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The FDA Sends Smoke Signals to Big Tobacco: Will the FDA Suffer Backlash, Will Alcohol Be Regulated Next, and Will the Health of Americans Prevail?

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INTRODUCTION

On August 28, 1996, the Food and Drug Administration (FDA) boldly announced its controversial regulation of tobacco products.[1] The ruling received sharp criticism from several members of Congress who believe the FDA has neither the time nor the resources to regulate the tobacco industry.[2] The tobacco, advertising, convenience store, and medical device industries also questioned the ruling and contended that the FDA has no business regulating tobacco.[3] President Clinton,[4] the Federal Trade Commission (FTC),[5] and groups such as the Campaign for

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1. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

2. *See* Jeanne Cummings, *Preventative Care Gains Support; But Gingrich Rejects Targeting Tobacco*, ATLANTA J. & CONST., Sept. 26, 1996, at 12A, *available in* LEXIS, News library, Curnws File; *see also* Interview by Natalie Allen with Rep. Scott Baesler (D-KY),(CNN television broadcast, Aug. 21, 1996), *available in* LEXIS, News Library, Curnws File (stating that Rep. Scott Baesler is against the FDA proposal because of the impact it will have on tobacco farmers).

3. *See* Coyne Beahm, Inc. v. United States FDA, 966 F. Supp. 1374 (M.D.N.C. 1997). Other plaintiffs in *Coyne Beahm, Inc.* include Brown & Williamson Tobacco Corp., Lorillard Tobacco Co., Philip Morris Inc., R.J. Reynolds Tobacco Co., American Advertising Federation, National Association of Convenience Stores, and United States Tobacco Co. *See id.* at 1374.

If the FDA's ruling and restrictions go into effect, the advertising industry will lose "thousands of jobs and between $712 million and $2.1 billion in billings per year." *See* Daryl Travis, *A Look At . . . Selling Tobacco: Advertising Our Dishonor; My Industry Should Be Ashamed of Itself for Pushing Cigarettes on Kids*, WASH. POST, Sept. 8, 1996, at C3.

4. *See Remarks By the President During the Announcement of Food and Drug Administration Rule on Children and Tobacco*, FDCH FED. DEP'T AND AGENCY DOCUMENTS, Aug. 23, 1996, *available in* LEXIS, News Library, Curnws File.

5. *See FTC Voices Support For FDA's Goal of Reducing Use by Children, Adolescents*, BNA HEALTH CARE DAILY, Jan. 8, 1996, at D3 *available in* LEXIS, Health Library, BNA Health Pubs.

Tobacco-Free Kids,[6] however, commended the FDA for taking affirmative action to protect the health of future generations. Additionally, a national opinion poll revealed that a majority of Americans, "including eighty percent of Southerners and smokers," support the FDA's ruling to regulate tobacco products.[7] Despite the nation's seeming approval of the ruling, the legalities and politics intertwined with the ruling may prevent implementation of these regulations.[8]

This Comment discusses the FDA's ruling, its criticisms and impact, as well as the politics involved. More specifically, Part I describes the purpose and function of the FDA,[9] the FDA's reasons for deciding to regulate tobacco,[10] and the FDA's assertion of jurisdiction over tobacco.[11] Part II analyzes the litigation opposing the FDA ruling,[12] as well as the impact of the ruling on the tobacco industry and society as a whole.[13] Part III explores the politics intertwined with the ruling,[14] the contemporaneous FDA reform legislation spawned in Congress,[15] and the proposed settlement between the state attorney generals and the tobacco companies.[16] Part IV sets forth the implications of the FDA ruling for other industries, focusing particularly on the alcohol industry.[17] This Comment concludes by discussing the likelihood that the ruling will be implemented as written and whether implementation of the ruling is socially desirable.[18]

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6. *See Anti-Tobacco Ads Hit Marks, Says Campaign for Tobacco-Free Kids*, U.S. NEWSWIRE, Oct. 7, 1996, *available in* LEXIS, News Library, Curnws File.

7. *See* Arnesa Howell, *Poll Shows Strong Support For FDA Rule to Prevent Sales, Marketing to Children*, BNA HEALTH CARE DAILY, Sept. 6, 1996, at D13, D13, *available in* LEXIS, Health Library, BNA Health Pubs. File.

8. *See infra* notes 95-130 and accompanying text.

9. *See infra* notes 19-24 and accompanying text.

10. *See infra* notes 25-85 and accompanying text.

11. *See infra* notes 86-94 and accompanying text.

12. *See infra* notes 95-130 and accompanying text.

13. *See infra* notes 131-49 and accompanying text.

14. *See infra* notes 150-69 and accompanying text.

15. *See infra* notes 170-91 and accompanying text.

16. *See infra* notes 192-219 and accompanying text.

17. *See infra* notes 220-58 and accompanying text.

18. *See infra* pp. 29-30.

I. THE FDA RULING

A. The History and Background of the FDA

In 1938, Congress enacted the Federal Food, Drug, and Cosmetics Act (FDCA) to protect consumers' health and welfare by preventing the introduction or receipt of misbranded or adulterated medicines, foods, or cosmetics.[19] To give effect to the FDCA, the FDCA conferred the authority to issue regulations to the Secretary of Health and Human Services.[20] Furthermore, the FDCA granted the Secretary authority to restrict the sale, distribution, or use of drug delivery devices.[21]

The Secretary delegated the authority to act under the FDCA to the Commissioner of the Food and Drug Administration (FDA).[22] To protect consumers, the FDA has the "power to approve and regulate drugs, vaccines, over-the-counter remedies, food additives, medical devices, and animal medications; to inspect factories and set standards on food production; to sample marketed foods for impurities; and to regulate advertising for food, drugs, and cosmetics."[23] The FDA claims jurisdiction to regulate tobacco products under these delegated powers.[24]

B. The FDA's Research of the Tobacco Industry

The FDA's extensive research of the tobacco industry led to the formulation of the 1996 Ruling regulating the sale, distribution, and advertising of tobacco products. The FDA uncovered the following statistics concerning tobacco use in general: (1) currently, almost fifty million people in America smoke cigarettes;[25] (2) an additional six million use smokeless tobacco;[26] (3) tobacco-related diseases claim the lives of

19. *See* 21 U.S.C. §§ 301-395 (1994 & Supp. 1997); *see also* United States v. Two Bags, Poppy Seeds, 147 F.2d 123, 126-27 (6th Cir. 1945) (discussing the intent of the FDCA).

20. *See* 21 U.S.C. § 371(a) (1994).

21. *See id.* § 360j(e)(1).

22. *See* 21 C.F.R. § 5.10(a) (1997).

23. *Perspectives GOP Sets Its Sight on Food & Drug Administration*, MED. & HEALTH, Feb. 20, 1995, *available in* LEXIS, News Library, Arcnws File.

24. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,400 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

25. *See id.* at 44,398 & n.1.

26. *See id.*

over 400,000 Americans each year,[27] exceeding the combined number of deaths due to "acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires."[28]

The FDA then focused its research on tobacco trends among children and adolescents.[29] A 1994 study revealed that almost three million adolescents in the United States smoke cigarettes and another one million male adolescents chew smokeless tobacco.[30] Seventy percent of smokers between the ages of twelve and seventeen regret starting to smoke and sixty-six percent of adolescent smokers want to quit.[31] More than half of the eighty-two percent of adults who have ever smoked evolved into regular smokers by the age of eighteen.[32] Furthermore, research indicates that an adult smoker who began smoking as a teen-ager increases his or her risk of dying from a tobacco-related disease.[33] Most importantly, one out of every three adult smokers who began smoking as an adolescent and continued smoking as an adult will die prematurely because of their addiction.[34]

Subsequent to the FDA ruling, a new study was released bolstering the FDA's findings.[35] The study issued by the Office on Smoking and Health at the Federal Centers for Disease Control and Prevention discovered that 5.3 million Americans under the age of eighteen smoke, equaling almost eight percent of the total population of adolescents.[36] The Center for Disease Control believes that these figures may be low because of the "recent increases in smoking rates among minors."[37]

C. *The FDA's Research Indicating How Advertising Affects Children and Adolescents*

Studies uncovered by the FDA indicate that teenagers are particularly vulnerable to advertising of tobacco products for two reasons.[38] First,

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27. *See id. at* 44,398 & n.3.
28. *See id.* at 44,398 & n.4.
29. *See id.* at 44,398.
30. *See id.* & n.7.
31. *See id.* at 44,398 & n.9.
32. *See id.* at 44,398 & n.8.
33. *See id.* at 44,399 & n.15.
34. *See id.* at 44,399 & n.17.
35. *See* John Schwartz, *5 Million Young Smokers Risk Early Death, CDC Report Says*, WASH. POST, Nov. 8, 1996, at A3; *see also* Chip Jones, *Smoking Losses Outlined: CDC Officials Say It Cuts 12 Years Off Life*, RICHMOND TIMES-DISPATCH, Nov. 8, 1996, at A1, *available in* LEXIS, News Library, Curnws File.
36. *See* Jones, *supra* note 35, at A1.
37. *See id.*
38. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,485.

teenagers are at an age when their friends and peers are very important to their identity.[39] Secondly, the "benefit" to using tobacco products is immediate while the health risks associated with smoking are not seen for many years.[40] Advertising works by relating the advertising to teenagers' lives and by suggesting that peers are smoking cigarettes.[41] In fact, an R.J. Reynolds Tobacco Corporation memorandom revealed that adolescent smokers' choice of cigarettes represents a part of their identity and that the better the advertised brand targets teenagers' needs, the greater the probability that the advertised brand will be bought.[42] Advertisers employ these factors to exploit the only growing market for tobacco products.[43]

Cigarette manufacturers spend approximately $3.25 billion per year advertising their products.[44] In 1994, a study revealed that eighty-six percent of young smokers smoke the three most aggressively advertised cigarette brands.[45] Two recent studies concluded that the Joe Camel logo is recognizable by thirty-three percent of all three-year olds and almost every child over the age of six.[46] Consequently, Camel cigarettes control one-third of the adolescent cigarette market.[47] Tobacco companies argue that despite the FDA's research, jurisdiction to regulate tobacco rests with Congress, not the FDA.[48]

D. Background of Tobacco Regulation

In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act which required cigarette packages and advertisements to con-

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39. *See id.*
40. *See id.*
41. *See id.*
42. *See id.* at n.150.
43. *See infra* notes 133-34 and accompanying text.
44. *See* Steven Shelov et al., *Children, Adolescents, and Advertising; Committee on Communications*, 95 PEDIATRICS 295 (1995), *available in* LEXIS, Genmed Library, Ped File.
45. *See* Travis, *supra* note 3, at C3.
46. *See* Paul Mitchell Fischer et al., *Brand Logo Recognition By Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145, 3145 (1991) (discussing advertising effects on children).
47. *See* Joseph R. DiFranza et al., *RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children*, 266 JAMA 3149, 3149-53 (1991) (discussing the cigarette industry's need to recruit new smokers and stating that 90% of new smokers are adolescents).
48. *See infra* notes 105-09 and accompanying text.

tain specific health warnings.[49] More recently, however, the act was amended to enable tobacco manufacturers the choice of including stronger, more effective warnings.[50] In 1970, Congress again amended the Act, making it illegal for cigarette companies to advertise cigarettes on any medium subject to Federal Communications Commission (FCC) regulation.[51] Additionally, Congress enacted the Comprehensive Tobacco Health Education Act in 1986, subjecting smokeless tobacco products and advertisements to many of the same restrictions as those placed on cigarette products.[52] This Act mandated warning labels on all packages and advertisements[53] and prohibited the advertisement of smokeless tobacco on all forms of electronic communication.[54] In 1992, Congress enacted the Synar Amendment (officially known as the ADAHMA Reorganization Act).[55] Although not implemented until January 1996,[56] the Act requires states to reduce the number of attempts made by minors to purchase tobacco products.[57] As an enforcement measure, the Act requires states to perform random checks of tobacco retailers. Any states failing to comply with the Act risk losing federal funds for alcohol and drug abuse prevention.[58]

Over the past ten years, various bills were introduced in Congress that would have restricted tobacco advertising and promotion, yet none

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49. *See* 15 U.S.C. §§ 1331-1341 (1994).

50. *See id.* § 1333. Section 1333 requires that one of the following four warnings be stated on cigarette packages and advertising:

> [1.] SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
>
> [2.] SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> [3.] SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
>
> [4.] SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

Id.

51. *See id.* § 1335.

52. *See id.* §§ 4401-4408.

53. *See id.* § 4402(a)(1)-(2).

54. *See id.* § 4402(f).

55. *See* ADAHMA Reorganization Act of 1992 § 1926, 42 U.S.C. § 300x-26 (1994).

56. *See Smoking and the '96 Election: Clinton Ad Blasts Dole*, HEALTH LINE, July 10, 1996, *available in* LEXIS, News Library, Curnws File.

57. *See* ADAHMA Reorganization Act of 1992 § 1926; *see also* David E. Wilson, *North Ridgeville Eighth-Grader Takes Pledge*, PLAIN DEALER, Mar. 21, 1996, at 1B, 1B, *available in* 1996 WL 3542638 (discussing the random checks required by the Synar Amendment).

58. *See* ADAHMA Reorganization Act of 1992 § 1926(b)(2)(A); *see also* Karen Merk, *Tobacco Foes Want to Police Sales to Kids; Groups Offer Plan to Monitor Ban in Jefferson Stores*, COURIER-J., Aug. 28, 1996, at 1B, *available in* LEXIS, News Library, Curnws File (discussing the effect of the Synar Amendment).

were enacted.[59] For example, in 1987, House Bills 1272 and 1563 were introduced in the House of Representatives.[60] These bills, if enacted, would have prohibited all advertising of tobacco products, including the sponsoring of sports activities and the distribution of free samples of tobacco products.[61] In 1989, House Bills 1250 and 1493 were introduced in the House of Representatives.[62] If approved, these bills would have restricted tobacco advertising to black-and-white text only.[63] Similar to the bills presented in 1987, these later bills would have prohibited tobacco companies from sponsoring sports activities and distributing promotional items featuring tobacco company logos.[64] In 1990, House Bill 5041 was introduced.[65] The provisions in House Bill 5041, although not enacted, emulated the mandate of the FDA's current ruling, restricting most tobacco product advertisements to a black-and-white text only format.[66] Additionally, the bill would have banned tobacco advertisements within one thousand yards of schools, tobacco company sponsorships of sports activities, and the distribution of free samples of tobacco products.[67]

E. The FDA Ruling

The final FDA ruling, entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," was the product of the aforementioned FDA research.[68] The ruling reiterates the current law which prohibits persons under the age of eighteen from purchasing tobacco products.[69] In an effort to ensure that minors do not purchase tobacco products, the ruling requires retailers to check the purchaser's picture identification

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59. *See infra* notes 60-67 and accompanying text.
60. *See* H.R. 1272, 100th Cong. (1987); H.R. 1563, 100th Cong. (1987).
61. *See* H.R. 1272; H.R. 1563.
62. *See* H.R. 1250 § 3(a)(2)(A)-(B), 101st Cong. (1989); H.R. 1493 § 3(a), 101st Cong. (1989).
63. *See* H.R. 1250 § 3(a)(2)(A)-(B); H.R. 1493 § 3(a).
64. *See* H.R. 1250 § 3(a)(2)(A); H.R. 1493 § 3(b)(2).
65. *See* H.R. 5041, 101st Cong. (1990).
66. *See id.* § 5(a)(1)-(2).
67. *See id.* § 5(a)(3), (b).
68. *See generally* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897) (discussing the FDA's extensive research).
69. *See id.* at 44,439-40.

to verify that the purchaser is over the age of eighteen.[70] Additionally, the ruling prohibits the distribution of free samples of tobacco products.[71] The rule also bans cigarette vending machines in any place where minors are permitted.[72]

Arguably, the most controversial elements of the ruling are the advertising restrictions. Pursuant to the ruling, tobacco product advertising and labeling is limited to "black-and-white, text only format."[73] Furthermore, billboard advertisements of tobacco products are prohibited within one thousand feet of schools.[74] The FDA ruling also prohibits the distribution of non-cigarette promotional items featuring cigarette brand names.[75] Lastly, tobacco companies are forbidden from sponsoring sporting events unless it is in the corporate name.[76] Although the above mentioned rules do not set forth all of the new FDA regulations governing tobacco products, they are representative of the ruling as a whole.[77]

The FDA's primary goal in issuing the ruling was to reduce the number of adolescents who smoke by fifty percent within seven years.[78] The FDA's purpose was twofold.[79] The FDA sought to reduce children's access to tobacco products by prohibiting the distribution of free samples, banning cigarette vending machines in locations where minors are permitted, and by requiring photo verification for tobacco purchases.[80] The FDA also hoped to decrease children's attraction to

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70. *See id.* at 44,438-39. This element of the ruling is not challenged in the ongoing FDA litigation and was implemented on February 28, 1997. *See* The Small Entity Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents; Availability, 62 Fed. Reg. 8974 (1997) (to be codified at 21 C.F.R. pt. 897).

71. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,439, 44,460.

72. *See id.* at 44,439, 44,441, 44,448.

73. *See id.* at 44,439, 44,465-66. This element of the ruling was implemented on August 23, 1997. *See* John Schwartz, *Judge Hears Arguments on Tobacco Regulation*, WASH. POST, Feb. 11, 1997, at A3 (discussing implementations of restrictions on tobacco advertising).

74. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,439, 44,465-66.

75. *See id.*

76. *See id.* at 44,439, 44,466.

77. *See id.* at 44,439, 44,448, 44,462. The ruling also requires a minimum package size and the labeling of intended use information. *See id.*

78. *See* Maggie Mahar, *Parting Shots: FDA Commissioner Sees No Special Deal Ahead for Tobacco Companies*, BARRON'S, Dec. 30, 1996, at 29, 30 (stating that 90% of all smokers begin smoking before the age of eighteen).

79. *See infra* notes 80-81 and accompanying text.

80. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smoke-

tobacco products by restricting print and billboard advertising and by banning sport sponsorships and promotional items.[81] The FDA believed its ruling would result in a decrease in the amount of tobacco-related illnesses in the future.[82]

When David Kessler, the Commissioner of the FDA, resigned, many speculated as to the impact of his departure on the FDA's regulation of tobacco.[83] Analysts predicted that Kessler's resignation would not significantly affect the ruling because the ruling is backed by the Clinton administration.[84] Kessler agreed and explained that the ruling was final and only the courts or Congress, not a new FDA Commissioner, could retract it.[85]

F. FDA's Claim to Jurisdiction Over Tobacco

The FDA asserted jurisdiction over tobacco products by classifying cigarettes and smokeless tobacco as "combination products consisting of drug (nicotine) and device components intended to deliver nicotine to the body."[86] The FDA was given the "discretion to determine which

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less Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,396.

81. *See id.*

82. *See id.*

83. *See* John Carey & Mike France, *Kessler is Leaving, His Crusades Aren't*, BUS. WK., Dec. 9, 1996, at 42, 42.

84. *See Tobacco Regulations are Likely to Proceed*, COURIER-J., Nov. 26, 1996, at 6A, *available in* LEXIS, News Library, Curnws File.

85. *See* Carey & France, *supra* note 83, at 42.

86. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,400.

> For the FDA to have jurisdiction over "combination products," the products must a) contain a "drug" as that term is defined by the FDCA, and b) have the primary purpose of delivering or aiding in the delivery of a drug. Cigarettes and smokeless tobacco products meet both of these requirements.

Allison M. Zieve, *FDA's Proposed Regulation of the Sale and Promotion of Tobacco Products to Minors*, U.S. DEP'T OF HEALTH & HUM. SERV. PUB. HEALTH REP., May 1996, at 280, *available in* LEXIS, News Library, Arcnws File.

Drugs are defined by the FDCA as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body . . . ." 21 U.S.C. § 321(g)(1) (1996); *see* Zieve, *supra*, at 280.

A device is any "instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man . . . ." 21 U.S.C. § 321(h)(3) (1996).

authorities to apply in the regulation of combination products to provide the most effective protection to the public health."[87] The FDA determined that tobacco products were "most appropriately regulated under the device provisions of the act, including the restricted device authority in section 520(e) of the act (21 U.S.C. 360j(e))."[88] Essentially, the FDA brought tobacco products within its regulatory jurisdiction by classifying nicotine as a drug and by classifying tobacco products as drug delivery devices.

The FDA's regulation of nicotine patches bolstered the argument for the FDA's jurisdiction over tobacco.[89] The regulation of the nicotine patches provided "direct precedent for the FDA's decision to regulate tobacco products as nicotine-delivery systems with the status of combination products."[90] Previously, the FDA did not consider tobacco products within its jurisdiction, but the FDA changed its position primarily because of the overwhelming evidence that tobacco manufacturers intended nicotine to "act as a drug."[91] The evidence portrayed the tobacco companies as controlling the amount, form, and delivery of nicotine in their products.[92] Additionally, the evidence indicated that the tobacco companies attempted to improve their products by researching the effect of nicotine on humans.[93] The tobacco companies adamantly objected to the FDA's claim of jurisdiction and filed a lawsuit contesting it.[94]

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87. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,400; *see* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended at 21 U.S.C. § 301 (1996)).

88. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,400.

89. *See id.*

90. *Id*; *see* Zieve, *supra* note 86, at 280 (discussing the FDA's jurisdiction over tobacco).

91. *See* Zieve, *supra* note 86, at 280. The Brown & Williamson Collection on the internet contains the controversial documents and memoranda which disclose what the tobacco companies really knew and when they knew it. *See Brown & Williamson Collection* (visited Feb. 26, 1998) <http://www.library.ucsf.edu/tobacco/bw.html>. *See generally* Clay Calvert, *Smoking Out Big Tobacco: Some Lessons About Academic Freedom, The World Wide Web, Media Conglomeration, and Public Service Pedagogy From the Battle Over the Brown & Williamson Documents*, 24 PEPP. L. REV. 391 (1997) (discussing the impact of the Brown & Williamson collection).

92. *See* Zieve, *supra* note 86, at 280.

93. *See id.*

94. *See* Coyne Beahm, Inc. v. United States FDA, 966 F. Supp. 1374 (M.D.N.C. 1997); *see also supra* note 3 and accompanying text.

II. THE RULING'S OPPOSITION AND IMPACT

A. The Litigation in Response to the FDA's Ruling

In September and October of 1995, members of the tobacco, advertising, and convenience store industries filed complaints against the FDA in the U.S. District Court for the Middle District of North Carolina.[95] The plaintiffs, Philip Morris Inc., R.J. Reynolds Tobacco Corp., and other related groups, sought an injunction to prevent the FDA from asserting jurisdiction now and in the future.[96] Kentucky, North Carolina, and Virginia[97] filed amicus briefs in support of the plaintiffs.[98] The plaintiffs filed a summary judgment motion in October of 1996.[99] On April 25, 1997, presiding Judge William Osteen granted partial summary judgment, holding that jurisdiction to regulate cigarettes and tobacco products rests with the FDA, but that the FDA had exceeded its authority by attempting to regulate tobacco manufacturers' advertising and marketing.[100] The FDA appealed this partial summary judgment on June 5, 1997.[101]

In the litigation, the plaintiffs primarily argue that the FDA has no authority or jurisdiction to regulate tobacco[102] and that the advertising restrictions established by the FDA's ruling violates the First Amendment.[103] The plaintiffs also argue that the FDA cannot regulate a drug

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95. *See Coyne Beahm, Inc.*, 966 F. Supp. at 1374; *see also supra* note 3 and accompanying text (discussing opposition to FDA regulation of tobacco).

96. *See Coyne Beahm, Inc.*, 966 F. Supp. at 1374; *see also* Hillary Kessler, *Big Suits*, AM. LAW., Oct. 1995, at 95, 95; *supra* note 3 and accompanying text.

97. *See Gilmore's Defense of Big Tobacco*, ROANOKE TIMES & WORLD NEWS, Nov. 19, 1996, at A4, *available in* LEXIS, News Library, Curnws File.

98. *See Lawsuits: Cos. File Against FDA Rules; Texas Trial Set*, HEALTH LINE, Oct. 16, 1996, *available in* LEXIS, News Library, Curnws File [hereinafter *Focus on Tobacco Lawsuits*].

99. *See id.*

100. *See Coyne Beahm, Inc.*, 966 F. Supp. at 1396-97, 1399-1400; *see also NC Judge Says FDA Can Regulate Cigarettes, But Not Advertising*, CONSUMER PRODUCT LITIG. REP., June 1997, at 6609, 6609, *available in* LEXIS, News Library, Curnws File.

101. *See FDA Asks 4th Circuit to Reverse Ruling on Power to Regulate Tobacco Ads*, 11 MEALEY'S LITIG. REP.: TOBACCO NO. 5 (1997) *available in* LEXIS, News Library, Curnws File.

102. *See Coyne Beahm, Inc.*, 966 F. Supp. at 1379; *see also Focus on Tobacco Lawsuits*, *supra* note 98.

103. *See* Charles J. Hardner, Comment, *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.J. 399, 413-21 nn.

that is known to be harmful because if the FDA did regulate it, it would have to ban it altogether.[104]

1. The Jurisdiction Argument

The plaintiffs' primary opposition to the FDA's assertion of jurisdiction and its subsequent ruling is their belief that Congress, not the FDA, has jurisdiction over tobacco.[105] The plaintiffs claim that if Congress intended for the FDA to regulate tobacco products it would have specifically given the FDA jurisdiction, but Congress has never granted the FDA that authority.[106] Additionally, in the past, Congress rather than the FDA regulated the tobacco industry.[107] The plaintiffs also contend that the FDA lacks jurisdiction because the tobacco manufacturers do not make the requisite "therapeutic claims."[108] The plaintiffs observe the inconsistency allowing the FDA to regulate tobacco—the FDA only approves drugs that it believes are safe, the FDA's regulation of tobacco products implies FDA approval which suggests that smoking cigarettes and chewing tobacco are not harmful.[109]

2. The First Amendment Argument

The second argument made by the plaintiffs is that the FDA restrictions on advertising violate free speech.[110] The *Central Hudson* Test[111] governs the modern commercial speech doctrine in determin-

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100-36 (1995).

104. *See* John Carey et al., *The FDA vs. Big Tobacco*, BUS. WK., Aug. 28, 1995, at 34, 34 (stating that "[i]f it is declared a drug, tobacco must be shown to be safe and effective in order to be legally sold–a test it cannot pass. Thus, the FDA could be forced into a total ban by smoking opponents.").

105. *See Coyne Beahm, Inc.*, 966 F. Supp. at 1379; *see also* Margaret A. Boyd, Comment, *Butt Out!! Why the FDA Lacks Jurisdiction to Curb Smoking of Adolescents and Children*, 13 J. CONTEMP. HEALTH L. & POL'Y. 169, 181 (1996) (stating that cigarette products are not medical devices and thus cannot be regulated by the FDA); Hardner, *supra* note 103, at 428-37. For more insight into the jurisdiction argument, see Lars Noah & Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 ALA. L. REV. 1, 7 (1996) ("[T]his article concludes that the FDA regulations exceed the Agency's delegated authority . . . .").

106. *See* Hardner, *supra* note 103, at 428.

107. *See supra* notes 49-67 and accompanying text.

108. *See* Zieve, *supra* note 86, at 280 (stating that the FDA cannot regulate a product unless the manufacturer makes a health-related claim regarding the product).

109. *See* Jeff Millar, *Joe Camel is "Happy" at FDA Ruling*, HOUS. CHRON., Sept. 1, 1996, at 6, *available in* LEXIS, News Library, Curnws File.

110. *See* Hardner, *supra* note 103, at 413-21 nn.100-36.

111. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980).

ing the protection of commercial speech.[112] Commercial speech is protected only if it is truthful and concerns a lawful activity.[113] After this determination, the government's restriction(s) will be valid if (1) the government's interest is substantial; (2) the restriction directly advances the government's interest; and (3) the regulation is not broader than necessary.[114] However, in *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*,[115] the Court weakened the last two prongs by deferring to the judgment of the local legislature.[116] The plaintiffs attack the FDA by claiming the government's interest is not substantial and that the FDA's regulation is broader than necessary.[117] The plaintiffs assert that there is a more direct way to achieve the FDA's goal, such as a more strict adherence to the law that prohibits minors from buying cigarettes.[118]

The most recent Supreme Court decision alleged to impact the tobacco litigation against the FDA is *44 Liquormart, Inc. v. Rhode Island*,[119] which overruled Rhode Island's statutory ban on liquor price advertising because it violated the First Amendment.[120] However, FDA proponents argue that the *44 Liquormart* decision is not applicable to the FDA ruling because the Court's holding was limited to factual information, such as the price of liquor, which is not comparable to imagery manipulated in advertisements used to entice children.[121]

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112. *See id.* at 561-65.
113. *See id.* at 563-64.
114. *See id.* at 564.
115. 478 U.S. 328 (1986).
116. *See id.* at 340-48.
117. *See* Hardner, *supra* note 103, at 413-21 nn.100-36 (providing an in-depth analysis of the commercial speech doctrine as applicable to the FDA ruling); *see also* Daniel Helberg, Comment, *Butt Out: An Analysis of the FDA's Proposed Restrictions on Cigarette Advertising Under the Commercial Speech Doctrine*, 29 LOY. L.A. L. REV. 1219, 1222 (1996) (stating that "[t]here is no doubt regarding the dangers of smoking and the power of the media to influence buying behavior. However, the decision to reduce cigarette smoking through advertising restrictions sacrifices First Amendment principles, personal autonomy, and the health of existing smokers in the name of political expediency.").
118. *See* Gail Appleson, *Lawyers Say Proposed Tobacco Rules Limit Speech*, REUTER'S FIN. SERVICE, Dec. 26, 1996, *available in* LEXIS, News Library, Curnws File.
119. 116 S. Ct. 1495 (1996).
120. *See id.* at 1515.
121. *See* John Carey et al., *The Fire This Time*, BUS. WK., Aug. 12, 1996, at 66, 66.

The FDA may find support from the United States Court of Appeals in the Fourth Circuit.[122] This court, which is where the FDA litigation will presumably visit in the near future, upheld Baltimore's ban of "cigarette and liquor advertising on billboards in areas of the city where children are expected to walk to school or play."[123] The Fourth Circuit Court of Appeals distinguished the *44 Liquormart* case in *Anheuser-Busch, Inc. v. Mayor of Baltimore*[124] and *Penn Advertising of Baltimore, Inc. v. Mayor of Baltimore*[125] and held the ordinances constitutional.[126] The decisions also cited the "Supreme Court's repeated recognition that children deserve special solicitude in the First Amendment balance because they lack the ability to assess and fully analyze the information presented through the commercial media."[127] In applying the *Central Hudson* Test, the Fourth Circuit court determined that the statutes in both cases were narrowly tailored to achieve their purpose of protecting minors and were thus held constitutional.[128] On April 28, 1997, the United States Supreme Court denied certiorari in both *Penn Advertising* and *Anheuser-Busch.*[129] Thus, precedent maintains that at least part of the FDA ruling does not violate the First Amendment.[130]

B. Impact of the FDA Rule on the Tobacco Industry

The tobacco industry vehemently opposes the FDA's decision to regulate tobacco, primarily because it fears FDA regulation will diminish revenues and profits.[131] In response to the FDA's ruling, the individual

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122. *See infra* notes 123-29 and accompanying text.

123. *See* John Schwartz, *Tobacco Foes Encouraged by Ruling on Ad Ban*, WASH. POST, Nov. 16, 1996, at A4; *see also* Penn Advertising of Baltimore, Inc. v. Mayor of Baltimore, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 117 S. Ct. 1569 (1997); Anheuser-Busch, Inc. v. Mayor of Baltimore, 101 F.3d 325 (4th Cir. 1996), *cert. denied*, 117 S. Ct. 1569 (1997); Milo Geyelin, *Appeals Court Again Upholds Ban Involving Billboard Cigarette Ads*, WALL ST. J., Nov. 15, 1996, at B10 (discussing the Fourth Circuit Court of Appeals decision to uphold the ban).

124. 101 F.3d 325.

125. 101 F.3d 332.

126. *See Anheuser-Busch, Inc.*, 101 F.3d at 330; *Penn Advertising of Baltimore, Inc.*, 101 F.3d at 333. For analysis favorable to the plaintiffs, see Thomas D. Blue, Jr., *Over the Edge: The Fourth Circuit's Commercial Speech Analysis in* Penn Advertising *and* Anheuser-Busch, 74 N.C. L. REV. 2086, 2088 (1996) (arguing that the opinions in *Penn Advertising* and *Anheuser-Busch* "violated the commercial speech doctrine").

127. *Anheuser-Busch, Inc.*, 101 F.3d at 329.

128. *See id.* at 330; *Penn Advertising of Baltimore, Inc.*, 101 F.3d at 333.

129. *See* Penn Advertising of Baltimore, Inc. v. Mayor of Baltimore, 117 S. Ct. 1569 (1997); Anheuser-Busch, Inc. v. Mayor of Baltimore, 117 S. Ct. 1569 (1997).

130. *See supra* notes 123-29 and accompanying text.

131. *See* Amanda Walmac, *Empty the Ashtray: Time is Running Out on Tobacco Stocks*, MONEY MAG., Nov. 1, 1996, at 76.

lawsuits against tobacco companies, and the state suits seeking Medicaid reimbursement, stocks of the major tobacco companies (and their suppliers) have fallen.[132] The tobacco companies view the youth market as the only explorable market from which to increase revenues because it is the only market where the number of people smoking is actually increasing.[133] The FDA's ruling seeks to destroy tobacco companies' efforts to exploit the only growing product market by preventing the companies from aiming advertisements at adolescents and children.[134]

If impeding the growing market does not decrease the tobacco companies' revenue stream enough, the implementation of the FDA's ruling may further decrease revenue by inhibiting effective marketing and advertising to adults.[135] The tobacco companies greatly need additional revenue in order to offset the major costs incurred in defending both the FDA lawsuit and the suits filed by the states for reimbursement of Medicaid/Medicare costs.[136] The cigarette companies will be forced to offset their costs through price increases.[137] Tobacco manufacturers also fear that FDA regulation will inevitably lead to a ban on tobacco.[138]

Furthermore, the ruling may force tobacco companies to change their products.[139] For example, the tobacco manufacturers may be driven to

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132. *See id.*

133. *See generally* George Dessart, *And the Kids Keep on Lighting Up*, WASH. POST, Aug. 21, 1996, at A25. A report from the Center for Disease Control concluded that 35% of students in high school smoke cigarettes representing a 7% increase from 1991. *See id.* In fact, smoking is a greater problem among adolescents according to the Center for Disease Control's recent report which concluded that only 25% of adults smoke. *See id.*

134. *See id.*

135. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,439 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

136. *See* Walmac, *supra* note 131, at 76; *see also Focus on Tobacco Lawsuits*, *supra* note 98.

137. *See* Walmac, *supra* note 131, at 76.

138. *See* Helberg, *supra* note 117, at 1270; *see also* John Head, *Tobacco's End Game? What's Next in the Continuing Battle Against Smoking? A Ban Against Tobacco—a Smoker's Greatest Fear? Probably Not, But Here Are Some Scenarios That Could Lie Ahead*, ATLANTA J. & CONST., Nov. 17, 1996, at 1H, *available in* LEXIS, News Library, Curnws File.

139. *See* Marlene Cimons, *Can Regulating Tobacco Get Smokers to Kick the Habit?*, L.A. TIMES, June 20, 1994, at A5.

alter the levels of nicotine.[140] Another possible reaction by tobacco manufacturers would be to produce cigarettes with less nicotine, causing consumers to buy more cigarettes and the manufacturers, in turn, would reap increased profits.[141] Additionally, if cigarette manufacturers change their products to decrease the amount of nicotine, a black market for the former type of cigarettes might emerge.[142]

C. Impact of the Rule on Society

By issuing the ruling, the FDA attempted to save some of the 400,000 lives lost each year from smoking-related diseases.[143] A major premise of the FDA's ruling is to protect the health of future generations by decreasing the number of children who begin smoking now, thereby reducing the number of people who suffer from tobacco-related illnesses in future years.[144] A positive externality of the FDA's goal is a decrease in future health care costs for taxpayers.[145] The FDA estimates that the economic benefits of the ruling will be between $28 billion and $43 billion a year due to the reduction in tobacco-related diseases.[146] The FDA's approach is an attempt to implement preventative measures, rather than America's typical approach of treatment.[147] On the other hand, the ruling will have a negative financial impact on tobacco farmers[148] and advertisers.[149]

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140. *See id.*

141. *See id.*; *see also* Head, *supra* note 138, at 1H.

142. *See* Cimons, *supra* note 139, at A5.

143. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

144. *See id.*; *see also* Carey et al., *supra* note 121, at 66 (stating that the goal of the FDA's ruling is to save lives).

145. *See generally* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,396; Carey et al., *supra* note 121, at 66.

146. *See* Travis, *supra* note 3, at C3.

147. *See* Cummings, *supra* note 2, at 12A.

148. *See* Joe Ward, *Tobacco Farmers' Profits Likely to Decline, Expert Says*, COURIER-J. (Louisville, Ky.), Nov. 13, 1996, at 1B, *available in* LEXIS, News Library, Curnws File.

149. *See* Travis, *supra* note 3, at C3; *see also supra* note 3 and accompanying text.

III. POLITICS AND FDA REFORM

A. Politics

In 1996, "in a strange reversal of the traditional debate over the ethics of political advertising, the growing debate [was] over the ethics of tobacco . . . ."[150] The media turned the 1996 election into a morality, ethics, and family values contest.[151] Contributions from the tobacco industry together with positions on the FDA's tobacco regulation were hotly debated political issues.[152] The tobacco industry's contributions to Congress over the past few years have been astounding.[153] In fact, regulation of addictive drugs, such as alcohol and cigarettes, never stemmed from those in politics because the tobacco and alcohol industries are such powerful players in the political arena.[154] Out of the current members of Congress, eighty-two percent of them received contributions from the tobacco industry.[155] According to a Common Cause study, the tobacco industry contributed $2.4 million in soft money to the Republican Party in 1995,[156] compared to $546,000 in 1993, the prior non-election year.[157] In 1995, the Democratic Party received less than one-fifth the amount of the contributions given to Republicans.[158] On the other hand, the Democrats were the leading recipients of soft money from litigators and law firms, who, incidentally, would be advantaged by increased tobacco litigation.[159] In 1996, Philip Morris donated

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150. Ira Teinowitz, *The Politics of Vice; Campaign '96: Once Campaigns Were Decided in Smoke-Filled Rooms, Now the Polls are Lighting Debates Over Product Ads*, ADVERTISING AGE, July 8, 1996, at 1, 1; *see* Jef I. Richards, *Politicizing Cigarette Advertising*, 45 CATH. U. L. REV. 1147, 1177 (1996) (discussing tobacco as a "political 'hot potato'").

151. *See* Teinowitz, *supra* note 150, at 26.

152. *See id.*

153. *See infra* notes 155-61 and accompanying text.

154. *See* Sylvia A. Law, *Addiction, Autonomy, and Advertising*, 77 IOWA L. REV. 909, 923 (1992).

155. *See* John Carey, *Commentary: Clinton's Antismoking Plan Won't Exactly Kick Butt*, BUS. WK., Sept. 9, 1996, at 42, 42.

156. *Here's What Some of those Campaign Donations Buy*, USA TODAY, Dec. 12, 1996, at 14A. Soft money is "large donations from corporations, unions and wealthy individuals that are exempt from the post-Watergate limits on campaign contributions." *Id.*

157. *See* Benjamin Wittes, *Tobacco Lobby Keeps on Smoking*, N.J.L.J., Apr. 22, 1996, at 8.

158. *See id.*

159. *See* Cummings, *supra* note 2, at 12A.

$1.76 million to Republican political campaigns and almost $500 million to the Democratic party.[160] R.J. Reynolds/Nabisco (RJR) contributed a total of $1.5 million to political campaigns as well.[161] These huge donations from the tobacco companies to the members of Congress represent an effort to fend off FDA regulation of tobacco.[162] These contributions, coupled with the influence of powerful lobbies, inhibit Congress from being an effective forum for tobacco regulation.[163]

Besides the tobacco, advertising, and litigation interest groups lobbying and contributing to Congress, the FDA has another enemy: the American Civil Liberties Union (ACLU).[164] The ACLU sided with the tobacco industry and has been fighting for the tobacco industry's right to advertise to children.[165]

The significant political impact of tobacco regulation also can be viewed by the remarks made by prominent elected officials concerning tobacco products and their regulation. When former Senator and 1996 presidential candidate Bob Dole remarked that nicotine was not addictive for everyone and that the FDA should not regulate tobacco, the Democrats were quick to acknowledge that Dole would just stand "idle while 3000 kids a day start a habit that will kill one-third of them."[166] Dole was not alone; House Speaker Newt Gingrich gave his opinion on the FDA and its regulations as well, stating, "I think the FDA is a bureaucracy that has overreached on a number of fronts. It is weakening American job creations, weakening the introduction of new medications."[167]

With President Clinton's re-election and the Republican majority remaining in Congress, the political situation with regard to the FDA remains the same: a supportive President and an opposing Congress.[168] Because the election is over, Congress and the President have

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160. *See Here's What Some of those Campaign Donations Buy*, *supra* note 156, at 14A.

161. *See id.*

162. *See id.*

163. *See* Wittes, *supra* note 157, at 8.

164. *See* Joshua Wolf Shenk, *Steve Forbes, Joe Camel, and the ACLU: Government Isn't the Only Threat to Our Civil Liberties, So is the Power of Money*, WASH. MONTHLY, Apr. 1996, at 8.

165. *See id.*

166. *See* Carey et al., *supra* note 121, at 66.

167. *See* Cummings, *supra* note 2, at 12A.

168. *See Clinton's Return: Status Quo for the Industry*, MARKETLETTER, Nov. 11, 1996, *available in* LEXIS, News Library, Curnws File; *see also Congressional Change Seen as More Significant*, MARKETLETTER, Nov. 11, 1996, *available in* 1996 WL 12725301 (discussing the impact of the election on the FDA ruling).

no fear of retaliation at the polls, and the FDA, sure to be at issue in the current Congress, will be in the crossfire.[169]

B. FDA Reform

The alleged main goal in reforming the FDA is to make safer drugs available to the public faster.[170] Yet, a major FDA concern is balancing speed with safety.[171] Excessive caution, slowness, bureaucracy, and intimidation have led to continuous criticism of the FDA.[172] To remedy these problems, the House Commerce Committee was to report on an FDA Reform Bill in September 1996 based on three measures: House Bills 3199, 3200, and 3201.[173] The Senate's reform bill, Resolution 1477, was also expected to be discussed on the floor in September 1996.[174]

Initially, the reforms were geared at getting drugs through the FDA faster, decreasing the amount of paperwork, allowing contracting out or third party review, and making the appellate process faster.[175] Other reforms included the "use of pilot biologics facilities . . . and exempting devices from notification requirements."[176] However, FDA reform bills did not see floor action for two reasons: (1) no one wanted to pass controversial FDA reform legislation with the 1996 election around the corner,[177] and (2) the bills were bogged down by "disputes over privatization, expedited approval based upon foreign approval and dissemination of scientific information about off-label uses of FDA approved drugs."[178] Now, FDA reform proposals include limiting the FDA's juris-

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169. *See Clinton's Return: Status Quo for the Industry*, *supra* note 168.

170. *See FDA Reform "Still Possible During This Congress"*, MARKETLETTER, Sept. 16, 1996, *available in* LEXIS, News Library, Curnws File.

171. *See FDA: Kessler Speaks on Reform, Tobacco*, HEALTH LINE, Aug. 19, 1996, *available in* LEXIS, News Library, Curnws File.

172. *See* Daniel Green, *Obstacle Course for Drug Producers: Pressure for Reform of the US Food and Drug Administration is Growing*, FIN. TIMES, Aug. 21, 1995, at 12.

173. *See* H.R. 3199, 104th Cong. (1996); H.R. 3200, 104th Cong. (1996); H.R. 3201, 104th Cong. (1996); *see also FDA Reform "Still Possible During This Congress," supra* note 170 (discussing the possibility that FDA reform legislation would be passed).

174. *See FDA Reform "Still Possible During This Congress," supra* note 170.

175. *See* Jill Wechsler, *FDA: Going up in Smoke?*, PHARMACEUTICAL EXECUTIVE, Oct. 1995, at 20.

176. *FDA Reform "Still Possible During This Congress," supra* note 170.

177. *See Biotechnology Protected in Rewrite of Medical Patent Ban*, BIOWORLD TODAY, Sept. 9, 1996, *available in* 1996 WL 10571849.

178. Lisa Seachrist, *BIO Looks to 105th Congress as Session Adjourns Without Progress on FDA Reform*, BIOWORLD TODAY, Sept. 25, 1996, *available in* 1996 WL

diction and possibly even reducing its budget.[179] Also, legislation to enact some of the provisions of the FDA ruling has been proposed.[180] Consequently, FDA reform will be a major part of the Republican agenda in the current session of Congress,[181] and analysts expect that Congressional FDA reform will be much easier with the resignation of FDA Commissioner David Kessler.[182]

Interestingly enough, the tobacco industry, drug manufacturers, and manufacturers of medical devices initiated and instigated the FDA reform movement.[183] These industries urging reform, diligently tried to convince Congress that the FDA should be spending more of its budget on accelerating the approval process for drugs and medical devices and less on tobacco.[184] Ironically, the FDA spends most of its budget regulating drugs and devices for the treatment of smoking-related diseases.[185]

Even though no reform bill passed, the FDA internally reformed itself in response to criticism from various groups.[186] The FDA increased its approval rate of drugs for marketing by thirty-two percent between 1994 and 1995.[187] These drugs also received approval thirteen percent faster in 1995 than in 1994.[188] In 1995, the FDA reduced the approval time for drugs with expected "important therapeutic value" by more than half compared to 1994.[189] The FDA also "approved a record forty-

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179. *See* Andrew Lawler & Richard Stone, *FDA: Congress Mixes Harsh Medicine; Efforts to Reform the Food and Drug Administration*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., Aug. 25, 1995, at 1038, *available in* LEXIS, News Library, Arcnws File.

180. *See* Mike France et al., *Is Big Tobacco Ready to Deal?*, BUS. WK., Dec. 23, 1996, at 32; *see also* Mike Brown, *Ford Again Offers Bill to Block FDA on Tobacco*, COURIER-J. (Louisville, Ky.), Jan. 24, 1997, at A8, *available in* LEXIS, News Library, Curnws File (discussing Senator Ford's introduction of legislation which prohibits the FDA's regulation of tobacco and imposes some of the FDA's restrictions on the sale and marketing of tobacco).

181. *See* Senator Judd Gregg, *The GOP Prescription for the 105th Congress, MSAs, Medicare and Medicaid Reform, Oversight of Public Health Service Are on the Horizon*, ROLL CALL, Sept. 16, 1996, *available in* LEXIS, News Library, Curnws File.

182. *See* Michael Rust & Susan Crabtree, *105th Congress Anticipates FDA Reform Party*, WASH. TIMES, Dec. 23, 1996, at 6.

183. *See* Wittes, *supra* note 157, at 8.

184. *See id.*

185. *See Tobacco Declared 'Restricted Device'; Is more Information-Regulation by FDA at Hand?*, MED. DEVICE APPROVAL LETTER, Sept. 1, 1995, *available in* LEXIS, News Library, Arcnws File.

186. *See FDA Reform: Both Parties Trade Blame For Failure*, HEALTH LINE, Sept. 10, 1996, *available in* LEXIS, News Library, Curnws File.

187. *See* Rep. Thomas Bliley Jr., *FDA Still Needs Reform Despite Improvements*, ROLL CALL, Sept. 16, 1996, *available in* LEXIS, News Library, Curnws File.

188. *See id.*

189. *See id.*

six 'breakthrough' drugs in 1996—medicines never before sold in this country—and took half as long as the European Union to get new treatments onto pharmacy shelves . . . ."[190] However, the average time to get a drug from the laboratory to a patient remained between twelve to fifteen years with the average cost surpassing $350 million.[191]

C. *Settlements Discussed Between Congress, the States, and the Tobacco Industry*

Moments after the FDA issued its ruling regulating tobacco, rumors flew that state attorney generals were already making deals with the tobacco companies.[192] The tobacco companies denied these rumors.[193] The rumors suggested that the ruling was just another political game, pushing the tobacco manufacturers to settle.[194] Besides the FDA ruling, another factor allegedly enticing tobacco manufacturers to make a deal was the pending lawsuits filed by attorney generals in forty states and at least two California cities[195] seeking reimbursement for

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190. Charles W. Henderson, *Drug Development FDA Boasts of Quick Drug Approval*, DISEASE WKLY. PLUS, Jan. 6, 1997, *available in* 1997 WL 7719051.

191. *See* Bliley, *supra* note 187.

192. *See* Mike France et al., *Big Tobacco May Be Ready to Deal*, BUS. WK., Oct. 7, 1996, at 150.

193. *See id.*

194. *See generally id.*

195. The states that have brought Medicare/Medicaid reimbursement claims against the tobacco companies are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Utah, Vermont, Washington, West Virginia, and Wisconsin. *See* Bob Van Voris, *AGs' Claims Mere Smoke?*, NAT'L L.J., Apr. 28, 1997, at A1 (stating that all the states listed above, except as discussed below in this footnote, have filed suit against the tobacco manufacturers for reimbursement); *see also* Gail Appleson, *Efforts Mount to Block Hasty Tobacco Pact*, REUTER BUS. REP., June 4, 1997, *available in* LEXIS, News Library, Curnws File (discussing that New Hampshire filed its lawsuit seeking reimbursement of medical costs); Tustin Amole, *DeGette Falls 7 Votes Short in Floor Debut*, ROCKY MOUNTAIN NEWS, July 25, 1997, at 5A, *available in* LEXIS, News Library, Curnws File (stating that Colorado has filed its lawsuit for medical cost reimbursements); Lauran Neergaard, *Tobacco Deal Near but Not All Groups on Board*, CHATTANOOGA FREE PRESS, May 28, 1997, at A5, *available in* LEXIS, News Library, Curnws File (stating that New Mexico filed its suit against the tobacco manufacturers); *Ohio*, STATES NEWS BRIEFS, May 8, 1997, *available in* LEXIS, News Library, Curnws File (discussing Ohio's filing of its lawsuit against the tobacco manufacturers); Vita Reed, *Nevada Follows Other States in Suing Big Tobacco*, LAS VEGAS BUS. PRESS, May 26, 1997, at 11,

millions of dollars in Medicare/Medicaid funds which the states had spent "treating smoking related illnesses."[196]

The Liggett Group was the first and only tobacco company to date to have officially accepted a deal.[197] Liggett agreed to abide by advertising regulations which target children and also dropped out of the North Carolina litigation.[198] Additionally, the Louisiana Castano class[199] would receive five percent of Liggett's income annually for twenty-five years, and the states suing for Medicaid reimbursement would get a percentage of Liggett's income plus a lump sum for the next ten years.[200]

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available in LEXIS, News Library, Curnws File (stating that Nevada filed its claim against the tobacco manufacturers); Liz Ruskin, *State Takes on Tobacco; Lawsuit Seeks Millions for Medical Expenses*, ANCHORAGE DAILY NEWS, Apr. 15, 1997, at 1A, *available in* LEXIS, News Library, Curnws File (discussing Alaska's filing of a lawsuit seeking, among other things, reimbursement of Medicaid expenditures); *Tobacco Litigation Update*, AG BULL., June 1997, *available in* LEXIS, News Library, Curnws File (noting that Vermont filed suit for reimbursement of medical expenses); *Tobacco Litigation Update*, AG BULL., May 1997, *available in* LEXIS, News Library, Curnws File (stating that Pennsylvania and South Carolina filed lawsuits seeking reimbursement from the tobacco manufacturers); Amy Trollinger, *Weston Growers Vilify Government*, KAN. CITY BUS. J., May 16, 1997, at 1, *available in* LEXIS, News Library, Curnws File (stating that Missouri has joined the other states by filing suit against the the tobacco manufacturers); Ron Word, *Jury Doesn't Blame RJR; Smoker's Death Result of Choice, Not Addiction*, CHATTANOOGA TIMES, May 6, 1997, at A1, *available in* LEXIS, News Library, Curnws File (reporting that Montana has filed its lawsuit against tobacco manufacturers); Assoc. Press, *2 More States Sue Tobacco Firms*, WASH. TIMES, June 19, 1997, at B6, *available in* LEXIS, News Library, Curnws File (reporting that Maine and Rhode Island filed their lawsuits against the tobacco manufacturers). The two cities which have filed suit against the tobacco companies for Medicare/Medicaid reimbursements are San Francisco and Los Angeles. *See Tobacco Foes Gleeful at Liggett Admission But Revelation Fails to Rattle Analysts; Case Called Symbolic*, ST. LOUIS POST-DISPATCH, Mar. 21, 1997, at 14A, *available in* 1997 WL 3330958.

196. *See Focus on Tobacco Lawsuits*, *supra* note 98; *see also Proposed Legislative Deal Would Shield Tobacco Industry For 15 Years*, MEALEY'S LITIG. REP.: TOBACCO, Sept. 6, 1996, *available in* LEXIS, News Library, Curnws File (discussing possible deals between the tobacco manufacturers and state attorney generals).

197. *See Tobacco Foes Gleeful at Liggett Admission But Revelation Fails to Rattle Analysts; Case Called Symbolic*, *supra* note 195, at 14A; *see also Stop Smoking!*, ECONOMIST, May 11, 1996, at 21, 22.

198. *See Stop Smoking!*, *supra* note 197, at 22.

199. Tobacco product liability cases have, until recently, never been won because the juries always felt that the smoker made the choice to smoke. *See* Benjamin Weiser, *Tobacco's Trials; Cigarette Makers Once Were So Hard to Beat in Court That Many Top Lawyers Refused to Take Them On. Then a Group of Attorneys, Mostly in Small Southern Towns, Found New Ways Past Tobacco's Defenses—and Now, the Industry is Hinting About a Deal*, WASH. POST MAG., Dec. 8, 1996, at 15, 19. The Castano class, however, based its claim on the idea that the smokers did not have a choice because of the nicotine addiction. *See id.* at 30.

200. *See id.* at 17.

Critics predicted that the bigger tobacco players would not take a deal and cautioned society not to accept a deal.[201] To the critics' surprise, on June 20, 1997, a proposal for the tobacco settlement with the forty states seeking to recoup their Medicaid expenditures for tobacco-related illnesses was announced.[202] Generally, the proposal provides that the cigarette manufacturers pay $368.5 billion during the next twenty-five years.[203] The $368.5 billion serves to "compensate states for the costs of treating smoking-related illness, to finance nationwide anti-smoking programs and to underwrite health care for millions of uninsured children."[204]

More specifically, the provisions of the proposal include, among other things, an initial payment of $10 billion by the cigarette companies to the states, followed by annual payments of $8.5 billion per year which eventually increase to $15 billion.[205] In return, the states will dismiss their lawsuits seeking Medicaid reimbursement.[206] The proposal also requires the dismissal of the aforementioned lawsuit pending in North Carolina challenging FDA jurisdiction over tobacco.[207] The settlement bans future punitive damage awards against the cigarette companies in exchange for their payment of fifty billion dollars in punitive damages.[208] The proposal sets forth penalties if the cigarette manufacturers do not attain specific goals for reduction in teenage smoking.[209] It

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201. *See* France et al., *supra* note 180, at 32; *see also* Michael Siegel, *Tobacco: The $10 Billion Dollar Debate*, WASH. POST, Dec. 22, 1996, at C7 (stating that "[w]hen the tobacco industry comes to the bargaining table, it does so with a hidden agenda . . . . Any deal that the tobacco industry is willing to accept is one that we should not want.").

202. *See* John M. Broder, *Major Concessions: Industry Would Pay for the Costs of Treating Diseases*, N.Y. TIMES, June 21, 1997, at 1; Marc Fisher & John Schwartz, *Trying to Snuff Out the Tobacco Culture; Industry Gambles It Can Survive Efforts to Stop Smoking's Seduction*, WASH. POST, June 22, 1997, at A1; *June 20, 1997 Settlement Terms* (visited Aug. 27, 1997) <http://stic.neu.edu/settlement/6-20-settle.htm> (discussing the different aspects of the settlement); *see also supra* note 195 and accompanying text (listing the 40 states).

203. *See* Broder, *supra* note 202, at 1.

204. *Id.*

205. *See id.*; *June 20, 1997 Settlement Terms*, *supra* note 202.

206. *See* Broder, *supra* note 202, at 1; *June 20, 1997 Settlement Terms*, *supra* note 202.

207. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

208. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

209. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note

mandates cessation of all cigarette advertising and marketing directed at teenagers, which includes a ban on all human and cartoon characters portrayed in such advertising.[210] It bans "product placement" in films and television programs and bans cigarette company sponsorships of sports events and concerts.[211] An important concession favoring tobacco companies is the preclusion of all class action suits.[212] The proposal also generally prohibits smoking in "public places, workplaces and fast-food restaurants."[213] Additionally, the proposal requires a stronger warning/caution label on cigarette packs to indicate that "smoking is addictive, causes fatal lung disease, causes cancer and can be deadly."[214] The proposal further requires the cigarette companies to disclose all data on addiction and drug dependence and itemize all ingredients and additives.[215]

The settlement proposal is not without its critics, including the American Medical Association and former FDA commissioner David Kessler.[216] Although the proposal acknowledges that the FDA retains jurisdiction over cigarettes and tobacco, the proposal also implements an unprecedented, "heavy legal burden" on the FDA to "justify controls on nicotine."[217] The proposal falls short of fully disclosing what the cigarette companies know about nicotine and its effects and also mandates the confidentiality of some of the information that the companies

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210. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

211. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

212. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

213. Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

214. Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

215. *See* Broder, *supra* note 202, at 8; *June 20, 1997 Settlement Terms*, *supra* note 202.

216. *See* Broder, *supra* note 202, at 8. "The companies are a lot smarter at selling cigarettes than the public health people are at unselling them." Myron Levin & Henry Weinstein, *Tobacco Foes Scour Pact for Smoke and Mirrors Settlement: Activists Fear Accord May Yet Give Industry a Way to Sidestep Significant FDA Regulation at Nicotine*, L.A. TIMES, June 22, 1997, at A1 (quoting Michael Pertschuk, a former chairman of the FTC); *see also* George Rodriquez, *AMA Lists Objections to Proposed Tobacco Deal Doctors Say Settlement Gives Too Much, Seeks Too Little in Enforcement, Money*, DALLAS MORNING NEWS, Aug. 1, 1997, at 1D (discussing AMA's perceived dangers of the proposal). "'The danger is that once the tobacco industry gets the relief it seeks, there is no incentive for them to cooperate further.'" *Id.* (quoting Richard F. Corlin, speaker of the AMA's House of Delegates). For a discussion of remarks made by David Kessler about the settlement proposal, see Broder, *supra* note 202, at 8. "[T]he industry ha[s] shown over the past 30 years that it can outwit—and outspend—its foes and win from Congress what it could not achieve in court." *Id.*

217. *See* Levin & Weinstein, *supra* note 216, at A1.

provide to the FDA.[218] Of course, Congress and President Clinton must still approve the settlement agreement which, judging by the criticisms, may take longer than the cigarette companies expected.[219]

IV. IMPACT OF THE FDA RULING ON THE ALCOHOL INDUSTRY

Alcohol and cigarettes often are mentioned in the same breath. Although both substances are classified as addictive, the regulation of the two products differs substantially.[220] For the most part, Congress regulated tobacco, and the alcohol industry internally and voluntarily regulated alcohol.[221] With the new FDA ruling, many groups such as Mothers Against Drunk Driving (MADD) and the Coalition for the Prevention of Alcohol Problems, urged a similar ruling aimed at curbing alcohol advertisements geared to entice adolescents to indulge.[222] Advertising firms speculated that advertising regulation would next target alcohol.[223] Legislators later proved them right by discussing and drafting legislation aimed at the alcohol industry which mimicked the FDA's tobacco advertising regulations.[224] In fact, President Clinton and the FCC threatened the alcohol industry with regulations similar to those imposed on tobacco.[225]

A. Alcohol Statistics

Tobacco and alcohol "each cause more death than all illicit drugs combined."[226] In 1991, "alcohol-related motor vehicle crashes" claimed the lives of 14,727 people between the ages of sixteen and twenty.[227]

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218. *See* Assoc. Press, *Shalala: Tobacco Deal Keeps Too Many Secrets*, CHI. TRIB., July 18, 1997, at C1.

219. *See* Fisher & Schwartz, *supra* note 202, at A1.

220. *See supra* notes 49-58 and *infra* notes 240-47 and accompanying text.

221. *See supra* notes 49-58 and *infra* notes 240-47 and accompanying text.

222. *See* Ira Teinowitz, *Alcohol Ad Restraints Suggested*, ADVERTISING AGE, Nov. 6, 1995, at 8; *Kennedy Unveils Ad Limits to Combat Underage Drinking*, ALCOHOLISM & DRUG ABUSE WK., May 20, 1996, at 1, *available in* 1996 WL 8970745.

223. *See Advertising Firm Fighting FDA on Tobacco Laws*, GREENBORO NEWS & REC., Nov. 6, 1996, at B6, *available in* LEXIS, News Library, NwsRec File.

224. *See* Ira Teinowitz & Joanne Ingrassia, *Hear No Evil, See No Evil Ads in 1997?: Legislators in North America Eye Extra Rules for Sin-Free Ad Environment*, ADVERTISING AGE, Oct. 14, 1996, at I16.

225. *See* David Leonhardt & Mike France, *Absolute Folly? Liquor's TV Foray May Create A Backlash Against All Alcohol Ads*, BUS. WK., Nov. 25, 1996, at 46, 46.

226. Law, *supra* note 154, at 910.

227. *See* Shelov et al., *supra* note 44 (citing results from a 1991 National Highway

Alcohol is also "involved in more than one-fourth of teenage suicides and homicides . . . ."[228] In general, children "begin drinking [alcohol] in junior high school and by the time they're seniors, nearly thirty percent of them binge drink, downing five or more at a time."[229] Furthermore, about four million adolescents and children are classified as "alcoholics or problem drinkers."[230]

B. Effect of Alcohol Advertising on Adolescents

Alcohol is the second most aggressively advertised product in America.[231] The average American child watches approximately thirty-five hours of television a week[232] and views almost two thousand alcohol-related commercials per year.[233] Additionally, adolescents are "three times as likely as adults to respond to ads."[234] Alcoholic beverage advertisers market to teenagers by showing that drinking will help them have more friends, fun, and sex appeal.[235] Alcohol advertisements, similar to those of cigarettes, are geared to entice young people to consume the manufacturer's product.[236] Advertisers of beer and wine spent $391 million on TV advertising from January to July of 1996.[237] In particular, Miller Light and Budweiser were the two most heavily advertised brands.[238] The statistics suggest that alcohol is effectively and aggressively advertised to adolescents.[239]

Traffic Safety Administration study).

228. *Id.* (citing a study of current adolescent trends).

229. Joseph P. Kennedy & George A. Hacker, *Bah, Humbug to TV Liquor Ads*, BOSTON HERALD, Dec. 13, 1996, at 40.

230. *Id.*

231. *See* Law, *supra* note 154, at 919. "Second to tobacco, alcohol is the most heavily advertised product in the United States." *Id.*

232. *See* Paul Froehlich, *No Alcohol TV Ads*, CHI. TRIB., Nov. 26, 1996, at 22 (stating that "[k]ids watch about five hours of TV a day").

233. *See* Shelov et al., *supra* note 44 (citing an *Adolescent Medicine* article on the relationship between the media and drugs).

234. Froehlich, *supra* note 232 (citing a recent study of cigarette advertising).

235. *See* Shelov et al., *supra* note 44.

236. *See* Teinowitz, *supra* note 222, at 8.

237. *See* Steve McClellan, *What Hath Seagram Wrought? Beer, Wine Advertisers Fearful Liquor Ads Will Backlash, Result in Ban for Them as Well*, BROADCASTING & CABLE, Nov. 4, 1996, at 6, *available in* LEXIS, News Library, Curnws File.

238. *See id.*

239. *See supra* notes 231-38 and accompanying text (discussing the alarming alcohol statistics and how advertising affects adolescents).

C. Background of Alcohol Advertisement Regulation

Generally, while Congress is responsible for regulating cigarette advertising, the states and the industry have assumed alcohol advertising regulation.[240] In 1933, after the end of Prohibition, Congress authorized the individual states to regulate alcohol within the states.[241] Some aspects of alcohol regulation, however, remained under the control of the Constitution and Congress.[242] Only a few states actually tried to restrict alcohol advertising, but all state regulation of the alcohol industry is limited by other interests.[243]

Until recently, the Distilled Spirits Council of the United States (DISCUS), the liquor trade association, maintained a voluntary ban of advertisements for "hard" liquor on radio and television.[244] In 1975, the alcohol and broadcasting industries also voluntarily banned radio and television alcohol advertisements.[245] However, on November 7, 1996, DISCUS removed the ban[246] in an effort to level the playing field between beer, alcohol, and spirits.[247] The lifting of the ban was a partial response to Seagram & Sons' violation of the ban through a broadcast advertisement on cable television for Crown Royal Whiskey on March 20, 1996.[248] Additionally, the twenty year decline in hard liquor sales and consumption contributed to the lifting of the ban.[249] The ban re-

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240. *See* Law, *supra* note 154, at 912.

241. *See* U.S. CONST. amend. XXI; *see also* Law, *supra* note 154, at 921.

242. *See generally* LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW 475-78 (2d ed. 1988) (explaining the regulatory aspects maintained by Congress and the Constitution).

243. *See id.*

244. *See Liquor Ads; Restraint Was Better*, ARIZ. REPUBLIC, Nov. 13, 1996, at B4, *available in* LEXIS, News Library, Curnws File; *see also* Leonhardt & France, *supra* note 225, at 46.

245. *See* Steve Younger, Comment, *Alcoholic Beverage Advertising on the Airwaves: Alternatives to a Ban or Counteradvertising*, 34 UCLA L. REV. 1139, 1144-45 (1987).

246. *See* Leonhardt & France, *supra* note 225, at 46; *see also* Anthony Faiola, *Liquor Ads on TV: A Glass Half Empty or Half Full?*, WASH. POST, Nov. 9, 1996, at H3 (discussing the lift of the ban and the refusal of the major networks to air "hard" liquor advertisements).

247. *See* Bob Kievra, *Restrictions Urged for Liquor, Tobacco Ads; McGovern and Meehan Want Federal Agencies to Adopt Tough New Standards*, TELEGRAM & GAZETTE WORCESTER, Nov. 14, 1996, at B5, *available in* LEXIS, News Library, Curnws File.

248. *See* Denise Gellene, *Seagram Bucks Voluntary Ban on TV Advertising With Spot on Cable*, L.A. TIMES, May 1, 1996, at D3.

249. *See* Leonhardt & France, *supra* note 225, at 46. "From 1980 to 1995, hard-liquor consumption in the United States dropped 27.7%, from 449 million gallons a

moval outraged President Clinton, the FCC, and Congress, all of whom urged DISCUS to resume the ban or face regulation similar to that which the FDA imposed on cigarette manufacturers.[250] DISCUS refused to resume the ban, but stated that the industry would not target children through its advertisements.[251]

D. Implications of the FDA Ruling on Alcohol and Other Industries

Particularly with the drop of the spirits advertisement ban, Congress[252] and groups such as the Coalition for the Prevention of Alcohol Problems and MADD,[253] seek alcohol advertising regulations similar to those the FDA issued for the tobacco industry.[254] These groups, dismayed with the double standard applied to tobacco and alcohol products, demand alcohol advertising regulations.[255] If the FDA is successful in regulating tobacco, expansion of regulation to industries such as the alcohol industry would be inevitable, and in fact, law makers have already drafted such legislation.[256] Other industries, such as the medical device industry, feel threatened by the expansion of regulation to tobacco and believe that they might be the next target for regulation.[257] Currently, the FDA regulates "products that account for 25 cents of every dollar spent" in America.[258] If the FDA expands its reach, that figure increases, but only time can tell by how much.

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year to 335 million. In that time, beer consumption rose 5.1% to 5.8 billion gallons, and wine consumption fell 0.5% to 470.2 million gallons." Harry Berkowitz, *Official: Keep TV Teetotal*, NEWSDAY, Nov. 9, 1996, at A4.

250. *See* Leonhardt & France, *supra* note 225, at 46.

251. *See* Kievra, *supra* note 247, at B5.

252. *See Kennedy Unveils Ad Limits to Combat Underage Drinking*, *supra* note 222, at 1. Ironically, Kennedy's bill to curb alcohol ads echoes the regulations issued by the FDA restricting tobacco advertisements. *See id.*

253. *See* Gellene, *supra* note 248, at D3.

254. *See* Teinowitz, *supra* note 222, at 8; *see also Field Supports Tobacco Focus, Seeks More Action on Alcohol; Addiction Field*, ALCOHOLISM & DRUG ABUSE WK., Aug. 21, 1995, at 1, *available in* 1995 WL 12027102.

255. *See* Gellene, *supra* note 248, at D3.

256. *See* Teinowitz & Ingrassia, *supra* note 224, at 116; *see also Tobacco Declared 'Restricted Device'; Is more Information-Regulation by FDA at Hand?*, *supra* note 185 (discussing the possibility of the FDA broadening its regulations into other industries such as the alcohol industry).

257. *See Tobacco Declared 'Restricted Device'; Is more Information-Regulation by FDA at Hand?*, *supra* note 185.

258. Joshua Wolf Shenk, *Warning: Cutting the FDA Could Be Hazardous to Your Health*, WASH. MONTHLY, Jan. 1996, at 17, 17, *available in* LEXIS, News Library, Arcnws File.

CONCLUSION

The FDA's ruling, which regulates tobacco sales, distribution, and advertising confronts several established American principles. The ruling has thrust tobacco into a tug of war with the First Amendment, capitalism, administrative agency power, and the health of the nation. In the ongoing litigation, the tobacco and advertising industries are fighting the FDA to protect their freedom of speech—their right to advertise. The FDA, on the other hand, is fighting to protect the health of future generations and the non-exhaustion of state funds. The real question is whether this ruling sufficiently balances the interests of the Constitution, big business, and health. The North Carolina court has answered that question, but its decision has been appealed. However, assuming the court battle takes three years and the litigation postpones the regulations from taking effect, that three years will allow approximately 3,285,000 adolescents to become regular smokers.[259]

The probability that the ruling in its entirety will go into effect is slim. The ruling has little support in Congress given the astounding Republican campaign contributions from tobacco manufacturers and the opposition of tobacco friendly representatives from the South. Additionally, the ruling faces opposition from the powerful alcohol and medical device industries fearful of being the next target of expansive regulation. Some view the FDA's expansive regulation into non-traditional industries as the FDA (and the government) going too far, and wonder where it will stop. Others, however, agreeing with the FDA, believe that the cost to society of not implementing the FDA ruling is greater than the threat of expansive regulation. If tobacco manufacturers are required to cease targeting children with their advertising and marketing, the number of future adult regular smokers that die prematurely will be reduced. As a direct result of a reduction in the number of smokers and tobacco-related illnesses, the states will save millions of dollars. Society, as a whole, will be healthier and happier.

The FDA and its supporters view the health of America's people as more important than the health of big business. It will be interesting to observe in the near future whether the health of America's people and

259. *See* Travis, *supra* note 3, at C3.

the overwhelming public support for the FDA ruling will be powerful enough to prevail over big business.

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