

With respect to cancer, the United States Surgeon General has reported that smoking is responsible for about thirty percent of all cancer related deaths, including eighty-seven percent of all lung cancer deaths and eighty-two percent of deaths from chronic obstructive pulmonary disease.⁵⁰ Furthermore, a relationship exists between cigarette smoking and cancers of the larynx, mouth, esophagus, and bladder.⁵¹ Cigarette smoking is also a probable cause of infertility and peptic ulcer disease, and contributes to or is associated with cancers of the pancreas, kidney, cervix, and stomach.⁵²

Moreover, cigarettes also cause serious pre-natal and post-natal health problems. Women who smoke are twice as likely to have low birth weight infants as women who do not smoke.⁵³ Smoking is also responsible for

44. See *infra* notes 147-150 and accompanying text.

45. See *infra* part III.B.

46. Carl E. Bartecchi et al., *The Human Costs of Tobacco Use*, 330 NEW ENG. J. MED. 907 (1994).

47. DEP'T OF HEALTH AND HUMAN SERVICES, THE HEALTH BENEFITS OF SMOKING CESSATION, A REPORT OF THE SURGEON GENERAL, Pub. No. 90-8416, 198 (1990) [hereinafter SGR 1990].

48. DHHS, *Cigarette Smoking—Attributable Mortality*, *supra* note 1, at 645.

49. 60 Fed. Reg. 41,318 (1995) (citing J.E. Fielding, *Smoking: Health Effects and Control*, PUBLIC HEALTH AND PREVENTATIVE MEDICINE 716 (1992)).

50. 60 Fed. Reg. 41,318 (1995) (citing DEP'T OF HEALTH AND HUMAN SERVICES, REDUCING THE HEALTH CONSEQUENCES OF SMOKING: 25 YEARS OF PROGRESS, A REPORT OF THE SURGEON GENERAL, EXECUTIVE SUMMARY 157, Pub. No. 89-8411 (1989) [hereinafter SGR 1989]).

51. SGR 1989, *supra* note 50, at 20.

52. SGR 1990, *supra* note 47, at 10.

53. 60 Fed. Reg. 41,319 (1995) (citing J.E. Fielding, *Smoking: Health Effects and Control*, PUBLIC HEALTH AND PREVENTATIVE MEDICINE 725 (1992)).

intrauterine growth retardation of the fetus,⁵⁴ increased rates of premature delivery,⁵⁵ and premature infant death.⁵⁶ A recent study reported that use of tobacco products by pregnant women causes 19,000 to 141,000 miscarriages per year.⁵⁷ The study also attributes maternal smoking during pregnancy to approximately two-thirds of all deaths from "sudden infant death syndrome" and a total of 3100 to 7000 infant deaths per year.⁵⁸

In addition to cigarettes, smokeless tobacco products have also been linked to damaging health effects. Studies show that use of smokeless tobacco causes oral cancer and oral leukoplakia and may be associated with an increased risk of cancer of the esophagus.⁵⁹ It has also been implicated in cancers of the gum, mouth, pharynx and larynx.⁶⁰ Moreover, snuff use causes gum recession, is associated with discoloration of the teeth, and long-term use increases the risk of cheek and gum cancers by nearly fifty times.⁶¹

Overall, tobacco use causes over 400,000 deaths per year in the United States—approximately twenty percent of all deaths nationwide.⁶²

IV. THE PROPOSED SOLUTION: THE 1995 FDA PROPOSED RULE

On August 10, 1995, the FDA proposed a rule to limit the exposure of young people to tobacco promotion and to ban the sale of tobacco products, by federal law, to all persons under the age of eighteen.⁶³ This part will discuss the procedural requirements, purpose, scope, and substantive provisions of the proposed rule.

54. Patricia H. Shiono et al., *Smoking and Drinking During Pregnancy: Their Effects on Preterm Birth*, 255 JAMA 82 (1986).

55. 60 Fed. Reg. 41,319 (1995) (citations omitted).

56. Joseph R. DiFranza & Robert A. Lew, *Effect of Maternal Cigarette Smoking on Pregnancy Complications and Sudden Infant Death Syndrome*, 40 J. FAM. PRAC. 385, 391-92 (1995).

57. *Id.*

58. *Id.*

59. SGR 1994, *supra* note 5, at 39.

60. *Id.*

61. Deborah M. Winn et al., *Snuff Dipping and Oral Cancer Among Women in the Southern United States*, 304 NEW ENG. J. MED. 745, 747 (1981).

62. DHHS, *Cigarette Smoking—Attributable Mortality*, *supra* note 1, at 645.

63. *See* 60 Fed. Reg. 41,314 (1995).

A. *Procedural Requirements:
Notice and Comment*

Pursuant to the Administrative Procedure Act ("APA"), a federal administrative agency must provide interested parties with notice and an opportunity to comment on a proposed rule prior to its promulgation.⁶⁴ The FDA has provided notice by publishing in the Federal Register the text of the proposed rule, entitled: "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents."⁶⁵ In addition, the FDA has published, in the same issue of the Federal Register, an "Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products."⁶⁶ Interested parties were given the opportunity to submit written comments and recommendations to the FDA by January 2, 1996.⁶⁷

B. *Purpose and Scope of the Proposed Rule*

The stated purpose of the proposed rule is to "help prevent persons younger than eighteen years of age from becoming addicted to nicotine, thereby avoiding the life-threatening consequences often associated with tobacco use."⁶⁸ The scope of the proposed rule is limited to cigarettes and smokeless tobacco products and would not apply to pipe tobacco or cigars because (1) the FDA claims it does not currently have sufficient evidence that these products conform to the definition of a drug delivery "device" under the FDCA,⁶⁹ and (2) young people predominantly use cigarettes and smokeless tobacco products.⁷⁰

64. The APA provides:

(b) General notice of proposed rule making shall be published in the Federal Register. . . . (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. . . . (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date.

5 U.S.C. § 553(b)-(d) (1994).

65. 60 Fed. Reg. 41,314 (1995).

66. 60 Fed. Reg. 41,453 (1995). See discussion *infra* part VI.

67. 60 Fed. Reg. 53,560 (1995); 60 Fed. Reg. 53,620 (1995).

68. 60 Fed. Reg. 41,322 (1995).

69. 21 U.S.C. § 321(h)(3) (1994).

70. 60 Fed. Reg. 41,322 (1995).

C. Substantive Provisions of Proposed Rule

The proposed rule attempts to accomplish the above-stated purpose with a two-pronged approach. Prong one would place restrictions on the sales of cigarettes and smokeless tobacco, making these products less accessible to young people.⁷¹ Prong two would work to reduce the appeal of tobacco products to young people by restricting advertising and funding a national educational campaign to deter young people from using tobacco products.⁷²

1. Prong One: Restricting the Sale of Tobacco Products to Young People

Under prong one, the proposed rule would create several restrictions. First, the proposed rule would prohibit the sale and distribution of cigarettes and smokeless tobacco products to individuals younger than eighteen.⁷³ To aid in the enforcement of this age restriction, the proposed rule would require all retailers of tobacco products to verify that purchasers of tobacco products are at least eighteen years old. Verification would be achieved by direct visual inspection of each prospective purchaser and would, if necessary, include the use of a photographic identification card with a birth date.⁷⁴

Prong one also would prohibit the retailer or its employees from selling or distributing single cigarettes and would establish twenty cigarettes as the minimum package size.⁷⁵ The FDA reasons that:

[T]he vast majority of cigarette packs in the United States contain [twenty] cigarettes. The proposal is intended to preclude firms from manufacturing packages that contain fewer than [twenty] cigarettes; these packs, sometimes referred to as "kiddie" packs, usually contain a small number of cigarettes, are

71. *Id.* at 41,315.

72. *Id.*

73. *Id.* at 41,322.

74. *Id.* at 41,323. The FDA justifies this identification verification provision by citing: [S]tudies indicate that minors who are able to purchase cigarettes and other tobacco products from stores are rarely asked to verify their age. . . . In contrast, in Everett, WA, where a local ordinance required proof of age if the prospective buyer did not appear to be of legal age to purchase cigarettes . . . tobacco use, among 14 to 17-year-olds, declined from 25.3 percent to 19.7 percent overall. *Id.*

60 Fed. Reg. 41,323 (citing M. Ward Hinds, *Impact of a Local Ordinance Banning Tobacco Sales to Minors*, 107 PUB. HEALTH REP. 355 (1992)).

75. 60 Fed. Reg. 41,324 (1995).

easier to conceal, and are less expensive than full-size packs. (Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases).⁷⁶

Also, prong one would prohibit "impersonal" modes of sale, requiring that "cigarettes and smokeless tobacco products be sold only in a direct, face-to-face exchange between the retailer or the retailer's employees and the consumer."⁷⁷ The proposed rule specifically would prohibit all cigarette vending machines, self-service displays, mail order sales, and mail order redemption of coupons.⁷⁸

2. Prong Two: Reducing the Appeal of Tobacco Products to Young People

To reduce the appeal of tobacco products to young people, prong two would impose several requirements on tobacco manufacturers. First, the proposed rule would require each tobacco manufacturer to contribute to a national educational campaign fund.⁷⁹ The campaign fund would purchase advertisements in media markets targeting young people to "combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products."⁸⁰ The FDA cites to similar programs in Vermont and California which have successfully decreased cigarette consumption.⁸¹

The media program would operate by establishing a total fund of \$150 million per year, raised by contributions from all cigarette and smokeless tobacco manufacturers. Each manufacturer would contribute an amount of money proportionate to its share of the total advertising and promotional expenditures of the cigarette and smokeless tobacco industry. Thus, a manufacturer whose expenditures equal ten percent of the total industry expenditures would be required to contribute \$15 million, or ten percent of the media fund.

76. *Id.*

77. *Id.*

78. *Id.* The FDA cites several studies which indicate that these impersonal modes of sale are primary sources by which young people obtain tobacco products. 60 Fed. Reg. 41,324-26 (1995).

79. See *infra* part VII (discussing of the legality of this educational campaign fund).

80. 60 Fed. Reg. 41,326 (1995).

81. *Id.* at 41,327.

Under the program, industry members could select from a variety of messages maintained by the FDA.⁸² Eighty percent of the media fund would be spent on television advertisements while the remaining twenty percent would be placed in other media, such as radio and outdoor advertising, that target young people.⁸³

The second requirement of prong two more specifically relates to advertising. First, it would prohibit all outdoor advertising of tobacco products, such as billboards, posters, and placards within 1000 feet of an elementary or secondary school or playground. The FDA reasons that this provision is necessary to keep advertisements away from areas with a high concentration of young children.⁸⁴ Second, it would require that all cigarette and smokeless tobacco product advertising (including outdoor advertising, in-store advertising, and advertisements in publications) use "black text on a white background and nothing else."⁸⁵ The only exception to this would be for publications that are read "primarily by adults." Publications read "primarily by adults" would be allowed to use imagery and color because the effect of such advertising on young people would be "nominal."⁸⁶ Adult publications include a publication "(a) [w]hose readers age 18 or older constitute 85 percent or more of the publication's total readership, or (b) [a publication] that is read by two million or fewer people under age 18, whichever method results in the lower number of young people."⁸⁷

Third, the proposed rule would prohibit the sale or distribution of all non-tobacco items (such as T-shirts, caps and sporting goods) displaying a cigarette or smokeless tobacco brand name (such as Marlboro or Camel) or their identifying characteristic (such as the "Marlboro Man" or "Joe

82. *Id.*

83. *Id.* at 41,328.

84. *Id.* at 41,327.

85. 60 Fed. Reg. 41,335 (1995). The FDA supports this provision by citing studies which conclude that:

Photographs, pictures, cartoons, and other graphics allow the advertiser to encode its sales messages in a way that makes the advertisement more compelling and memorable. Imagery ties the products to a positive visual image Adding visual images to a text advertisement can produce greater recall and a more positive product rating. Not surprisingly, studies have shown that children and adolescents react more positively to advertising with pictures and other depictions than to advertising . . . that contains only print or text.

Id. (citing John R. Rossiter, *Visual and Verbal Memory in Children's Product Information Utilization*, 3 *ADVANCES IN CONSUMER RES.* 523 (1976)).

86. 60 Fed. Reg. 41,335 (1995).

87. *Id.*

Camel”).⁸⁸ However, company names (such as Philip Morris or R.J. Reynolds) would be permitted on non-tobacco items. Fourth, the rule would prohibit all contests, lotteries, or games of chance that are linked to the purchase of a tobacco product.⁸⁹ Fifth, the rule would prohibit any sponsored event, including athletic, musical, artistic, or other social or cultural event from being identified with a cigarette or smokeless tobacco product brand name or any other brand identifying characteristic.⁹⁰ An event could be sponsored in the name of the tobacco *company* but could not include any brand name, logo, symbol or other indicia of product identification.⁹¹

The aforementioned proposed restrictions raise questions as to whether the First Amendment free speech rights of tobacco manufacturers, advertisers, and vendors to promote tobacco products would be impinged. These issues are discussed in Part V.

V. FIRST AMENDMENT CONSIDERATIONS

A. *Early Commercial Speech Doctrine*

Until only recently, the United States Supreme Court refused to protect commercial speech under the First Amendment. In 1942, the Court held in *Valentine v. Chrestensen*⁹² that the United States Constitution imposes “no . . . restraint on government as respects purely commercial

88. *Id.* at 41,336. The FDA reasons that:

Young people have relatively little disposable income, so promotions are appealing because they represent a means of “getting something for nothing.” . . . Some items [including T-shirts, caps and sporting goods], when used or worn by young people, also create a new advertising medium—the “walking billboard”—which can come into schools and other locations where advertising is usually prohibited. A 1992 Gallup survey found that about half of adolescent smokers and one quarter of non-smokers owned at least one of these items.

Id. (citing The George H. Gallup International Institute, *Teen-Age Attitudes and Behavior Concerning Tobacco—Report of the Findings*, at 17, 59 (1992)).

89. 60 Fed. Reg. 41,336 (1995).

90. *Id.*

91. *Id.* The FDA notes that:

Sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events, such as car racing and rodeos. It provides an opportunity for what sponsorship experts call “embedded advertising” that actively creates a “friendly familiarity” between tobacco and sports enthusiasts, many of whom are children and adolescents.

Id.

92. 316 U.S. 52 (1942).

advertising.”⁹³ However, by 1975, the Supreme Court had completely reversed its position. In *Bigelow v. Virginia*,⁹⁴ the Court struck down a Virginia statute that criminalized any advertisement that “encourage[d] or prompt[ed] the procuring of abortion.”⁹⁵ In voiding the statute, the Court reinterpreted *Valentine*, holding that “[t]he existence of ‘commercial activity, in itself, is no justification for narrowing the protection of expression secured by the First Amendment.’”⁹⁶

The following year, the Supreme Court reaffirmed *Bigelow* in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*.⁹⁷ The Court stated:

Our question is whether speech which does “no more than propose a commercial transaction,” is so removed from any “exposition of ideas,” and from “truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government,” that it lacks all protection [under the First Amendment]. Our answer is that it is not.⁹⁸

The Court held that pharmacies have a constitutional right to advertise their businesses so long as the information contained in the advertisement is truthful and the activity advertised is lawful.⁹⁹

B. Modern Commercial Speech Doctrine

It was not until 1980 that the Supreme Court established the modern commercial speech test. In *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*,¹⁰⁰ the Court developed a four prong test for determining whether commercial speech should be afforded protection under the First Amendment:¹⁰¹ (1) commercial speech receives

93. *Id.* at 54.

94. 421 U.S. 809, 812-13 (1975).

95. *Id.*

96. *Id.* at 818 (quoting *Ginsburg v. United States*, 383 U.S. 463, 474 (1966)).

97. 425 U.S. 748 (1976).

98. *Id.* at 762 (citing *Pittsburg Press Co. v. Human Relations Comm’n*, 413 U.S. 376, 385 (1973); *Chaplinsky v. New Hampshire*, 315 U.S. 568, 572 (1942); *Roth v. United States*, 354 U.S. 476, 484 (1957)).

99. *Id.* at 773.

100. 447 U.S. 557 (1980).

101. *Id.* at 563. The Supreme Court noted, in establishing its four part test, that the Constitution “accords a lesser protection to commercial speech than to other constitutionally guaranteed expression. The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation.” *Id.* (citations omitted).

protection only if it is truthful and concerns a lawful activity,¹⁰² if the first prong is met, the remaining prongs provide that government's restriction will be upheld only if (2) the government's interest is "substantial," (3) the regulation directly advances the government's interest,¹⁰³ and (4) the regulation is not more extensive than necessary to serve that interest.¹⁰⁴

Central Hudson involved a New York State regulation prohibiting all promotional advertising (even truthful ads) relating to the consumption of energy (a lawful activity).¹⁰⁵ The Court found that the state's interest in energy conservation was "substantial" and the regulation "directly advanced" that interest.¹⁰⁶ However, with respect to prong four, the Court found that the state's complete suppression of speech was more restrictive than necessary to further the goal of energy conservation and was therefore in violation of the First Amendment.¹⁰⁷

In *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*,¹⁰⁸ the Court applied, and substantially weakened, the *Central Hudson* test. In *Posadas*, the Puerto Rico Legislature passed a legislative ban on all casino advertising directed toward Puerto Rico residents (but casino advertisements could still be directed at tourists).¹⁰⁹ In upholding the advertising restriction, the Court applied the *Central Hudson* test. First, it found that the advertising was entitled to First Amendment protection

102. *Id.* at 563-64. The Supreme Court noted that "[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity." *Id.* (citing *Friedman v. Rogers*, 440 U.S. 1, 13, 15-16 (1979); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 464-65 (1978)).

103. *Central Hudson*, 447 U.S. at 564. The Supreme Court stated: "The regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.*

104. *Id.* The Court noted that "if the governmental interest could be served *as well* by a more limited restriction on commercial speech, the excessive restrictions cannot survive." *Id.* (emphasis added). In a 1989 decision, the Supreme Court clarified this fourth prong, stating:

What our decisions require is a "'fit' between the legislature's ends and the means chosen to accomplish those ends,"—a fit that is not necessarily perfect, but *reasonable*; . . . that employs not necessarily the least restrictive means but, as we have put it in the other contexts discussed above, a means *narrowly tailored to achieve the desired objective*. Within those bounds, we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.

Board of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989) (emphasis added) (citations omitted).

105. *Central Hudson*, 447 U.S. at 558-59.

106. *Id.* at 569.

107. *Id.* at 570. The Court held the regulation more extensive than necessary because it prohibited all advertisements for electric services, including services that would actually reduce energy use by diverting demand from less efficient sources. *Id.*

108. 478 U.S. 328 (1986).

109. *Id.*

because it concerned a legal activity and was not false or misleading.¹¹⁰ Next, it found that the Puerto Rico Legislature had a substantial interest in reducing gambling among its residents as a means of reducing local and organized crime and prostitution.¹¹¹ The Court then found that prong three was met by deferring to the legislature's judgment that the advertising restrictions directly advanced the governmental interest.¹¹² Similarly, the Court found that prong four was met by deferring to the legislature's judgment that no less intrusive means would accomplish the government's goal.¹¹³ By deferring to the legislature's judgment on the two most stringent prongs, the Court effectively decimated the *Central Hudson* test.

C. *Applicability of Posadas to the
FDA Proposed Rule*

It is not entirely clear whether the *Posadas* decision would apply to an analysis of the FDA proposed rule. First, the Court gave extreme deference to the decision of the Supreme Court of Puerto Rico because "[a] rigid rule of deference to interpretations of Puerto Rico law by Puerto Rico courts is particularly appropriate, given the unique cultural and legal history of Puerto Rico."¹¹⁴ Second, the Court recognized that, because the Puerto Rico Legislature had the power to ban gambling in Puerto Rico altogether, it should also have the power to set limits on the promotional activities of gambling casinos.¹¹⁵

110. *Id.* at 340-41.

111. *Id.* at 341.

112. *Id.* at 341-42. The Court stated:

The Puerto Rico Legislature obviously believed, when it enacted the advertising restrictions at issue here, that advertising of casino gambling aimed at residents of Puerto Rico would serve to increase the demand for the product advertised. We think the legislature's belief is a reasonable one, and the fact that appellant has chosen to litigate this case all the way to this Court indicates that appellant shares the legislature's view.

Posadas, 478 U.S. at 341-42.

However, in *Edenfield v. Fane*, the Supreme Court held that the Florida Board of Accounting failed to meet the third prong of the *Central Hudson* test because its ban on advertisements by certified public accountants did not directly and materially advance the government's asserted interests. 507 U.S. 761 (1993). Thus, unlike *Posadas*, the *Edenfield* court declined to defer to the government on *Central Hudson*'s third prong.

113. *Posadas*, 478 U.S. at 343-44.

114. *Id.* at 339 n.6 (citing *Diaz v. Gonzalez*, 261 U.S. 102, 105-06 (1923)).

115. *Id.* at 346. Justice Rehnquist, in the majority opinion, stated that "it is precisely because the government could have enacted a wholesale prohibition of the underlying conduct that it is permissible for the government to take the less intrusive step of allowing the conduct, but reducing the demand through restrictions on advertising." *Id.*

In determining whether the *Posadas* decision applies to an analysis of the FDA proposed rule, the question is whether the FDA has the power, under the FDCA, to ban all sales and promotion of tobacco products. The FDA claims it has the power to do so.¹¹⁶ If the reviewing court—the United States District Court for the Middle District of North Carolina (“the reviewing court”)—finds that this is the case, it may also find that the FDA has the power, under *Posadas*, to regulate the promotion and sale of tobacco products.¹¹⁷ However, if the reviewing court finds that the FDA does not have such power, then *Posadas* is distinguishable and the *Central Hudson* test should be applied without the use of the Court’s highly deferential approach in *Posadas*.

D. Application of the Central Hudson Test to the FDA Proposed Rule

The FDA proposed rule would impose restrictions on both the advertising of tobacco products and other promotional activities. The First Amendment considerations for these two categories will be discussed separately.

1. The Constitutionality of Advertising Restrictions

Under the first prong of the *Central Hudson* test, tobacco advertisements will receive no protection under the First Amendment unless they are truthful and promote a legal activity.¹¹⁸ Although it is legal to smoke

116. 60 Fed. Reg. 41,355 (1995). The FDA proposed rule states: “The agency believes that, because it could have banned the sale or distribution of the product, or banned certain of the marketing and promotional practices of the tobacco industry, the lesser steps of regulating labeling and advertising and requiring manufacturers to fund a government approved educational campaign are reasonable.” *Id.* (citing *Posadas*, 478 U.S. at 346).

It should also be noted, however, that the Supreme Court affirmed a district court ruling that “Congress has the power to prohibit the advertising of cigarettes in any media” pursuant to its power to regulate interstate commerce. *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582, 584 (D.D.C. 1971), *aff’d mem.*, 405 U.S. 1000 (1972).

117. However, even if the reviewing court finds that the FDA *does* have the power under the FDCA to ban all promotion and sales of tobacco, it could nevertheless distinguish *Posadas* because the case involved a statute passed by a legislature, whereas the FDA proposed rule is merely a regulation by a federal agency.

118. The FDA-proposed regulations may still violate the First Amendment even though they permit the plaintiffs to communicate their messages in black and white text. The Supreme Court has held that “commercial illustrations are entitled to the First Amendment protections afforded verbal commercial speech: restrictions on the use of visual media of expression in advertising must survive scrutiny under the *Central Hudson* test.” *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 647 (1985).

cigarettes and use smokeless tobacco products, the FDA charges that tobacco advertisements are misleading and therefore not entitled to First Amendment protection. Specifically, the FDA argues that cigarette advertisements depict smokers as young, healthy, active people when the reality is that cigarette smoking is unhealthful and causes disease and premature death among long-term users.¹¹⁹ Moreover, the FDA argues that tobacco advertisements generally contain little information that is important or useful to consumers. In *Virginia State Board of Pharmacy*, the Supreme Court protected commercial speech because it contained information that was important, if not essential, to particular consumers.¹²⁰ However, tobacco advertisements featuring no more than images of young, healthy people at play, or a “cool” cartoon camel, lack any such important or essential information and, coupled with the misleading nature of the message, should not be entitled to First Amendment protection.

The tobacco industry may assert that tobacco advertisements are not false or misleading because they make no statements or implications as to the health effects of tobacco use. Moreover, *Central Hudson*, which was decided after *Virginia State Board of Pharmacy*, did not require that the commercial speech contain important consumer information to receive First Amendment protection.¹²¹ Therefore, because tobacco use is legal and tobacco advertisements make no false or misleading statements, the speech

119. See *supra* text accompanying notes 46-58.

120. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 763-64 (1976) (footnote omitted). Justice Blackmun, in the majority opinion, stated:

[T]he particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his [or her] interest in the day's most urgent political debate. . . . Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs; yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities.

Id.

121. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 562 (1980). On this issue, the Supreme Court stated:

In applying the First Amendment to [commercial speech], we have rejected the “highly paternalistic” view that government has complete power to suppress or regulate commercial speech. “[P]eople will perceive their own best interests only if they are well enough informed, and . . . the best means to that end is to open the channels of communication, rather than to close them. . . .” Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.

Id. (citations omitted).

should receive First Amendment protection under the first prong of the *Central Hudson* test.

Assuming the first prong of the *Central Hudson* test is met, the burden then shifts to the FDA to demonstrate that: (1) its interest in restricting tobacco promotion is substantial,¹²² (2) the proposed rule would directly advance that interest,¹²³ and (3) the proposed rule is narrowly tailored to achieve the desired objective.¹²⁴ First, the FDA would argue that it is a “substantial” governmental interest to prevent young people from becoming addicted to tobacco products which, over the long term, cause a multitude of adverse health effects (including lung cancer, heart disease, and stroke) and 400,000 American deaths every year.¹²⁵ In *Central Hudson*, the Court held that promoting energy conservation was a “substantial” governmental interest.¹²⁶ In *Posadas*, the Court held that protecting the citizens of Puerto Rico from the negative effects of legalized gambling (including crime, prostitution, and corruption) was a “substantial” governmental interest.¹²⁷ Moreover, the Fifth Circuit held in *Dunagin v. City of Oxford* that, without question, the State of Mississippi had a “substantial” interest in “safeguarding the health, safety and general welfare of its citizens by controlling the artificial stimulation of liquor sales and consumption created by the advertising of liquor.”¹²⁸ Analogously, the reviewing court should hold that the FDA’s interest in safeguarding the health, safety, and general welfare of America’s youth by reducing their consumption of tobacco products is also a “substantial” governmental interest. The fact that all fifty states have prohibited the sale of tobacco products to minors suggests the interest is not only substantial but unanimous among state governments. Even the tobacco industry has made repeated public statements that children under age eighteen should be

122. *Id.* at 564.

123. *Id.*

124. *Board of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

125. See DHHS, *Cigarette Smoking—Attributable Mortality*, *supra* note 1, at 645.

126. *Central Hudson*, 447 U.S. at 569.

127. *Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986).

128. 718 F.2d 738, 747 (5th Cir. 1983), *cert. denied*, 467 U.S. 1259 (1986).

prohibited from smoking.¹²⁹ Therefore, prong two of the *Central Hudson* test is satisfied.

Next, the FDA could argue that the regulation “directly advances” the government interest because it specifically addresses ways to block the access of tobacco products to young people as well as reduce the promotional messages that increase their demand to use these products.¹³⁰ Opponents, however, could argue that the regulation is merely an *indirect* way of advancing the government interest and the only *direct* way is for the government to enforce the laws now on the books in all fifty states that prohibit minors from purchasing tobacco products. However, the FDA could respond that because young people obtain cigarettes from indirect modes of sale, including vending machines, mail order sales, and cigarette giveaways, merely enforcing current state purchasing laws will not solve the problem. Alternatively, the federal government is powerless to enforce state laws, thus a national minimum purchasing age and federal enforcement program is required. Moreover, it is unrealistic to presume that government can eliminate all underage tobacco use simply by “enforcing” the existing underage purchasing laws. Even if all tobacco products were banned, people, including minors, would find ways to obtain them. Therefore, the FDA measures designed to reduce the *appeal* of these products to young people—including “tombstone” advertising formats and a national educational program—are also necessary to combat the problem.

However, the FDA need not show that these measures are necessary, only that they “directly advance” the government interest of reducing tobacco use among young people. In *Central Hudson*, the Supreme Court found that because there was an immediate connection between advertising and demand for electricity, there is a “direct link” between the ban on

129. In a recent advertising campaign, the R.J. Reynolds Tobacco Company placed full-page ads in several editions of the *Los Angeles Times*, *New York Times*, and other major periodicals. One such advertisement stated: “We all agree we must do something to keep cigarettes out of the hands of children under the age of eighteen. . . . A proven solution is to . . . enforce the existing laws in 50 states denying children access to cigarettes.” L.A. TIMES, Oct. 19, 1995, at A21. A similar ad stated: “Only adults should ever face the decision to smoke or not to smoke. . . . As a parent . . . you need to add your voice to the many others trying to discourage kids from smoking. [The] R.J. Reynolds Tobacco Company offers parents brochures which can help them talk to their kids about smoking. . . .” L.A. TIMES, Oct. 12, 1995, at A17. Accompanying the brochures sent by R.J. Reynolds is a letter stating: “At R.J. Reynolds we’re committed to doing everything possible to combat underage smoking.” Letter from Herbert E. Osmon, Staff Vice President, R.J. Reynolds Tobacco Company, to parents and concerned citizens (Sept., 1995) (on file with the *Loyola of Los Angeles Entertainment Law Journal*).

130. See *supra* part IV.C.2.

advertising of electricity and the state interest in conservation.¹³¹ Several other courts have also found that advertising is directly related to the consumption of the advertised product.¹³² Similarly, here, the proposed restrictions on sales and promotion of tobacco would “directly advance” the government’s interest by decreasing youth demand and access to tobacco products. Therefore, prong three is satisfied.

The FDA’s foremost challenge will be in the fourth prong: Is the proposed rule narrowly tailored to achieve the desired objective? The opponents to the proposed rule could argue that the rule is not narrowly tailored because it would ban all tobacco advertisements except those that the government believes are suited for children. The Supreme Court has stated that the government may not “reduce the adult population . . . to reading only what is fit for children.”¹³³

However, the Supreme Court held in *Central Hudson* that the test is whether the government’s interest could be served as effectively by a more limited restriction on commercial speech.¹³⁴ If not, the fourth prong is satisfied. Opponents, in their respective complaints, do not address specifically how the FDA could serve its interests as effectively, but with a less restrictive policy. Indeed, it would be difficult, if not impossible, to conceive of a federal program that would accomplish all that the proposed rule would accomplish, and yet be less restrictive to tobacco manufacturers, advertisers, and vendors. If the reviewing court cannot conceive of such

131. 447 U.S. at 569.

132. See *Dunagin v. City of Oxford, Miss.*, 718 F.2d 738, 750 (5th Cir. 1983) (finding that alcohol advertising and alcohol consumption are directly linked), *cert. denied*, 467 U.S. 1259 (1984); *Williams v. Spencer*, 622 F.2d 1200, 1205 (4th Cir. 1980) (finding that “an advertisement encouraging the use of drugs encourages actions which in fact endanger the health or safety of students”); *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582, 586 (D.D.C. 1971) (noting a “close relationship between cigarette commercials broadcast on the electronic media and their potential influence on young people”); *Queensgate Inv. Co. v. Liquor Control Comm’n*, 433 N.E.2d 138, 142 (Ohio Sup. Ct. 1982) (finding that “[t]he advertising of drink prices and price advantages would encourage and stimulate excessive consumption of alcoholic beverages; an advertising prohibition aids the interest in preventing that consumption”), *appeal dismissed*, 459 U.S. 807 (1982).

133. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 73-74 (1983) (quoting *Butler v. Michigan*, 352 U.S. 380, 383 (1957)). However, *Bolger* and *Butler* are factually and legally distinguishable from the FDA proposed rule. *Bolger* relates to a federal statute banning the mailing of unsolicited advertisements for contraceptives. The Supreme Court held the ban unconstitutional because it related to an activity that is protected from unwarranted governmental interference. *Id.* at 69 (citing *Carey v. Population Servs. Int’l*, 431 U.S. 678, 700-01 (1977)). *Butler* is distinguishable because it related to a Michigan state law prohibiting obscene language from books available to the general reading public. The case did not relate to commercial speech but focused primarily on the obscenity doctrine. *Butler*, 352 U.S. at 381-83.

134. *Central Hudson*, 447 U.S. at 564.

a feasible program, then it should find the fourth prong of the *Central Hudson* test is satisfied.

The FDA could also make the following affirmative arguments that the proposed rule is narrowly tailored to achieve the desired objective. The FDA objective is to decrease tobacco use by young people. The proposed rule would not restrict *all* advertising but only advertisements that would be read by young people; advertisements read predominantly by adults are not affected. Also, the proposed rule would not *ban* such advertisements but merely impose *restrictions* on the advertising, such as prohibiting the use of color and pictures, which make the advertisements more appealing to young people. Further, the proposed rule would not affect *all* tobacco products but only those products which young people use predominantly: cigarettes and smokeless tobacco. Cigars and tobacco pipes are not subject to the regulation, in part, because they are not used as predominantly by young people.¹³⁵ Therefore, the proposed rule is narrowly tailored to achieve the desired objective of reducing tobacco use among young people, and thus the fourth prong of the *Central Hudson* test is satisfied.¹³⁶

2. The Constitutionality of Restrictions on Other Promotional Activities

In addition to restricting tobacco advertisements, the proposed rule would prohibit the following: brand name sponsorship of sporting events; the manufacturing and sale of non-tobacco items that feature tobacco brand-names (such as T-shirts, caps and sporting goods); vending machines, self-service displays, mail order sales, and mail order redemption of coupon programs; and all contests, lotteries, and games of chance linked to the purchase of a tobacco product.¹³⁷ Opponents of the proposed rule argue that these activities are also protected by the First Amendment.

These promotional activities, however, would receive no greater protection than that afforded to commercial speech because they are either (1) a form of advertising (banners at a sporting event, a logo on a T-shirt, etc.); (2) a mode of sale (vending machine, mail order, etc.); or (3) some other attempt to propose or entice a commercial transaction (contests,

135. 60 Fed. Reg. 41,322 (1995).

136. For comparison, the Fifth Circuit upheld a Mississippi statewide ban on all liquor advertisements (including newspaper, billboard, circular, radio and television advertisements) originating within the state. *Dunagin*, 718 F.2d at 751. Applying the *Central Hudson* test, the court found the total ban passed the fourth prong because it was "not more extensive than necessary" to serve the state interest of reducing alcohol consumption. *Id.*

137. See *supra* part IV.C.1.

lotteries, etc.). As such, they are various forms of commercial speech and are protected by the First Amendment only to the extent that the government does not have a substantial interest in restricting that speech. The *Central Hudson* analysis applies here and, for the reasons herein discussed, the government is likely to prevail.

3. Application of the Overbreadth Doctrine

The Supreme Court has held that restrictions on unprotected speech may still be unconstitutional if the restriction is "overbroad" such that it would "chill" constitutionally protected speech.¹³⁸ Opponents of the proposed rule argue that the overbreadth doctrine applies here because tobacco manufacturers, advertisers, and vendors would be chilled from communicating constitutionally protected speech.¹³⁹ However, because the proposed rule only applies to commercial speech, and because commercial speech is not protected by the First Amendment if the *Central Hudson* test is satisfied, the overbreadth doctrine does not apply unless opponents can show that fully protected, non-commercial speech would be chilled. Because the opponents would be free to communicate any message in black and white text—only color and pictures would be banned—it is unlikely that non-commercial speech would be affected by the proposed rule. The Supreme Court has held that the overbreadth doctrine applies weakly, or not at all, to commercial speech.¹⁴⁰ Therefore, opponents should not prevail under the overbreadth doctrine.

In addition to possible First Amendment violations, the FDA proposed rule raises issues of jurisdiction. Specifically, does the FDA have jurisdiction to promulgate such a rule? And does the United States District Court have jurisdiction to hear a challenge to the proposed rule before it is ever promulgated? These issues are discussed in Part VI.

138. See generally LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 1022-24 (2d ed. 1988).

139. See *American Advertising Fed'n*, *supra* note 15, at 15.

140. In *Bates*, the Supreme Court stated that "[s]ince advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 381 (1977).

VI. JURISDICTIONAL CONSIDERATIONS

A. *Does the FDA Have Jurisdiction to Regulate Tobacco Promotion and Sales?*

1. FDA's Assertion of Jurisdiction

The Federal Food, Drug, and Cosmetic Act ("FDCA")¹⁴¹ was enacted to regulate consumer products, including food, drugs, medical devices, biologics and cosmetics to safeguard the public health and protect consumer welfare. To achieve this purpose, the FDCA grants the Secretary of Health and Human Services the authority to "promulgate regulations for the efficient enforcement of [the FDCA]."¹⁴² Additionally, the FDCA authorizes the Secretary to issue regulations restricting the sale, distribution, or use of a drug delivery "device."¹⁴³

The FDA, acting under authority delegated by the Secretary,¹⁴⁴ has determined that nicotine conforms with the definition of a "drug" and cigarettes and smokeless tobacco products conform with the definition of a drug delivery "device" under the FDCA. A "drug," as defined by the FDCA, is an article, other than food, "intended to affect . . . any function of the body."¹⁴⁵ Similarly, a "device" is an instrument or other similar article "intended to affect . . . any function of the body."¹⁴⁶

According to the FDA, nicotine is a "drug" within the meaning of the FDCA because it is "highly addictive, causes other psychoactive effects, such as relaxation and stimulation, and affects weight regulation."¹⁴⁷ The FDA cites several medical authorities to support its conclusion that nicotine is an addictive drug. First, the United States Surgeon General reported in

141. 21 U.S.C. §§ 301-95 (1994).

142. *Id.* § 371(a).

143. *Id.* § 360j(e)(1).

144. 21 C.F.R. § 5.10(a) (1995) (granting to the Commissioner of the FDA the authority to act on matters falling under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301-95 (1994))).

145. 21 U.S.C. § 321(g)(1)(C) (1994).

146. *Id.* § 321(h)(3).

147. 60 Fed. Reg. 41,464 (1995). The FDA notes that "[t]he quantity, quality and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products." *Id.* at 41,464 n.1. The FDA makes this statement, in part, to refute statements by previous FDA officials that the FDA is without jurisdiction to regulate cigarettes as drugs or devices. See *infra* note 162.

1986 and 1988 that nicotine in smokeless tobacco products and cigarettes causes addiction.¹⁴⁸ Second, several major studies show that eighty to ninety percent of frequent smokers are addicted to cigarettes.¹⁴⁹ Third, since 1980, nicotine has been recognized as addictive by seven major national and international health organizations.¹⁵⁰

The FDA reasons that cigarettes and smokeless tobacco products are "devices" within the meaning of the FDCA because they deliver doses of the drug, nicotine, into the human body and are therefore "instruments . . . intended to affect . . . any function of the body."¹⁵¹

To assert jurisdiction, the FDA must also establish that tobacco manufacturers objectively intend nicotine to affect a function of the human body.¹⁵² The FDA argues that manufacturers have this objective intent. First, it is widely known and published in scientific, government and lay publications that nicotine is addictive.¹⁵³ Second, over the past thirty years, tobacco manufacturers themselves have engaged in more than 600 research studies on nicotine's psychoactive and addictive effects.¹⁵⁴ Third, industry officials have made repeated statements acknowledging or implying that nicotine is addictive.¹⁵⁵ Fourth, tobacco manufacturers

148. DEP'T OF HEALTH AND HUMAN SERVICES, PUB. NO. 86-2874, THE HEALTH CONSEQUENCES OF USING SMOKELESS TOBACCO, A REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL 182 (1986); DEP'T OF HEALTH AND HUMAN SERVICES, PUB. NO. 88-9406, THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, A REPORT OF THE SURGEON GENERAL 215 (1988) [hereinafter SGR 1988].

149. According to the Centers for Disease Control ("CDC"), 87% of people who smoke cigarettes smoke every day. 60 Fed. Reg. 41,547 (1995) (citing CENTERS FOR DISEASE CONTROL, 1991 NATIONAL HEALTH INTERVIEW SURVEY, Atlanta, GA (1991)). Further, the CDC has reported that each year in the U.S. fifteen million people (one third of all U.S. smokers) try to quit smoking, but less than three percent have long-term success. 60 Fed. Reg. 41,547-48 (citing DHHS, *Cigarette Smoking Among Adults*, *supra* note 3). Also, 70% of current smokers reported that they would "like to completely stop smoking" but cannot. *Id.* Moreover, a Department of Health and Human Services survey found that 83% to 87% percent of cigarette smokers who smoke more than 26 cigarettes a day believe they are addicted. 60 Fed. Reg. 41,487 (1995) (citing DEP'T OF HEALTH AND HUMAN SERVICES, 1991/1992 NATIONAL HOUSEHOLD SURVEY ON DRUG ABUSE).

150. 60 Fed. Reg. 41,484 (1995). These include the World Health Organization, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Society of Addiction Medicine, the Royal Society of Canada, and the Medical Research Council in the United Kingdom. *Id.*

151. 21 U.S.C. § 321(h)(3) (1994).

152. *See generally* 60 Fed. Reg. 41,471-82 (1995).

153. *See generally* 60 Fed. Reg. 41,539-46 (1995).

154. *See* 60 Fed. Reg. 41,625-43 (1995) (listing these studies).

155. The FDA cites several statements made by tobacco industry officials acknowledging or implying that nicotine in tobacco is addictive. A small sampling of these statements includes the following. In a 1963 internal memorandum, the general counsel to Brown & Williamson

intentionally manipulate the nicotine levels in cigarettes and smokeless tobacco products to ensure continued addiction by consumers.¹⁵⁶ Therefore, the FDA argues, because tobacco companies manufacture cigarettes and smokeless tobacco products knowing the addictive and other psychoactive effects of nicotine, they objectively intend to affect the function of the human body by selling their products.

Moreover, the jurisdictional analysis asserts that the FDA has broad authority over the definition of whether a product is a drug or a device.¹⁵⁷ To support this position, the FDA cites *Weinberger v. Bentex Pharmaceuticals*, in which the Supreme Court held that the “FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided [in the FDCA], the . . . status of individual drugs or classes of drugs.”¹⁵⁸ Therefore, the FDA concludes, it has authority to regulate cigarettes and smokeless tobacco products as drug delivery devices.

2. Arguments Opposing Jurisdiction

Opponents of the proposed rule—consisting of tobacco manufacturers, advertising firms, smokeless tobacco companies, and convenience stores—contend that the FDA lacks jurisdiction to promulgate a rule on this issue. Primarily they argue that Congress has, in both its words and actions, indicated clearly and unambiguously that the FDA should not have jurisdiction over cigarette labeling, promotion, or sales. First, Congress has repeatedly acted in the area of labeling and advertising of tobacco products and has never delegated power to the FDA, though it has delegated power

Tobacco Co. stated: “Moreover, nicotine is addictive We are, then, in the business of selling nicotine, an addictive drug” 60 Fed. Reg. 41,611 (1995) (emphasis omitted) (quoting Memorandum from A. Yeaman, Implications of Battelle Hippo I and II and the Griffith Filter, July 17, 1963, at 4).

Also, F. Ross Johnson, former CEO of RJR Nabisco, has openly acknowledged that tobacco is addictive and that its addictive properties are why people smoke. In an interview with the *Wall Street Journal*, Mr. Johnson was asked about tobacco. He responded: “Of course it’s addictive. That’s why you smoke” Eben Shapiro, *Big Spender Finds a New Place to Spend*, WALL ST. J., Oct. 6, 1994, at B1.

Further, William L. Dunn, Jr. of Philip Morris characterized the cigarette as a nicotine delivery system when he wrote: “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” 60 Fed. Reg. 41,617 (1995) (quoting William L. Dunn, *Motives and Incentives in Cigarette Smoking, Summary of CTR-Sponsored Conference in St. Martin*, Philip Morris Research Center, VA (1972)).

156. See generally 60 Fed. Reg. 41,693-749 (1995).

157. 60 Fed. Reg. 41,463 (1995).

158. 412 U.S. 645, 653 (1973).

to other agencies, including the Federal Trade Commission ("FTC") and the FCC.¹⁵⁹

Second, opponents note that Congress has repeatedly considered and rejected the specific tobacco advertising proposals contained in the FDA's proposed restrictions. Specifically, Congress considered legislation in 1987, 1989, 1990, and 1993, that contained many of the same provisions as the 1995 FDA proposed rule, including giving the FDA jurisdiction to regulate tobacco sales and advertising.¹⁶⁰ However, because the legislation was never enacted, opponents contend, the proposed rule directly contradicts the will of Congress *not* to give the FDA jurisdiction in this area.¹⁶¹

Third, opponents cite specific statements made by previous FDA officials to the effect that, without express Congressional delegation of authority, the FDA does not have jurisdiction to regulate the labeling, promotion, or sale of tobacco products.¹⁶² However, these statements do not preclude the FDA from re-evaluating the issue and reaching a different conclusion.¹⁶³

159. See *infra* part VI.A.4.

160. See *supra* part II.B.

161. See American Advertising Fed'n, *supra* note 15, at 11.

162. See *Coyne Beahm*, *supra* note 14, at 14-17. Opponents cite several statements by FDA officials. For example, in 1972, FDA Commissioner Charles Edwards, M.D. stated that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug and Cosmetic Act." *Id.* at 15 (quoting *Public Health Cigarette Amendments of 1971, Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce, 92d Cong., 2d Sess. 239 (1972)*).

Also in 1972, FDA Chief Counsel Peter Barton Hutt stated in a letter to Congress: "The Public Health and Cigarette Smoking Act of 1969 does not allow FDA either to require additional warning statements on the label or to ban cigarettes from interstate commerce." *Id.* at 16.

In 1980, the FDA filed a brief with the United States Court of Appeals, D.C. Circuit which stated:

In the 73 years since the enactment of the original [FDCA] and in the 41 years since the promulgation of the modern [FDCA], the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.

See *Coyne Beahm*, *supra* note 14, at 17 (quoting Brief for Appellee (FDA) at 14-15, Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir. 1980) (No. 79-1397)).

163. The FDA has reconsidered the issue in light of new studies conducted in the last 15 years which show that nicotine causes chemical addiction in people. It was not until 1986 and 1988 that the U.S. Surgeon General published findings that nicotine in smokeless tobacco and cigarettes are addicting, that nicotine is the drug in tobacco that causes addiction, and that the pharmacological and behavioral processes that cause tobacco addiction are similar to those that cause addiction to drugs such as heroin and cocaine. 60 Fed. Reg. 41,541-43 (1995) (citing SGR 1988, *supra* note 148).

3. Standard of Review: The *Chevron* Test

In *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*,¹⁶⁴ the Supreme Court set forth a two part analysis for reviewing an agency's interpretation of a statute. First, "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."¹⁶⁵ However, the second part states that if "Congress has not directly addressed the precise question at issue," the reviewing court must give effect to the agency's interpretation if that interpretation is "reasonable."¹⁶⁶ The *Chevron* test is important to an analysis of the FDA proposed rule for obvious reasons. If the reviewing court finds that Congress has not clearly intended to preclude the FDA from regulating in the area of tobacco sales and promotion, then the reviewing court must give effect to the FDA's assertion of jurisdiction, if the FDA's statutory interpretation is "reasonable."¹⁶⁷

164. 467 U.S. 837 (1984).

165. *Id.* at 842-43.

166. *Id.* at 843-44. It should be noted that the facts in *Chevron* involved the dissemination and interpretation of complex scientific data concerning air pollution emissions. The Supreme Court gave substantial deference to the federal agency (the Environmental Protection Agency) because these issues fell within the expertise of the agency and the Court felt it was inappropriate to second-guess the technical findings of the agency. *Id.* at 865. Opponents of the FDA proposed rule could argue that *Chevron* does not apply because the issues relating to tobacco use do not present equally complex scientific issues. The FDA, however, could counter that the issue of whether nicotine should be classified as a "drug" involves complex scientific data on the chemical and physiological affects of nicotine on the human body. As such, *Chevron* does apply and compels the district court to defer to the FDA's reasonable interpretation.

167. Two additional Supreme Court cases interpreting the *Chevron* test are also important in analyzing this issue. First, in *INS v. Cardoza-Fonseca*, a five-justice majority reversed an INS interpretation of a federal statute, holding that the interpretation was inconsistent with the "plain language of the Act." 480 U.S. 421, 432 (1987). The majority concluded that if the question is one purely of statutory construction, absent facts specific to the case, the reviewing court may interpret the statute under *Chevron's* step one. *Id.* at 446-48.

However, in *NLRB v. United Food & Commercial Workers*, the Court unanimously retracted dicta from *Cardoza-Fonseca* that was inconsistent with *Chevron*, and reaffirmed the *Chevron* policy of giving substantial deference to the agency. 484 U.S. 112 (1987). The Court in *United Food* held that Congress had not resolved the issue in dispute, and thus the agency's reasonable construction must be affirmed under *Chevron's* step two. *Id.* at 125, 133.

See also KENNETH C. DAVIS & RICHARD J. PIERCE, ADMINISTRATIVE LAW TREATISE 124-26, 130-31 (3d ed. 1994).

4. Congressional Intent and Preemption

Under *Chevron*, the reviewing court must first determine whether “the intent of Congress is clear” on the issue of whether the FDCA gives the FDA the power to regulate nicotine as a drug. Congress has never formally stated whether nicotine is a drug under the FDCA; nor has Congress ever expressly stated whether the FDA has jurisdiction over tobacco products or nicotine. However, Congress has enacted statutes regulating the promotion of tobacco products, including the Federal Cigarette Labeling and Advertising Act of 1965 (“the Cigarette Act”),¹⁶⁸ and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (“the Smokeless Act”).¹⁶⁹ The Cigarette Act states:

It is the policy of Congress, and the purpose of this chapter, to establish a *comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby*—(1) the public may be adequately informed about any adverse health effects of cigarette smoking . . . and (2) *commerce and the national economy may be* (A) protected to the maximum extent consistent with this declared policy and (B) *not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations* with respect to any relationship between smoking and health.¹⁷⁰

The Cigarette Act grants the FTC the power to promulgate regulations consistent with the provisions of the Cigarette Act.¹⁷¹ Moreover, in 1970, an amendment to the Cigarette Act banned all cigarette advertisements from television, radio, and other electronic media within the jurisdiction of the FCC.¹⁷² Congress granted the FCC jurisdiction over the amendment.¹⁷³

Opponents of the FDA proposed rule argue that Congress clearly intended the Cigarette Act to constitute the “comprehensive” federal law with respect to the labeling and advertising of cigarettes.¹⁷⁴ Therefore,

168. 15 U.S.C. §§ 1331-41 (1994).

169. *Id.* §§ 4401-08.

170. *Id.* § 1331 (emphasis added).

171. *Id.* § 1333(c)(1), (c)(2)(A).

172. *Id.* § 1335.

173. 15 U.S.C. § 1335 (1994). Though no express statement is made here to this effect, it can be implied that the FCC has such power because the advertising ban is within “the jurisdiction of the Federal Communications Commission.” *Id.*

174. See *Coyne Beahm*, *supra* note 14, at 8-9.

with the exception of the FTC and FCC, all other federal agencies lack authority to act in this area.

The Smokeless Act mirrors the Cigarette Act in that it appears to set forth a comprehensive national policy with respect to the labeling and advertising of *smokeless* tobacco products. Specifically, the Smokeless Act empowers the Secretary of Health and Human Services to “carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products.”¹⁷⁵ The Smokeless Act also empowers the Secretary to “make grants to States—(1) to assist in the development of educational programs and materials and public service announcements . . . (2) to assist in the distribution of such programs, materials, and announcements throughout the States, and (3) to establish 18 as the minimum age for the purchase of smokeless tobacco.”¹⁷⁶

The Smokeless Act also requires manufacturers of smokeless tobacco products to affix one of three warning labels (similar to the warning labels required on packages of cigarettes by 15 U.S.C. § 1333) upon all packages of smokeless tobacco products.¹⁷⁷ One of the three warnings is also required on all advertisements, other than outdoor billboard advertisements, for smokeless tobacco products.¹⁷⁸ The Smokeless Act further bans the advertising of smokeless tobacco products from television, radio and all other electronic media subject to the jurisdiction of the FCC.¹⁷⁹ Congress expressly delegated power to the FTC and FCC to take administrative actions consistent with, and for the enforcement of, the Smokeless Act.¹⁸⁰

Opponents of the FDA proposed rule argue that Congress clearly intended for the Smokeless Act to serve as the comprehensive federal law on labeling and advertising of smokeless tobacco products (just as the Cigarette Act is the comprehensive federal law on the labeling and advertising of cigarettes). Therefore, with the exception of the FTC and FCC, all other federal agencies lack authority to act in this area.

Contrarily, the FDA argues that Congress has not precluded FDA jurisdiction in this area because (1) Congress has never *expressly* precluded FDA jurisdiction, and (2) when Congress had the opportunity to preclude FDA jurisdiction—in the preemption clauses of the Cigarette Act and the

175. 15 U.S.C. § 4401 (1994).

176. *Id.*

177. *Id.* § 4402. See *supra* note 25 (text of the three warning labels).

178. 15 U.S.C. § 4402(a)(2) (1994).

179. *Id.* § 4402(f).

180. *Id.* § 4402(b), (f).

Smokeless Act—it declined to do so.¹⁸¹ The FDA argues that it is only preempted with respect to a “statement relating to smoking and health” that is placed on a “cigarette package”¹⁸² or a statement placed on “any package or in any advertisement . . . of a smokeless tobacco product.”¹⁸³ Otherwise, the FDA is free to regulate the promotion and sales of cigarettes and smokeless tobacco products in other ways—within its jurisdiction under the FDCA.

5. Analysis: The *Chevron* Test Applied

Two issues must be resolved before the reviewing court can conclude that the FDA has jurisdiction to promulgate the regulations in the proposed rule. First, Congress must not have intended to preclude FDA jurisdiction in the area of tobacco promotion and sales. Second, the FDA must have the statutory authority, under the FDCA, to promulgate the regulations in the proposed rule.

Both of these issues require the application of the two prong analysis in *Chevron*. Under *Chevron*, the first question is whether Congress has clearly intended to preclude FDA jurisdiction in this area.¹⁸⁴ If the intent is clear, that ends the analysis. If it is not, the court must defer to the FDA’s reasonable interpretation that its jurisdiction has not been precluded.

181. The preemption clause of the Cigarette Act provides:

Section 1334. Preemption

(a) Additional Statements

No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any *cigarette package*.

(b) State regulations

No requirement or prohibition based on smoking and health shall be imposed under *State law* with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. § 1334 (1994) (emphasis added).

Similarly, the preemption clause of the Smokeless Act provides:

Section 4406. Preemption

(a) Federal action. *No statement* relating to the use of smokeless tobacco products and health, other than the statements required by section 3, *shall be required by any Federal agency to appear on any package or in any advertisement . . . of a smokeless tobacco product*.

(b) State and local action. No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 3, shall be required by any *State or local statute or regulation* to be included on any package or in any advertisement . . . of a smokeless tobacco product.

Id. § 4406 (emphasis added).

182. *Id.* § 1334.

183. *Id.* § 4406.

184. *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984).

As previously stated, opponents to the proposed rule argue that the FDA is without jurisdiction because (1) Congress has never delegated specific authority on this issue to the FDA, (2) Congress rejected legislation containing the same or similar regulations, and (3) previous FDA officials have stated that the FDA lacks jurisdiction in this area. However, none of these points is dispositive on the issue of congressional intent. Particularly, Congress' decision to abstain from action is not, itself, a definitive statement of congressional intent.

More persuasive is the fact that Congress had the opportunity to preclude the jurisdiction of federal agencies, other than the FTC and FCC, when crafting the preemption clauses of the Cigarette Act and Smokeless Act. However, Congress declined to do so, presenting a genuine ambiguity as to whether Congress intended to preclude FDA action in the area of labeling and advertising of tobacco products. Therefore, the reviewing court must consider prong two of *Chevron* and determine whether the FDA's interpretations of the Cigarette Act and Smokeless Act are "reasonable."¹⁸⁵ The FDA has interpreted these Acts to mean that FDA jurisdiction is not precluded.¹⁸⁶ This interpretation seems "reasonable" because had Congress wished to preclude the jurisdiction of the FDA, or other federal agencies, it would have done so in the preemption clause. Therefore, the reviewing court should hold that the FDA is not precluded from regulating in the area of tobacco promotion and sales.

However, just because the FDA is not precluded from acting in this area does not mean the FDA has the statutory authority to do so. Next, the reviewing court must determine whether the FDCA authorizes the FDA to regulate nicotine as a drug, and tobacco products as drug delivery devices. Again, under *Chevron*, the reviewing court must first determine whether Congressional intent is clear on this issue.¹⁸⁷ Because the FDCA makes no mention of tobacco or nicotine regulation by the FDA, Congressional intent is not clear.¹⁸⁸

185. *Id.* at 843-44.

186. 60 Fed. Reg. 41,353 (1995).

187. *Chevron*, 467 U.S. at 842-43.

188. The facts here are analogous to the facts in *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633 (1990). In *LTV*, the Supreme Court noted that Congress had authorized the Pension Benefit Guarantee Corporation ("PBGC") to take over the assets and liabilities of an insolvent pension plan, created under Title IV of the Employee Retirement Income Security Act (29 U.S.C. § 1347 (1995)). The PBGC adopted a policy whereby it restored plan liabilities whenever a firm created a "follow on" plan—an action that Congress had never explicitly authorized. *LTV*, 496 U.S. at 637, 648-49. Nevertheless, the Supreme Court held that the district court need only determine whether there is "any clear congressional desire to *avoid*" such action by the PBGC. *Id.* at 648 (emphasis added). If not, the district court must defer to the agency's

Second, the reviewing court must determine whether the FDA's interpretation of the FDCA is "reasonable." Because the issue involves technically complex matters within the agency's expertise, the reviewing court must give substantial deference to the FDA.¹⁸⁹ Applying the facts to the FDCA definitions of "drug" and "device," it seems reasonable to conclude that nicotine is a "drug" because it causes addiction and other psychoactive effects.¹⁹⁰ Thus, it affects "any function of the body."¹⁹¹ Moreover, it is reasonable to conclude that cigarettes and smokeless tobacco products are "devices" because they are used to deliver the drug, nicotine, into the body and are therefore "instrument[s] . . . intended to affect . . . any function of the body."¹⁹² Therefore, the FDA's interpretation is "reasonable" and the reviewing court should conclude that the FDA has the statutory authority to promulgate the proposed regulations.

reasonable interpretation of the statute.

Analogously, Congress has expressly authorized the FDA to regulate drugs and devices, but has not explicitly authorized the FDA to regulate nicotine as a drug, or tobacco products as delivery devices. However, under the reasoning in *LTV*, the reviewing court must only determine whether Congress clearly intended to *avoid* such action by the FDA. If not, the reviewing court must defer to the FDA's reasonable interpretation of the FDCA. Because Congress has not spoken on this issue, it has shown no clear intent to preclude such FDA action. Therefore, the reviewing court must defer to the FDA's "reasonable" interpretation of the FDCA.

189. *Chevron*, 467 U.S. at 865-66. The Supreme Court stated:

[T]he Administrator's interpretation . . . is entitled to deference: the regulatory scheme is technical and complex [and] the agency considered the matter in a detailed and reasoned fashion Judges are not experts in the field, and are not part of either political branch of the Government. . . . [A]n agency to which Congress has delegated policymaking responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices [F]ederal judges—who have no constituency—have a duty to respect legitimate policy choices made by those who do.

Id.

Moreover, on the issue of judicial deference to the FDA regarding the classification of a substance as a "new drug" under the definition in the FDCA, the Supreme Court stated:

We think that it is implicit in the regulatory scheme . . . that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the "new drug" status of individual drugs or classes of drugs. . . . Clearly, if the FDA were required to litigate, on a case-by-case basis, the "new drug" status of each drug now marketed, the regulatory scheme of the Act would be severely undermined, if not totally destroyed. . . . *Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.*

Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653-54 (1973) (emphasis added).

190. See *supra* notes 147-50 and accompanying text.

191. 21 U.S.C. § 321(g)(1)(C) (1994).

192. *Id.* § 321(h)(3).

*B. Does the United States District Court Have
Jurisdiction over the Pending Actions?*

A second jurisdictional issue is whether the reviewing court has jurisdiction to hear the actions challenging the FDA proposed rule. Federal courts generally do not hear challenges to agency actions unless the agency action is "final," the case is "ripe," and the plaintiff has exhausted all available administrative remedies.¹⁹³

1. Final Agency Action

The Administrative Procedures Act ("APA") gives jurisdiction to federal courts only over a "final agency action."¹⁹⁴ According to the Supreme Court, an "agency action" includes any "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."¹⁹⁵ Furthermore, the Court has noted that "finality" exists when "regulations have the force of law" or when they are promulgated by an agency "and the expected conformity to them causes injury cognizable by a court of equity."¹⁹⁶

Applied to the challenges to the proposed rule, the FDA has taken two actions. First, the FDA has declared that it has jurisdiction to regulate the promotion and sales of tobacco products pursuant to its statutory authority under the FDCA. Second, the FDA has proposed a number of regulations to restrict the promotion and sales of tobacco in order to protect children and adolescents. Both of these actions are agency actions because they are "designed to implement . . . or prescribe law or policy."¹⁹⁷ For an action to be reviewable, however, it must be "final."¹⁹⁸ A separate analysis must be made for each.

In determining whether an agency action is "final" and "fit for judicial review," the Supreme Court has considered whether: (1) the action was

193. See generally DAVIS & PIERCE, *supra* note 167, at 307-15, 360-71. It should be noted that ripeness and exhaustion are not jurisdictional issues but discretionary doctrines which allow a United States district court to dismiss an action, or otherwise refrain from hearing the merits, until the case is ripe and the administrative remedies have been exhausted. See *infra* parts VI.B.2-3.

194. 5 U.S.C. § 704 (1994).

195. *Abbott Lab. v. Gardner*, 387 U.S. 136, 149 (1967) (quoting 5 U.S.C. § 551(4)).

196. *Id.* at 150 (citing *Columbia Broadcasting Sys. v. United States*, 316 U.S. 407, 418-19 (1942)).

197. *Id.* at 149 (quoting 5 U.S.C. § 551(4)).

198. 5 U.S.C. § 704 (1994).

definitive; (2) the action had a direct practical effect on the plaintiff; (3) the question at issue is fit for judicial resolution; and (4) immediate judicial review would foster agency and judicial efficiency.¹⁹⁹

Under the four part *Standard Oil* test, the specific regulations in the FDA proposed rule should not be held a final agency action for the following reasons. First, the proposed rule is not “definitive” because it does no more than present a proposal that may or may not be promulgated and enforced as written. Second, the proposed rule is not “fit” for judicial review because no rule has been made and the reviewing court would only waste its time adjudicating a proposed rule that may never be promulgated as written, or at all. Third, immediate judicial review of the proposed rule would not likely foster agency or judicial efficiency. The FDA should have an opportunity to review written comments and amend the proposed rule; a reviewing court’s intervention would only interfere with this process. Also, it would not be efficient for the court to address the issues only to have the FDA amend the proposal, thus forcing the court to re-adjudicate these issues after the final rule is promulgated.

However, the FDA’s assertion of jurisdiction should be held to be a final agency action, under the *Standard Oil* test, for the following reasons. First, the assertion of jurisdiction appears to be “definitive” because the FDA has made a conclusive statement that it has the authority to regulate tobacco products as drug delivery devices.²⁰⁰ Given the definitiveness of the FDA’s statement, it does not appear likely that the FDA will change its mind after reviewing written comments from opponents and decide that it has no jurisdiction. Second, the assertion of jurisdiction (and the specific regulations in the proposed rule) have already had, and will continue to have, a “direct practical effect” upon the plaintiffs. Specifically, tobacco manufacturers, advertisers, and vendors claim that they have been forced to make adjustments for likely major disruptions in tobacco sales and advertising revenues as a result of the FDA’s proposed rule.²⁰¹ Third, the assertion of jurisdiction is “fit” for judicial review because the FDA has already asserted jurisdiction—nothing will make the jurisdictional issue any more fit for review. Fourth, immediate judicial review of the FDA’s

199. *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 239-40 (1980). See *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 857 F. Supp. 1137 (M.D.N.C. 1994) (applying the four part test in *Standard Oil*). See also discussion *infra* part VIII.B.

200. The FDA states: “The agency’s comprehensive investigation and legal analysis support a finding at this time that cigarettes, cigarette tobacco, and smokeless tobacco are subject to regulation on the basis of their nicotine content and intended use FDA may, in its discretion, regulate them using the [FDCA’s] device provisions.” 60 Fed. Reg. 41,351 (1995).

201. See *American Advertising Fed’n*, *supra* note 15, at 11-12.

assertion of jurisdiction is likely to foster agency and judicial efficiency. If the reviewing court concludes, at the outset, that the FDA has no jurisdiction to regulate in this area, both the reviewing court and the agency would avoid an unnecessary expenditure of time, money and effort to litigate the legality of each proposed regulation.

Therefore, under the *Standard Oil* test, the reviewing court should hear the challenges to the FDA's assertion of jurisdiction but should refrain from hearing the merits of the legality of each proposed regulation until the FDA has promulgated a final rule.

2. Ripeness

The ripeness doctrine authorizes a federal court to abstain from hearing a case if it is not yet fit for judicial review. In *Abbott Laboratories*,²⁰² the Supreme Court stated the rationale behind the ripeness requirement and established a two prong test for determining ripeness.

[T]he ripeness doctrine . . . is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a two fold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.²⁰³

As applied here, the two prong test of *Abbott Laboratories* shows that the proposed rule is not yet fit for judicial review because it is just that, a proposal. Until the FDA has had an opportunity to review all written comments, make any appropriate changes, and promulgate a final rule in accordance with these changes, the case will not be fit for judicial review. However, the court must consider the hardship to the parties in withholding court consideration. On the one hand, if the reviewing court determines that the FDA will likely promulgate a final rule very similar to the proposed rule, immediate review would save time and money for both the FDA and the companies challenging the proposed rule.

If the rule is upheld, its enforcement thereafter can be swift, efficient, and inexpensive. Moreover, the agency is then in a

202. *Abbot Lab. v. Gardner*, 387 U.S. 136 (1967).

203. *Id.* at 148-49.

position to build the rest of its regulatory . . . policies around the rule. Even if the rule is reversed, the agency benefits from prompt resolution of the issue. The agency then can begin immediately to pursue an alternative means of performing its statutory missions.²⁰⁴

Also, the tobacco manufacturers, advertisers and vendors challenging the FDA action claim that they have suffered and will continue to suffer hardship resulting from the issuance of the proposed rule. Specifically, the billions of dollars spent annually on tobacco promotion and advertising,²⁰⁵ and the many more billions in tobacco product sales revenue, hang in the balance of the determination of whether the FDA has jurisdiction and whether the regulations are legally sound. As a result, long-term business planning is severely disrupted by the likely impacts of the proposed rule on tobacco-related industries.

Because ripeness is a discretionary doctrine, the reviewing court may apply the *Abbott Laboratories* test as it sees fit, and it has full discretion on whether the merits of the case should be heard. It seems apparent from the facts, however, that reviewing the challenges to each provision of the proposed rule would be premature if done prior to the FDA's promulgation of a final rule.

3. Exhaustion of Administrative Remedies

A second, and related, discretionary doctrine is that of exhaustion. Federal courts generally require a plaintiff to exhaust all remedies available in the administrative agency before bringing suit in federal court. In *Myers v. Bethlehem Shipbuilding Corp.*,²⁰⁶ the Supreme Court stated unequivocally: "[It is] the long settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted."²⁰⁷ The FDA

204. DAVIS & PIERCE, *supra* note 167, at 376. Davis & Pierce also note that "practical concerns" exist when opponents of a rule seek review in court before the rule is ever enforced because this allows the challenger "to frustrate an agency's pursuit of its goals for a protracted period of time by seeking review . . . in the district court most sympathetic to the petitioner's views." *Id.* With notable prescience, Davis & Pierce state:

If, for instance, the rule adversely affects the tobacco industry, the industry might seek review in a district court located in the heart of the tobacco growing region. As a result, a single district judge, perhaps with aberrational views on the issue, could delay significantly an agency's pursuit of a major national goal.

Id.

205. See *supra* text accompanying note 39.

206. 303 U.S. 41 (1938).

207. *Id.* at 50-51. See DAVIS & PIERCE, *supra* note 167, at 307.

proposed rule provides that interested parties may provide the FDA with written comments that will be taken into consideration when the agency crafts the final rule. Because the plaintiffs brought suit prior to the promulgation of a final rule, they have not exhausted the administrative procedures required of a formal rulemaking—specifically, the notice and comment period, an opportunity for the agency to respond to comments, and the promulgation of a final rule. However, if the reviewing court determines that the case should be heard before a final rule is promulgated, due to either likely hardship on the parties or other factors weighing in favor of immediate review, the court may waive the exhaustion requirement.

This Comment has discussed the constitutional and jurisdictional considerations relating to the proposed regulations on the advertising, promotion, and sales of tobacco products. However, a separate analysis must be conducted to determine the legality of the proposed national educational program, funded by tobacco manufacturers.²⁰⁸

VII. LEGALITY OF THE EDUCATIONAL CAMPAIGN FUND

The question to be resolved is whether the FDA has the authority to require manufacturers to pay into a \$150 million educational fund for the purpose of financing anti-tobacco advertisements directed at young people. The FDA notes that a similar program was implemented by the FCC between July 1967 and December 1970.²⁰⁹ Under the program, the FCC required broadcasters to run anti-smoking messages on television and radio in response to industry-sponsored, pro-smoking advertisements in these media.²¹⁰ The FCC based its authority for the program on the “Fairness Doctrine.”²¹¹ During the FCC program, one anti-smoking message appeared for every three or four industry-sponsored, pro-smoking advertisements, amounting to approximately \$75 million (in 1970 dollars) in commercial air time for anti-smoking messages annually.²¹² On

208. An outline of the proposed educational program is presented *supra* part IV.C.2.

209. 60 Fed. Reg. 41,326-27 (1995).

210. 60 Fed. Reg. 41,327 (1995).

211. 60 Fed. Reg. 41,326-27 (1995). The “Fairness Doctrine” required that broadcast media licensees provide a reasonable opportunity for the presentation of contrasting viewpoints on the coverage of important controversial issues. See *Syracuse Peace Council v. FCC*, 867 F.2d 654, 655 (D.C. Cir. 1989) (upholding FCC’s repeal of the “Fairness Doctrine”).

212. 60 Fed. Reg. 41,327 (1995).

January 1, 1971 all tobacco advertisements were banned from television and radio,²¹³ thus ending the FCC's "counterspeech" program.²¹⁴

The FDA cannot claim the same authority for its educational program because the Fairness Doctrine has been repealed.²¹⁵ Therefore, the FDA must claim authority under the FDCA—specifically, under the FDA's power to regulate all labeling and advertising of drugs and drug delivery devices.²¹⁶ However, regulating labeling and advertising of drugs and delivery devices is a far cry from requiring manufacturers of a drug or delivery device to contribute to a fund for the purpose of buying advertisements to dissuade the public from using that drug or delivery device. Congress has not authorized the FDA to take such action either in the FDCA or any other federal statute. Without clear statutory authority, the reviewing court should hold that the FDA is without authority to create the educational campaign fund.

VIII. THE BACKGROUND OF JUDGE OSTEEN

A full analysis of the issue requires examination of the record of the judge assigned to the cases challenging the proposed rule. United States District Judge William L. Osteen, Sr., who will hear the four cases brought by tobacco manufacturers, advertisers and vendors,²¹⁷ has a history on tobacco issues that may provide some insight on how he will approach the litigation.

A. Past Lobbying Activity

In 1974, William Osteen, as a private attorney, was hired by an organization of North Carolina tobacco growers to lobby the Secretary of Agriculture in Washington, D.C., to save a federal tobacco production quota program slated for elimination.²¹⁸ Osteen was successful in keeping the quota program alive.²¹⁹ However, prior to his appointment to the bench, Osteen was a private attorney for more than twenty years in North Carolina, a major tobacco producing and manufacturing state. Because this one instance was Osteen's only representation of a tobacco

213. 15 U.S.C. § 1335 (1994).

214. 60 Fed. Reg. 41,327 (1995).

215. See *Syracuse*, 867 F.2d at 655.

216. 60 Fed. Reg. 41,350 (1995).

217. For a list of the plaintiffs, see *supra* notes 14-17.

218. *Judge Once Worked as Tobacco Lobbyist*, N.Y. TIMES, Aug. 23, 1995, at D3.

219. Scott Solomo, *Judge's Past Poses No Conflict, Observers Say*, NEWS & REC., Aug. 19, 1995, at B1.

company or organization, it does not necessarily indicate a bias in favor of the tobacco industry.

B. *The Flue-Cured Tobacco Decision*

In June 1995, Judge Osteen entered a preliminary ruling in *Flue-Cured Tobacco Cooperative Stabilization, Corp. v. United States Environmental Protection Agency*.²²⁰ The case, currently pending in Judge Osteen's court, involves a challenge by tobacco manufacturers to the Environmental Protection Agency's ("EPA") determination that second-hand smoke (technically referred to as "environmental tobacco smoke" or "ETS") is a known human carcinogen. The EPA moved to dismiss the case, arguing that its determination was not an "agency action," as defined by the Administrative Procedure Act, and therefore the court had no jurisdiction to hear the challenge.²²¹

In his memorandum opinion, Judge Osteen held that the issuance of the report and classification constituted an "agency action" because (1) the EPA was required by statute to issue such a report; (2) the issuance of the report had completed a notice and comment process (similar to a rulemaking); and (3) the report and classification had an indirect regulatory effect by leading the United States Postmaster General and the General Services Administration to independently institute regulations within their departments on second-hand smoke.²²²

Applying the four part test from *Standard Oil*,²²³ Judge Osteen also found that the agency action was "final" because (1) it classified ETS as a known human carcinogen and was therefore "definitive;" (2) it had a direct practical effect on the plaintiffs, given the actions by the Postmaster General and GSA; (3) the questions at issue were "fit" for judicial resolution; and (4) immediate judicial review would foster agency and judicial efficiency.²²⁴

220. 857 F. Supp. 1137 (M.D.N.C. 1994). Additional plaintiffs include: The Council for Burley Tobacco, Inc.; Universal Leaf Tobacco Co., Inc.; Philip Morris Inc.; R.J. Reynolds Tobacco Co.; and Gallins Vending Co.

Judge Osteen was assigned the four actions challenging the FDA proposed rule by the middle district's court clerk, J.P. Creekmore, for reasons of judicial economy—both the *Flue-Cured Tobacco* case and the four FDA challenges involve government regulation of tobacco. Harvey Berkman, *Question of Judicial Bias Raised*, NAT'L L.J., Aug. 28, 1995, at A21.

221. *Flue-Cured Tobacco*, 857 F. Supp. at 1139.

222. *Id.* at 1141-42.

223. *See supra* part VI.B.1.

224. *Flue-Cured Tobacco*, 857 F. Supp. at 1143-44.

The preliminary ruling in *Flue-Cured Tobacco* may be helpful in predicting how Judge Osteen might rule on the reviewability of the FDA's proposed rule and assertion of jurisdiction prior to the promulgation of a final rule. Part VI.B.1 of this Comment applies the four part *Standard Oil* test to the FDA proposed rule and assertion of jurisdiction in the same way Judge Osteen applied the *Standard Oil* test in *Flue-Cured Tobacco*. Judge Osteen is likely to conclude that the FDA's assertion of jurisdiction is a "final agency action" and therefore immediately reviewable. However, the specific proposed regulations will not be "final" and thus not reviewable until a final rule has been promulgated.

C. Other Commentary on Judge Osteen

Some anti-tobacco activists are speculating that due to Judge Osteen's past history and recent decision in *Flue-Cured Tobacco*, he will not give the issue a fair hearing. John Banzhaf, an attorney and executive director of Action on Smoking and Health in Washington, D.C., was quoted as saying that the tobacco companies "chose from all the federal judges the single federal judge most likely to be sympathetic to their point of view."²²⁵ Also, Richard A. Daynard, chairman of the Tobacco Products Liability Project at Northeastern University School of Law in Boston, was quoted as saying, "I think the [tobacco] industry expects to have a series of favorable preliminary rulings, and at the very least, as much delay as they can possibly get . . . [a]mong Southern lawyers it's called home cooking, helping out the friends and neighbors."²²⁶

D. Analysis

Despite the above statements, there is little evidence to suggest that Judge Osteen will not give the matter a fair hearing. First, the preliminary ruling in *Flue-Cured Tobacco* appears to be a fair analysis of the facts applied to his reasonable interpretation of administrative law. Judge Osteen seemed to show no outward sympathies favoring one side over another. Second, news reports indicate that the judge is a non-smoker.²²⁷ Third, the FDA has not filed a motion objecting to Judge Osteen's assignment to the case or requesting the judge to recuse himself from the case. Perhaps the FDA does not question the judge's fairness or the FDA may suspect

225. Solomo, *supra* note 219.

226. Glenn Collins, *Judge Who Ruled Pro-Tobacco Named to Hear Companies' Suit*, N.Y. TIMES, Aug. 15, 1995, at D1.

227. Berkman, *supra* note 220.

such a motion would fail and does not want to risk offending the judge, or it hopes to avoid other judges in the Middle District of North Carolina who may be entirely unsympathetic to the FDA's position.

IX. CONCLUSION

The FDA proposed rule addresses one of the largest preventable health problems in the United States. Despite the fact that every state prohibits young people from using tobacco products, four million people under the age of eighteen use these products.²²⁸ Statistics indicate that eighty to ninety percent of young people who regularly smoke will become addicted to the nicotine²²⁹ and, of this group, one third will die from illnesses caused by their smoking.²³⁰ Currently, 400,000 Americans die *every year* from tobacco-caused illnesses.²³¹ In comparison, 46,000 American soldiers were killed during the *fourteen years* of the Vietnam War.²³²

Congress has refused to act on this issue in any meaningful manner and has preempted the states from taking any action with respect to the advertising or promotion of cigarettes.²³³ Given that the tobacco industry can afford to spend \$6.2 billion every year on advertising and promotion of its products,²³⁴ it is not difficult to imagine that the industry is equally generous regarding the reelection efforts of enough key members of Congress to ensure the defeat of all meaningful reform legislation. As a result, the tobacco industry has been left to regulate itself.

In response, the FDA has claimed jurisdiction over the issue by declaring nicotine a drug, thus enabling it to regulate cigarettes and smokeless tobacco products. The proposed rule presents two sets of legal issues. First, is the proposed rule constitutional? As discussed above, this Comment concludes that it is. Commercial speech is given only limited protection under the Constitution. If the government can show that its restriction will directly advance a substantial governmental interest, and the

228. See SGR 1994, *supra* note 5.

229. See *supra* text accompanying note 149.

230. 60 Fed. Reg. 41,338 (1995).

231. See DHHS, *Cigarette Smoking—Attributable Mortality*, *supra* note 1, at 645.

232. RICHARD B. MORRIS, *ENCYCLOPEDIA OF AMERICAN HISTORY* 505 (1976).

233. 15 U.S.C. § 1334(b) (1994); *Id.* § 4406(b).

234. See *supra* note 39.

restriction is narrowly tailored to achieve the desired objective, the restriction will be upheld.²³⁵

Second, does the FDA have jurisdiction to regulate in this area? As discussed above, this Comment concludes that it does. The FDA has the power to regulate "drugs" and drug delivery "devices" under the FDCA. The FDA has determined that nicotine, which causes addiction and other psychoactive effects, is a "drug" because it is an article "intended to affect . . . any function of the body."²³⁶ Similarly, nicotine-containing tobacco products are "devices" under the same definition.²³⁷

In *Chevron*, the Supreme Court held that if the intent of Congress is not clear, the reviewing court must defer to the agency's reasonable statutory interpretation.²³⁸ Here, Congress may preclude FDA jurisdiction concerning tobacco regulations at any time. However, it is not clear that Congress has intended yet to do so. The preemption clauses of the two federal statutes concerning tobacco regulation²³⁹ are narrowly drafted and do not preclude other agencies, including the FDA, from regulating in the area of tobacco promotion and sales. In matters involving technically complex issues within the agency's expertise, a reviewing court must give substantial deference to the agency's reasonable interpretation of the federal statute.²⁴⁰ Here, the FDA's interpretation that nicotine is a drug and tobacco products are devices, under their respective definitions in the FDCA, is reasonable. As such, the reviewing court should give effect to the FDA's interpretation.

A final consideration is whether the FDA proposed rule is sound public policy. Because this question is not legally based, it is beyond both the scope of this legal analysis and the District Court's scope of reviewability. However, it merits consideration.

Most people would agree that children under eighteen should not be permitted to smoke or use smokeless tobacco products. Indeed, the law in every state prohibits them from doing so. But four million of them still use these products, and the number increases every year. The meager efforts expended have not been successful. The FDA proposed rule seeks to take several major steps to address the problem. To buy cigarettes, minors

235. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-64 (1980).

236. 21 U.S.C. § 321(h)(3) (1994).

237. *Id.* § 321(g)(1)(C).

238. 467 U.S. at 865.

239. 15 U.S.C. § 1334 (1994); *Id.* § 4406.

240. *Chevron U.S.A. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 865-66 (1984).

would need picture identification to prove that they are at least eighteen and they could only purchase from sales clerks, not from vending machines or other indirect sales methods. The proposal would also eliminate the barrage of pro-tobacco advertisements featuring “cool” camel cartoons, “rugged” cowboys, and “victorious” race car drivers—images that play to young people’s natural insecurities, enticing them to begin smoking or using smokeless tobacco.

These measures will not solve the problem entirely. The FDA hopes to cut the rate of underage tobacco use in half—a reasonable goal.²⁴¹ As a result, the proposed rule would preserve millions of lives in the future, save the American public an estimated twenty-eight to forty-three billion dollars per year from reduced medical costs, productivity gains from reduced morbidity, and averted premature fatalities.²⁴² Notwithstanding the inevitable costs and inconvenience to tobacco manufacturers, advertisers, and vendors, the tremendous benefits the regulations would have on the nation in general make the proposal most worthwhile.

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241. 60 Fed. Reg. 41,314 (1995).

242. 60 Fed. Reg. 41,359 (1995).

* The author would like to thank Professor William Araiza for his assistance, as well as the staff and editors of the Entertainment Law Journal, notably Tamara Kapan and Cynthia Barnes. This Comment is dedicated to those who work to protect the health and welfare of America’s youth.

